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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 51 and 602

[TD 9544]

RIN 1545–BK34

Branded Prescription Drug Fee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations that provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs. This fee was enacted by section 9008 of the Patient Protection and Affordable Care Act, as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010. The regulations affect persons engaged in the business of manufacturing or importing certain branded prescription drugs. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on August 18, 2011.

Applicability Date: For dates of applicability, see §§ 51.11T and 51.6302–1T(b).

FOR FURTHER INFORMATION CONTACT: Celia Gabrysh, (202) 622–3130 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

These temporary regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information contained in these regulations has been reviewed and pending receipt and evaluation of public comments, approved by the Office of Management and Budget under control number 1545–2209.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

For further information concerning this collection of information, and where to submit comments on the collection of information and the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-reference notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document adds the Branded Prescription Drug Fee Regulations to the Code of Federal Regulations (26 CFR Part 51) under section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111–148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111–152 (124 Stat. 1029 (2010)). All references in this preamble to section 9008 are references to section 9008 of ACA, as amended by section 1404 of HCERA. Section 9008 did not amend the Internal Revenue Code (Code) but cross-references to specified Code sections.

Statutory Provisions

Section 9008(a) imposes an annual fee on each covered entity engaged in the business of manufacturing or importing branded prescription drugs, to be paid not later than the annual date specified by the Secretary of the Treasury or his delegate (Secretary), but in no event later than September 30th of each calendar year in which a fee must be paid (fee year).

Section 9008(d)(1) defines a *covered entity* as any manufacturer or importer with gross receipts from branded prescription drug sales. Section 9008(d)(2) provides a controlled group rule under which all persons treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code are treated as a single covered entity. For this purpose, a foreign entity subject to tax under section 881 is included within a controlled group under section 52(a) or 52(b). Under section 9008(d)(3), all persons treated as a single employer under section 9008(d)(2) are jointly and severally liable for the fee.

Section 9008(e)(2) defines *branded prescription drug* as (i) any prescription drug the application for which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 355(b)), or (ii) any biological product the license for which was submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)). For this purpose, a *prescription drug* is any drug that is subject to section 503(b) of the FFDCA (21 U.S.C. 353(b)).

Section 9008(b) provides rules for determining the amount of the annual fee for each covered entity. Under section 9008(b)(4), the aggregate fee amount each year for all covered entities (referred to as the *applicable amount*) is $2.5 billion for fee year 2011; $2.8 billion for fee years 2012 and 2013; $3 billion for fee years 2014 through 2016; $4 billion for fee year 2017; $4.1 billion for fee year 2018; and $2.8 billion for fee year 2019 and thereafter. Section 9008(b)(1) requires the applicable amount for each year to be allocated, using a specified formula, among covered entities with aggregate branded prescription drug sales of over $5 million to specified government programs or pursuant to coverage under such programs. Section 9008(e)(4) provides that the *specified government programs* are the Medicare Part B program, the Medicare Part D program, the Medicaid program, any program under which branded prescription drugs are procured by the Department of Veterans Affairs, any program under which branded prescription drugs are procured by the Department of Defense, and the TRICARE retail pharmacy program (collectively, the Programs).

Specifically, section 9008(b)(1) provides that the annual fee for each covered entity is calculated by determining the ratio of (i) the covered entity's branded prescription drug sales

taken into account during the preceding calendar year to (ii) the aggregate branded prescription drug sales taken into account for all covered entities during the same year, and applying this ratio to the applicable amount. *Sales taken into account* means branded prescription drug sales after the application of the percentage adjustment table in section 9008(b)(2). The sales data is generally to be provided by the Centers for Medicare and Medicaid Services of the Department of Health and Human Services (CMS), the Department of Veterans Affairs (VA), and the Department of Defense (DOD) (collectively, the Agencies) pursuant to section 9008(g).

Section 9008(b)(3) requires the Secretary to determine the amount of each covered entity's fee and permits the Secretary to rely on reports submitted by the Agencies and any other source of information available to the Secretary in determining that amount. Section 9008(i) also directs the Secretary to publish guidance necessary to carry out the purposes of the statute.

Section 9008(f) treats the fee as an excise tax with respect to which only civil actions for refunds under the provisions of subtitle F of the Code will apply. Thus, the fee may be assessed and collected using the procedures in subtitle F without regard to the restrictions on assessment in section 6213 (relating to petitions to the Tax Court). Section 9008(f) also characterizes the fee as a nondeductible tax under section 275 of the Code.

IRS Guidance

On November 29, 2010, the Internal Revenue Service (IRS) released Notice 2010–71 (2010–50 IRB 822), which proposed an approach to implementing the section 9008 fee and requested comments on the proposed approach. The proposed approach included an opportunity to report certain information to the IRS relevant to the fee calculation and provided that the IRS would provide each covered entity with notice of a preliminary fee calculation. This notice was modified and superseded by Notice 2011–9 (2011–6 IRB 459), which was released on January 14, 2011.

On April 29, 2011, the IRS released Rev. Proc. 2011–24 (2011–20 IRB 787), which established a process for covered entities to submit claimed errors in their preliminary fee calculations for consideration before final fee calculations for 2011. On May 27, 2011, the IRS released Notice 2011–46 (2011–25 IRB 887) to defer the due date for submission of error reports and the last possible date for sending final fee calculations for 2011.

Explanation of Provisions

The temporary regulations describe the rules related to the fee and the actions to be taken before the September 30th due date of each year's fee. The temporary regulations first provide a general overview of the rules and then provide an explanation of terms used in implementing the fee. Next, the temporary regulations describe the information requested from covered entities and provided by the Agencies. The temporary regulations then describe how the fee is calculated and provide for a subsequent adjustment. The temporary regulations then provide for a notice of the preliminary fee calculation, a dispute resolution process to allow covered entities to submit error reports relating to the preliminary fee calculation, and a notice of the final fee calculation. The temporary regulations also explain how to pay the fee, how the fee is treated for tax purposes, and how to make refund claims.

These temporary regulations are generally consistent with the approach proposed in previous IRS guidance. Certain modifications and additions were made in response to public comments that were received in response to the solicitation in Notice 2011–9. The changes and the public comments are discussed in more detail in this preamble.

I. Overview

The temporary regulations provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs by section 9008. Generally, each covered entity with aggregate branded prescription drug sales of over $5 million to the Programs (or pursuant to the Programs) is liable for an annual fee in each fee year that is based on its sales of branded prescription drugs in the sales year that corresponds to the fee year in an amount determined by the IRS under these temporary regulations.

II. Explanation of Terms

The temporary regulations define numerous key terms used in section 9008 and in these regulations, including *agencies, branded prescription drug, covered entity, fee year, government programs, sales taken into account,* and *sales year.* Explanations of several terms are discussed in more detail in this preamble.

A. Manufacturer or Importer

Section 9008(d)(1) provides that *covered entity* means any manufacturer or importer with gross receipts from branded prescription drug sales. Consistent with the proposal in previous IRS guidance, the temporary regulations define a manufacturer or importer of a branded prescription drug as the person identified in the Labeler Code of the National Drug Code (NDC) for such a drug. The NDC is an identifier assigned by the FDA to a prescription drug. The Labeler Code is the first five numeric characters of the NDC or the first six numeric characters when the available five-character code combinations are exhausted.

B. Designated Entity

Consistent with the proposal in previous IRS guidance, the temporary regulations provide that, in the case of a controlled group that is treated as a single covered entity under section 9008(d)(2), the controlled group may identify a person as the designated entity that acts for the controlled group concerning the section 9008 fee. However, the temporary regulations further provide that if the controlled group, without regard to foreign corporations included under section 9008(d), is also an affiliated group that filed a consolidated return for Federal income tax purposes, the designated entity is the common parent of the affiliated group identified on the tax return filed for the sales year. If the controlled group is not an affiliated group that filed a consolidated return for Federal income tax purposes, it may select a person as the designated entity on Form 8947, ''Report of Branded Prescription Drug Information.'' If the controlled group does not select a person as a designated entity on its Form 8947, the IRS will select a person as a designated entity for the controlled group and advise the filer accordingly.

C. Orphan Drug Sales

Section 9008(e)(3) excludes orphan drug sales from the definition of branded prescription drug sales. Consistent with the proposal in previous IRS guidance, the temporary regulations define *orphan drug,* subject to certain exceptions, as any branded prescription drug for which any person claimed a section 45C credit and that credit was allowed for any taxable year. The temporary regulations further provide that an orphan drug does not include any drug for which there has been a final assessment or court order disallowing the full section 45C credit taken for the drug. Additionally, an

orphan drug does not include any drug for any sales year after the calendar year in which the FDA approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed, regardless of whether a section 45C credit was allowed for the drug either before, at the same time, or after this FDA approval.

Several commentators suggested that a drug should be considered an orphan drug if the section 45C credit was ''allowable''; that is, the section 45C credit could have been claimed, rather than was claimed. Other commentators suggested that orphan drug status should be given to a drug for which a section 45C credit was allowed even though the drug had been approved by the FDA for marketing for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed.

The temporary regulations do not adopt these suggestions. The plain language of section 9008(e)(3) requires the section 45C credit to have actually been allowed rather than to have merely been allowable. In addition, the Treasury Department and the IRS interpret section 9008(e)(3) to mean that if a drug is ever approved for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed, whether before, during, or after a section 45C credit was allowed for the drug, sales of that drug are not considered sales of an orphan drug. However, a drug will retain its orphan drug status if the drug receives approval for a subsequent indication for a rare disease or condition for which a subsequent section 45C credit was allowed.

III. Information Requested From Covered Entities

Consistent with the proposal in previous IRS guidance, the temporary regulations give each covered entity the opportunity to provide information relevant to the determination of the section 9008 fee by annually submitting Form 8947, ''Report of Branded Prescription Drug Information,'' and providing the information specified by the form and instructions, including the NDCs for branded prescription drugs that the covered entity sold to the Programs (or pursuant to coverage under the Programs), Medicare and Medicaid rebate information, section 45C orphan drug information, members of controlled groups, and designated entity information.

One commentator suggested that the Treasury Department and the IRS confirm that submission of Form 8947 is voluntary. Section 51.3T(a) of the temporary regulations provides that a covered entity *may* file a completed Form 8947; thus, the submission of Form 8947 is voluntary.

Commentators expressed a preference for CMS to include all rebate data in their reports to the IRS rather than collecting rebate data from the covered entities on Form 8947. The IRS and CMS are continuing to work on this issue. Until CMS can report all the relevant rebate data, covered entities will continue to have the opportunity to submit rebate data as requested on Forms 8947 and in the format prescribed in the form instructions.

Several commentators suggested that the Treasury Department and the IRS provide guidance on how covered entities may amend their Form 8947 to correct errors or omissions in the information reported. A number of covered entities notified the IRS of corrections to their Forms 8947 in the error reports that they submitted as part of the dispute resolution process provided under Rev. Proc. 2011–24. That proved to be an efficient and effective way to relay corrections. Accordingly, under the temporary regulations, a covered entity may notify the IRS of any changes or additions to information it submitted on Form 8947 by submitting error reports in the dispute resolution process, discussed later in this preamble.

IV. Information Provided by the Agencies

Consistent with the proposal in the previous IRS guidance, the temporary regulations provide that the IRS will (1) compile a list of branded prescription drugs by NDC using the data submitted on Forms 8947; (2) apply appropriate due diligence; and (3) provide the Agencies with the list. The temporary regulations describe the data the Agencies are to provide the IRS annually for each NDC on the list by Program. The temporary regulations further clarify that the IRS may revise the list of NDCs as a result of information received in the dispute resolution process, and that the data the IRS uses to produce the final fee determination includes any revisions provided by the Agencies at the completion of the dispute resolution process.

Commentators raised questions about the descriptions in previous IRS guidance of the methodology used by the Agencies to report branded prescription drug sales to the IRS and asked that these descriptions be clarified. In addition, some of the error reports submitted as part of the dispute resolution process under Rev. Proc. 2011–24 identified the need for clarification in describing Agency data. In response to the comments and the issues illuminated by the error reports, the temporary regulations provide revised descriptions of the data and computations for some of the Programs.

Commentators raised questions about the methodology proposed for computing branded prescription drug sales for Medicare Part B. Specifically, they questioned the use of Medicare-allowed charges to establish the sales rather than a computation based on the per-unit average sales price (ASP) and the units paid for under Medicare Part B as specified in section 9008(g)(2). Commentators also asked whether CMS would use ASP (that is, ASP plus 0%) or ASP plus 6% (which reflects amounts actually paid) in computing the sales figures. After considering the comments, CMS refined its calculation process. Thus, the temporary regulations provide that branded prescription drug sales for Medicare Part B will be computed based on ASP and units paid for under Medicare Part B.

Commentators also requested clarification about how sales will be calculated for branded prescription drugs that are not separately payable or reported. In the unusual situation where CMS is unable to establish a reliable proportion of sales by NDC, for example due to unavailable, inaccurate, or incomplete manufacturer sales data, the temporary regulations clarify that CMS has a back-up method that will use Medicare Part D utilization percentages in lieu of manufacturer data. It should be noted, however, that for the 2011 fee calculations, this back-up method was not required.

Commentators also expressed concerns about whether Medicare Part B is capturing complete data with respect to non-separately payable drugs, that is, drugs that are not directly correlated with a specific HCPCS Code. CMS recognizes the commentators' concern and has made extensive efforts to gather as complete a data set as possible. CMS will continue to work with the data available to capture non-separately payable drugs.

Some commentators asked whether the sales data from Medicaid reflected sales where Medicaid was the secondary payer, resulting potentially in duplicate reporting where another one of the Programs (for example, Medicare Part B), was the primary payer. In response, CMS has revised the Medicaid methodology to exclude non-Medicaid payments, and the temporary regulations include a description of this aspect of the methodology.

Commentators asked whether TRICARE sales data would be net of refunds and rebates associated with specific NDCs. The temporary regulations make clear that DOD will report for TRICARE the sales data for each NDC based on retail pharmacy claims submitted during the sales year, net of any refunds or rebates. Commentators questioned whether the VA sales data excluded purchases made at individual treatment facilities. The VA includes most of its purchases made at the individual medical treatment facility level in its data because most of these purchases are made via VA's Pharmaceutical Prime Vendor. The description of VA sales data contained in the temporary regulation is revised from the description contained in earlier guidance to eliminate language suggesting that sales at the individual medical treatment facility level are not included and to clarify that the sales data is net of refunds and rebates.

V. Fee Calculation Including Adjustment

The temporary regulations clarify that the IRS will compute the fee for a covered entity based on the branded prescription drug sales data for each NDC reported by the Agencies and any rebate data for each NDC reported by the covered entities. For purposes of computing the fee, each NDC will be assigned to the covered entity that owns the NDC as of the end of the day on December 31st of the sales year. For a covered entity that is a controlled group, this includes all NDCs that a member of the covered entity owns as of the end of the day on December 31st of the sales year.

The temporary regulations provide that two years are relevant to the calculation of the section 9008 fee: The fee year, and the calendar year of the branded prescription drug sales, which will be used to determine the amount of the fee (the sales year). As proposed in previous IRS guidance, the temporary regulations use the second calendar year preceding the fee year as the sales year for purposes of calculating the section 9008 fee. The Treasury Department and the IRS have determined that, although DOD and VA are expected to have complete data on branded prescription drug sales for the calendar year immediately preceding the fee year within the time frame necessary to administer the fee, CMS is not expected to have comparable data because it cannot complete its data processing within the necessary time frame. Accordingly, the IRS will calculate the fee based on the branded prescription drug sales data provided by the Agencies for the second calendar year preceding the fee year. Because the use of the second preceding year as the sales year, rather than the immediately preceding year, may affect the amount of the fee paid by a covered entity, the annual fee due in every year after 2011 will include an adjustment amount. This adjustment amount will be added (or subtracted), as appropriate, to (or from) the fee otherwise payable by the covered entity in the fee year in which the adjustment is calculated.

The proposal in previous guidance was to compute the adjustment separately for each NDC. Commentators raised questions about the effect of the adjustment where a drug is owned by different covered entities in the second preceding year and immediately preceding year and asked whether the adjustment could be computed at the covered entity level rather than the NDC level. The Treasury Department and the IRS have considered these questions, and have decided to calculate the adjustment at the covered entity level.

The adjustment will reflect the difference between the fee determined for a covered entity in the immediately preceding fee year, using data from the second calendar year preceding that fee year, and what the fee for the covered entity would have been for the immediately preceding fee year using data from the calendar year immediately preceding the prior fee year. For example, for 2012, the adjustment amount for a covered entity will be the difference between the 2011 fee computed using 2009 sales data, and what the 2011 fee would have been using 2010 sales data. Although the adjustment reflects a revision of the prior year's fee based on data from the sales year immediately preceding the prior fee year, the adjustment is only taken into account by adding it to or subtracting it from the fee computed for the current fee year.

VI. Notice of Preliminary Fee Calculation

Consistent with the proposal in the previous IRS guidance, the temporary regulations provide that the IRS will provide each covered entity with a notice of preliminary fee calculation each year that will include the covered entity's preliminary fee calculation; the covered entity's branded prescription drug sales, by NDC, for each Program; the covered entity's branded prescription drug sales taken into account after application of section 9008(a)(2); the aggregate branded prescription drug sales taken into account for all covered entities; after the 2011 fee year, a preliminary adjustment amount; and a reference to the fee dispute resolution process set forth in guidance published in the Internal Revenue Bulletin. The date by which the IRS will send the preliminary fee calculation notice will be specified for future years in guidance published in the Internal Revenue Bulletin. For 2011, the IRS sent the notices by May 16, 2011. The Treasury Department and the IRS anticipate sending these notices earlier in future years.

VII. Dispute Resolution Process

Consistent with previous IRS guidance, the temporary regulations provide for a dispute resolution process that allows a covered entity to submit error reports in response to the preliminary fee calculation for the IRS to consider before performing a final fee calculation. The temporary regulations describe the information that covered entities must submit. The IRS will specify in guidance published in the Internal Revenue Bulletin the format for error report submissions and the date by which a covered entity must submit an error report(s). For 2011, a covered entity's error report was required to be submitted no later than June 10, 2011. The Treasury Department and the IRS anticipate that covered entities will have more time to prepare and send their error reports to the IRS in future years.

Several commentators requested the ability to submit additional error reports after the IRS sends notification of the final fee determination. In the interest of providing finality to the fee calculation process, the temporary regulations do not adopt this suggestion.

VIII. Notification and Payment of Fee

Section 9008(a) provides that the annual fee must be paid not later than the annual date specified by the Secretary, but in no event later than September 30th of each fee year. The temporary regulations provide that the IRS will send each covered entity its final fee calculation for that year no later than August 31st and that the covered entity must pay the fee by September 30th by electronic funds transfer. For 2011, the IRS will send covered entities notification of their 2011 final fee calculation by August 24th. This notification will include the covered entity's final fee; the covered entity's branded prescription drug sales by NDC for each Program; the covered entity's branded prescription drug sales taken into account after application of section 9008(a)(2); the aggregate branded prescription drug sales taken into account for all covered entities; after the 2011 fee year, an adjustment

amount; and the final determination with respect to error reports.

There is no tax return to be filed for the section 9008 fee.

IX. Tax Treatment of Fee

Section 9008(f)(1) provides that the branded prescription drug fee for purposes of subtitle F of the Internal Revenue Code shall be treated as an excise tax with respect to which only civil actions for refund under procedures of subtitle F shall apply. Thus, under the temporary regulations, the section 9008 fee is treated as an excise tax for purposes of subtitle F of the Code (sections 6001–7874) to which the deficiency procedures of sections 6211–6216 do not apply. The temporary regulations provide that the IRS must assess the amount of the section 9008 fee for any fee year within three years of September 30th of that fee year.

X. Refund Claims

The temporary regulations provide that any claim for refund must be filed on Form 843, ''Claim for Refund and Request for Abatement.''

Availability of IRS Documents

IRS notices and the revenue procedure cited in this preamble are published in the Internal Revenue Bulletin or Cumulative Bulletin and are available at IRS.gov.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. chapter 5) does not apply to these regulations. For applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6), please refer to the Special Analysis section in the preamble to the cross-referenced notice of proposed rulemaking in the Proposed Rules section in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

Section 553(b) of the APA does not apply to these regulations because they are interpretative rules. Alternatively, the Treasury Department and the IRS have determined that good cause exists under section 553(b)(B) of the APA. That section provides that an agency is not required to publish a notice of proposed rulemaking in the **Federal Register** when the agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. Due to the novel and complex issues raised by the branded prescription drug fee provision and the required coordination with other governmental agencies, the Treasury Department and the IRS have concluded that it would take significantly longer than the time between enactment (March 23, 2010) and the date of collection of the first fee (no later than September 30, 2011) to draft and issue a proposed rule with a comment period, review comments thoroughly, and then draft and issue a final rule. Accordingly, the Treasury Department and the IRS have determined that the notice and comment procedures are impracticable.

In the months following enactment of section 9008, the Treasury Department and the IRS, in coordination with other governmental agencies, developed the proposed methodologies and processes to compute, verify, assess and collect the annual fee amounts, and published notices and a revenue procedure in the Internal Revenue Bulletin describing the proposed approach and soliciting public comments. The Treasury Department and the IRS provided an extended comment period to give the covered entities an opportunity to review their preliminary fee calculations before submitting comments on the proposed approach. In addition, the Treasury Department and the IRS engaged in discussions with affected external stakeholders and extensively coordinated with other governmental agencies. Consequently, the Treasury Department and the IRS also have determined that additional notice and comment before implementation of the process set forth in these regulations is unnecessary.

Since Congress mandated that the IRS collect the applicable fee amount for the first fee year no later than September 30, 2011, it is necessary that these regulations be issued immediately in order to provide covered entities with the rules governing the fee and payment prior to issuance of final fee determinations. However, comments are being solicited in the cross-referenced notice of proposed rulemaking that is in the Proposed Rules section in this issue of the **Federal Register** and will be considered before final regulations are issued regarding the branded prescription drug fee.

Drafting Information

The principal author of these regulations is Celia Gabrysh, Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects

26 CFR Part 51

Drugs, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR chapter 1 is amended by adding part 51 to subchapter D and amending part 602 as follows:

■ **Paragraph 1.** Part 51 is added to read as follows:

PART 51—BRANDED PRESCRIPTION DRUG FEE

Sec.

51.1T Overview (temporary).
51.2T Explanations of terms (temporary).
51.3T Information requested from covered entities (temporary).
51.4T Information provided by the agencies (temporary).
51.5T Fee calculation (temporary).
51.6T Notice of preliminary fee calculation (temporary).
51.7T Dispute resolution process (temporary).
51.8T Notification and payment of fee (temporary).
51.9T Tax treatment of fee (temporary).
51.10T Refund claims (temporary).
51.11T Effective/applicability date (temporary).
51.12T Expiration date (temporary).
51.6302–1T Method of paying the branded prescription drug fee (temporary).

Authority: 26 U.S.C. 7805; sec. 9008, Public Law 111–347 (124 Stat. 119).

Section 51.8 also issued under 26 U.S.C. 6302(a).

Section 51.6302–1 also issued under 26 U.S.C. 6302(a).

§ 51.1T Overview (temporary).

(a) The regulations in this part 51 are designated ''Branded Prescription Drug Fee Regulations.''

(b) The regulations in this part 51 provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs by section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111–148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111–152 (124 Stat. 1029 (2010)). All references in

these regulations to section 9008 are references to section 9008 of the ACA, as amended by section 1404 of HCERA. Unless otherwise indicated, all other section references are to sections in the Internal Revenue Code. All references to ''fee'' in these regulations are references to the fee imposed by section 9008.

(c) Section 9008(b)(4) sets an applicable fee amount for each year, beginning with 2011, that will be apportioned among covered entities with aggregate branded prescription drug sales of over $5 million to government programs or pursuant to coverage under such programs. Generally, each covered entity is liable for a fee in each fee year that is based on its sales of branded prescription drugs in the sales year that corresponds to the fee year in an amount determined by the Internal Revenue Service (IRS) under the rules of this part.

§ 51.2T Explanation of terms (temporary).

(a) *In general*. This section explains the terms used in this part for purposes of the fee imposed by section 9008 on branded prescription drugs.

(b) *Agencies*. The term *agencies* means—

(1) The Centers for Medicare and Medicaid Services of the Department of Health and Human Services (CMS);

(2) The Department of Veterans Affairs (VA); and

(3) The Department of Defense (DOD).

(c) *Branded prescription drug*—(1) *In general*. The term *branded prescription drug* means—

(i) Any prescription drug the application for which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)); or

(ii) Any biological product the license for which was submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(2) *Prescription drug*. The term *prescription drug* means any drug that is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

(d) *Branded prescription drug sales*. The term *branded prescription drug sales* means sales of branded prescription drugs to any government program or pursuant to coverage under any such government program. However, the term does not include sales of orphan drugs.

(e) *Covered entity*—(1) *In general*. The term *covered entity* means any manufacturer or importer with gross receipts from branded prescription drug sales including—

(i) A single-person covered entity; or

(ii) A controlled group.

(2) *Single-person covered entity*. The term *single-person covered entity* means a covered entity that is not affiliated with any other covered entity.

(3) *Controlled group*. The term *controlled group* means a group of at least two covered entities that are treated as a single employer under section 52(a), 52(b), 414(m), or 414(o).

(4) *Special rules for controlled groups*. For purposes of paragraph (e)(3) of this section (related to controlled groups)—

(i) A foreign entity subject to tax under section 881 is included within a group under section 52(a) or 52(b); and

(ii) A covered entity is treated as being a member of a controlled group if it is a member of the group on the end of the day on December 31st of the sales year.

(f) *Designated entity*—(1) *In general*. The term *designated entity* means the person that acts for a controlled group regarding the fee by—

(i) Filing Form 8947, ''Report of Branded Prescription Drug Information'';

(ii) Receiving IRS communications about the fee for the group;

(iii) Filing an error report for the group, if applicable, as described in § 51.7T; and

(iv) Paying the fee to the IRS.

(2) *Selection of designated entity*—(i) *Choice of controlled group*. Unless the controlled group is an affiliated group that filed a consolidated return for Federal income tax purposes, the controlled group may select a person as the designated entity by filing Form 8947 in accordance with the form instructions. Among other requirements, the designated entity must state that all the manufacturers or importers of branded prescription drugs that are members of the group have consented to the selection of the designated entity.

(ii) *Requirement for affiliated groups; common parent*. If the controlled group, without regard to foreign corporations included under section 9008(d)(2)(B), is also an affiliated group that filed a consolidated return for Federal income tax purposes, the designated entity is the common parent of the affiliated group as identified on the tax return filed for the sales year. The covered entities in an affiliated group must name the common parent as the designated entity on Form 8947.

(iii) *IRS selection of a designated entity*. If a controlled group does not select a designated entity, the IRS will select a member of the controlled group as the designated entity for the controlled group.

(g) *Fee year*. The term *fee year* means the calendar year in which the fee for a particular sales year must be paid to the government.

(h) *Government programs*. The term *government programs* (collectively ''Programs''), means—

(1) The Medicare Part B program;

(2) The Medicare Part D program;

(3) The Medicaid program;

(4) Any program under which branded prescription drugs are procured by the Department of Veterans Affairs;

(5) Any program under which branded prescription drugs are procured by the Department of Defense; and

(6) The TRICARE retail pharmacy program.

(i) *Manufacturer or importer*. The term *manufacturer or importer* means the person identified in the Labeler Code of the National Drug Code (NDC) for a branded prescription drug.

(j) *NDC*. The term *NDC* means the National Drug Code. The NDC is an identifier assigned by the Food and Drug Administration (FDA) to a branded prescription drug, as well as other drugs. The Labeler Code is the first five numeric characters of the NDC or the first six numeric characters when the available five-character code combinations are exhausted.

(k) *Orphan drugs*—(1) *In general*. Except as provided in paragraph (j)(2) of this section, the term *orphan drug* means any branded prescription drug for which any person claimed a section 45C credit and that credit was allowed for any taxable year.

(2) *Exclusions*. The term *orphan drug* does not include—

(i) Any drug for which there has been a final assessment or court order disallowing the full section 45C credit taken for the drug; or

(ii) Any drug for any sales year after the calendar year in which the FDA approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed, regardless of whether a section 45C credit was allowed for the drug either before, in the same year as, or after this FDA designation.

(3) *FDA marketing approval for treatment of another rare disease or condition*. If a drug has prior FDA marketing approval for the treatment of a rare disease or condition for which a section 45C credit was allowed, and the FDA subsequently gives the drug marketing approval for the treatment of another rare disease or condition for which another section 45C credit was also allowed, the drug retains its status as an orphan drug provided the FDA has never approved the drug for marketing for any indication other than the treatment of a rare disease or condition

for which a section 45C credit was allowed.

(4) *Examples.* The following examples illustrate the rules of this paragraph (k):

Example 1: Allowance of section 45C credit and later FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition. (i) *Facts.* Drug A is a branded prescription drug that was not on the market before 2008. In 2008, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug A. There was no final IRS assessment or court order that disallowed the full credit for Drug A. In 2009, the FDA approved Drug A for marketing for an indication other than the treatment of the rare disease or condition for which the section 45C credit was allowed and this indication was not for another rare disease or condition for which a section 45C was allowed.

(ii) *Analysis.* In 2008 and 2009, Drug A is an orphan drug because: first, it was a branded prescription drug for which a person claimed a section 45C credit and for which that credit was allowed for a taxable year; second, there was not a final assessment or court order disallowing the full credit taken for the drug; and third, before 2009, the FDA did not approve the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. However, Drug A is not an orphan drug for the 2010 sales year or later sales years because in 2009 the FDA approved Drug A for marketing for an indication other than the treatment of the rare disease or condition for which the section 45C credit was allowed and this indication was not for treatment of another rare disease or condition for which a section 45C credit was allowed.

Example 2: FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition and later allowance of section 45C credit. (i) *Facts.* Drug B is a branded prescription drug that was not on the market before 2008. In 2008, FDA approved Drug B for marketing for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. In 2009, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug B. There was no final IRS assessment or court order that disallowed the full credit for Drug B.

(ii) *Analysis.* In 2008, Drug B is not an orphan drug because no section 45C credit was allowed. In 2009, although the covered entity was allowed a section 45C credit for its qualified clinical testing expenses related to Drug B and there was no final IRS assessment or court order that disallowed the full credit, Drug B still is not an orphan drug because the FDA had approved the drug in 2008 for marketing for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed in 2009. Thus, Drug B is not an orphan drug for the 2009 sales year or later sales years.

Example 3: Allowance of section 45C credit and subsequent allowance of section 45C credit with no intervening FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. (i) *Facts.* Drug C is a branded prescription drug that was not on the market before 2007. In 2007, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug C. In 2009, a covered entity claimed an additional section 45C credit for its qualified clinical testing expenses related to Drug C for marketing for the treatment of a rare disease or condition different than the one for which the section 45C credit was claimed in 2007. There was no final IRS assessment or court order that disallowed the full credit for Drug C in 2007 or 2009. The FDA has not approved Drug C for an indication other than the treatment of a rare disease or condition for which a section 45C was allowed.

(ii) *Analysis.* In 2007 and 2008, Drug C is an orphan drug because: first, it was a branded prescription drug for which a person claimed a section 45C credit and for which that credit was allowed for a taxable year; second, there was not a final assessment or court order disallowing the full credit taken for the drug; and third, FDA had not approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. In 2009, Drug C retains its orphan drug status because another section 45C credit was allowed and the FDA did not approve Drug C for marketing for any indication other than the treatment of another rare disease or condition for which a section 45C credit was allowed. Thus, Drug C is an orphan drug for the 2010 sales year.

(l) *Sales taken into account.* The term *sales taken into account* means branded prescription drug sales after application of the percentage adjustment table in section 9008(b)(2) (relating to annual sales less than $400,000,001). See § 51.5T(a)(3).

(m) *Sales year.* The term *sales year* means the second calendar year preceding the fee year. Thus, for example, for the fee year of 2011, the sales year is 2009.

§ 51.3T Information requested from covered entities (temporary).

(a) *In general.* Annually, each covered entity may submit a completed Form 8947, ''Report of Branded Prescription Drug Information,'' in accordance with the instructions for the form. Generally, the form solicits information from covered entities on NDCs, orphan drugs, designated entities, rebates, and other information specified by the form or its instructions.

(b) *Due date.* Form 8947 must be filed by the date prescribed in guidance in the Internal Revenue Bulletin.

§ 51.4T Information provided by the agencies (temporary).

(a) *In general.* For each sales year, the IRS will compile a list of branded prescription drugs by NDC using the data submitted on Forms 8947 and in error reports submitted as part of the dispute resolution process (described in § 51.7T) and, after applying appropriate due diligence, will provide this list to the Agencies. The Agencies will provide data to the IRS on branded prescription drug sales during the sales year by Program and NDC. The Agencies will provide data for use in preparing the preliminary fee calculation (described in §§ 51.5T and 51.6T) and may revise or supplement that data following review of error reports submitted as part of the dispute resolution process. The calculation methodology for calculating the sales amounts for each Program, including any reasonable estimation techniques and assumptions that the Agencies expect to use, is described in this section.

(b) *Medicare Part D.* CMS will aggregate the ingredient cost reported in the ''Ingredient Cost Paid'' field and the units reported in the ''Quantity Dispensed'' field of the Prescription Drug Event (PDE) records at the NDC level for each sales year. Only PDE data that Part D sponsors have submitted by the PDE submission deadline (within 6 months after the end of the sales year) and have been approved for inclusion in the Part D payment reconciliation will be included.

(c) *Medicare Part B*—(1) *In general.* CMS will determine branded prescription drug sales under Medicare Part B using the following two data sources:

(i) CMS will use data reported by manufacturers pursuant to section 1847A(c) of the Social Security Act to calculate the annual weighted average sales price (ASP) for each Healthcare Common Procedure Coding System (HCPCS) code for the sales year.

(ii) CMS will use the Medicare Part B National Summary Data File located at *http://www.cms.gov/NonIdentifiableDataFiles/03_PartBNationalSummaryDataFile.asp* to obtain the number of allowed billing units per HCPCS code for claims incurred during the sales year.

(2) *Calculation.* Using the data described in paragraph (c)(1) of this section, CMS will determine branded prescription drugs sales under Medicare Part B as described in paragraphs (c)(3), (4), and (5) of this section.

(3) *HCPCS code; single entity.* For each HCPCS code consisting solely and exclusively of branded prescription drugs (as identified by their respective NDCs) manufactured by a single entity, CMS will multiply the annual weighted ASP by the total number of allowed billing units paid during the sales year

to determine the total sales for all NDCs associated with the HCPCS code attributed to Medicare Part B.

(4) *HCPCS code; multiple manufacturers and/or multiple drugs*—(i) *Step one.* For each HCPCS code consisting of a mixture of branded prescription drugs made by different manufacturers and/or a mixture of branded prescription and generic drugs, CMS will determine—

(A) The annual weighted ASP for the HCPCS code;

(B) The total number of allowed billing units paid by Medicare Part B for each HCPCS code during the sales year;

(C) The names of the entities engaged in manufacturing each NDC assigned to the HCPCS code; and

(D) Those entities (if any) identified in paragraph (c)(4)(C) of this section that are manufacturing branded prescription drugs assigned to the HCPCS code.

(ii) *Step two.* Using the information from paragraph (c)(4)(i) of this section, CMS will then do the following:

(A) Calculate the proportion of sales, expressed as a percentage, attributed to each NDC assigned to the HCPCS code by determining the percentage of total sales reported to CMS by each manufacturer of NDC(s) that are assigned to the HCPCS code. For example, if HCPCS code JXXXX contains three drugs with a total of $310,000 sales reported by manufacturers to CMS for the sales year, and $100,000 was reported for Drug A, $200,000 was reported for Drug B, and $10,000 was reported for Drug C, the proportion of sales attributed to each NDC will be 32.26 percent for Drug A, 64.52 percent for Drug B, and 3.22 percent for Drug C; and

(B) For each NDC, multiply the product of the annual weighted ASP and the total allowed billing units paid by Medicare Part B for the HCPCS code by the proportion of sales calculated in paragraph (c)(4)(ii)(A) of this section to determine the sales reportable to the IRS (that is, percentage × (annual weighted ASP × allowed units) = total sales reported to IRS for the NDC). The sales for each manufacturer's NDCs assigned to a HCPCS code are summed and the total sales for each manufacturer's NDCs in a HCPCS code will be reported to the IRS.

(5) *HCPCS code; unable to establish a reliable proportion of sales.* If CMS is unable to establish a reliable proportion of sales attributable to each NDC assigned to the HCPCS code using the method described in paragraph (c)(4)(ii)(A) of this section, CMS will use Medicare Part D utilization percentages in lieu of the proportion of sales determined under paragraph (c)(4)(ii)(A) of this section to perform the calculation described in paragraph (c)(4)(ii)(B) of this section.

(d) *Medicaid.* (1) CMS will determine the branded prescription drug sales for Medicaid as the per-unit Average Manufacturer Price (AMP) less the Unit Rebate Amounts (URA) that CMS calculates based on manufacturer-reported pricing data multiplied by the number of units reported billed by states to manufacturers. This data will be based on the data reported to CMS during the sales year by covered entities and the states for drugs paid for by the states in the Medicaid drug rebate program during the sales year.

(2) For any covered entity identified in the first five (or six) digits of an NDC during any of the four quarters of a sales year, CMS will use the following methodology to derive the sales figures that account for third-party payers, such as Medicare Part B:

(i) Report total dollars per NDC for AMP–URA multiplied by the units reported by a state or states.

(ii) Determine the percentage of the total amount reimbursed that is the Medicaid amount of that reimbursement. For example, if the total amount reimbursed is $100,000, and the Medicaid amount reimbursed is $20,000, then the percentage is 20 percent.

(iii) Multiply the percentage of the Medicaid amount of that reimbursement (in the example in paragraph (d)(2)(ii) of this section, 20 percent) by the dollar figure derived from paragraph (d)(2)(i) of this section (AMP minus URA multiplied by units) to get the new adjusted sales dollar totals.

(e) *Department of Veterans Affairs.* VA will provide, by NDC, the total amount paid (net of refunds and rebates, when they are associated with a specific NDC) for each branded prescription drug procured by the VA for its beneficiaries during the sales year. For this purpose, a drug is procured on the invoice (billing) date. The basis of this information will be national procurement data reported during the sales year by VA's Pharmaceutical Prime Vendor to the VA Pharmacy Benefits Management Service and National Acquisition Center.

(f) *Department of Defense.* The DOD will provide, by Labeler Code, the manufacturer's name, the NDC, brand name, and the amount paid (net of rebates and or refunds) for each branded prescription drug procured by DOD (for DOD programs other than the TRICARE retail pharmacy program) during the sales year. For DOD programs other than the TRICARE retail pharmacy program, a drug is procured based upon the date it was ordered. DOD will provide, by Labeler Code, the manufacturer's name, the NDC, brand name, and the amount paid (net of rebates or refunds) for each branded prescription drug procured by DOD through the TRICARE Retail Pharmacy Program during the sales year. For the TRICARE retail pharmacy program, a drug is procured based upon the date it was dispensed. The amount paid is based on the submitted ingredient cost paid, aggregated by NDC, for eligible TRICARE retail pharmacy claims submitted during the program year, minus any refunds or rebates for the corresponding claims.

§ 51.5T Fee calculation (temporary).

(a) *Fee components*—(1) *In general.* For every fee year, the IRS will calculate a covered entity's total fee as described in this section. For each fee year after 2011, the IRS will determine a covered entity's total fee by applying, if applicable, the adjustment amount described in paragraph (e) of this section to the entity's allocated fee described in paragraph (d) of this section.

(2) *Calculation of branded prescription drug sales.* Each covered entity's allocated fee for any fee year is equal to an amount that bears the same ratio to the applicable amount as the covered entity's branded prescription drug sales taken into account during the sales year bears to the aggregate branded prescription drug sales of all covered entities taken into account during the sales year.

(3) *Applicable amount.* The applicable amounts for fee years are—

Fee year	Applicable amount
2011	$2,500,000,000
2012	2,800,000,000
2013	2,800,000,000
2014	3,000,000,000
2015	3,000,000,000
2016	3,000,000,000
2017	4,000,000,000
2018	4,100,000,000
2019 and thereafter	2,800,000,000

(3) *Sales taken into account.* A covered entity's branded prescription drug sales taken into account during any calendar year are as follows:

Covered entity's branded prescription drug sales during the calendar year that are:	Percentage of branded prescription drug sales taken into account is
Not more than $5,000,000	0
More than $5,000,000 but not more than $125,000,000	10
More than $125,000,000 but not more than $225,000,000	40
More than $225,000,000 but not more than $400,000,000	75
More than $400,000,000	100

(b) *Determination of branded prescription drug sales.* The IRS will compile each covered entity's branded prescription drug sales for each Program by NDC. Each NDC will be attributed to the covered entity that owns the NDC as of the end of the day on December 31st of the sales year. For a covered entity that is a controlled group, this includes all NDCs that a member of the covered entity owns as of the end of the day on December 31st of the sales year. For this purpose, the IRS may revise the list of NDCs as a result of information received in the dispute resolution process, and the data the IRS uses to produce the final fee calculation will include any revisions provided by the Agencies at the completion of the dispute resolution process. Each covered entity's branded prescription drug sales will be reduced by its Medicare Part D rebates and Medicaid state supplemental rebate amounts in the following manner. If CMS has the rebate information for these Programs for a sales year, CMS will report to the IRS branded prescription drug sales net of rebates. If CMS does not have the rebate information for these programs for a sales year, the IRS will reduce the branded prescription drug sales reported for these Programs by rebates reported by the covered entities on Forms 8947.

(c) *Determination of sales taken into account.* (1) For each sales year and for each covered entity, the IRS will calculate sales taken into account. The resulting number is the numerator of the ratio described in paragraph (d)(1) of this section.

(2) For each sales year, the IRS will calculate the aggregate branded prescription drug sales taken into account for all covered entities. The resulting number is the denominator of the ratio described in paragraph (d)(2) of this section.

(d) *Allocated fee calculation.* For each covered entity for each fee year, the IRS will calculate the entity's allocated fee by multiplying the applicable amount from paragraph (a)(2) of this section by a fraction—

(1) The numerator of which is the covered entity's branded prescription drug sales taken into account during the sales year (described in paragraph (c)(1) of this section); and

(2) The denominator of which is the aggregate branded prescription drug sales taken into account for all covered entities during the same year (described in paragraph (c)(2) of this section).

(e) *Adjustment amount.* For each fee year after 2011, in addition to the allocated fee computed under paragraph (d) of this section, the IRS will also calculate an adjustment amount that reflects the difference between the allocated fee determined for the covered entity in the immediately preceding fee year, using data from the second calendar year preceding that fee year, and what the allocated fee would have been for that entity for the immediately preceding fee year using data from the calendar year immediately preceding that fee year. For example, for 2012, the adjustment amount for a covered entity will be the difference between the entity's 2011 allocated fee, using 2009 data, and what the 2011 allocated fee would have been using 2010 data. Although the adjustment reflects a revision of the prior year's fee based on data from the year immediately preceding the prior fee year, the adjustment is only taken into account by adding it to or subtracting it from the allocated fee computed under paragraph (d) of this section for the current fee year to arrive at the total fee for the current fee year.

§ 51.6T Notice of preliminary fee calculation (temporary).

(a) *Content of notice.* For each sales year, the IRS will make a preliminary calculation of the fee for each covered entity as described in § 51.5T. The IRS will notify each covered entity of its preliminary fee calculation for that sales year. The notification to a covered entity of its preliminary fee calculation will include—

(1) The covered entity's allocated fee;

(2) The covered entity's branded prescription drug sales, by NDC, by Program;

(3) The covered entity's branded prescription drug sales taken into account after application of § 51.5T(a)(3);

(4) The aggregate branded prescription drug sales taken into account for all covered entities;

(5) After the 2011 fee year, the covered entity's adjustment amount calculated as described in § 51.5T(e); and

(6) A reference to the fee dispute resolution procedures set forth in guidance published in the Internal Revenue Bulletin.

(b) *Time of notice.* The IRS will send each covered entity notice of its preliminary fee calculation by the date prescribed in guidance published in the Internal Revenue Bulletin.

§ 51.7T Dispute resolution process (temporary).

(a) *In general.* Upon receipt of its preliminary fee calculation, each covered entity will have an opportunity to dispute this calculation by submitting to the IRS an error report as described in this section. The IRS will provide its final determination with respect to error reports no later than the time the IRS provides a covered entity with a final fee calculation.

(b) *Program errors.* To assert that there has been one or more errors in drug sales data, a covered entity must submit a separate error report for each Program with the asserted errors. Each report must include the following information—

(1) Entity name, entity number (if applicable, from Part I (a) of the Form 8947), address, and Employer Identification Number (EIN) as previously reported on the Form 8947;

(2) The name, telephone number, and e-mail address (if available) of one or more employees or representatives of the entity with whom the Agencies may discuss the claimed errors. A Form 2848, ''Power of Attorney and Declaration of Representative,'' must be filed with the error report; and

(3) The name of the Program that reported the data, the NDC, the specific amount of sales data disputed, the proposed corrected amount, an explanation of why the Agency should use the proposed corrected data instead,

and documentation of any Program drug sales data or other information used to establish the existence of any errors.

(c) *Errors other than Program drug sales errors.* To assert that there has been one or more errors in the mathematical calculation of the fee, the rebate data, the listing of an NDC for an orphan drug, or any other error (other than Program drug sales data errors), a covered entity must submit one error report, separated into sections by type of error, and must include the following information—

(1) Entity name, entity number (if applicable, from Part I (a) of the Form 8947), address, and EIN as previously reported on the Form 8947;

(2) The name, telephone number, and e-mail address (if available) of one or more employees or representatives of the entity with whom the IRS and/or the Agencies may discuss the claimed errors. If the representative is not an employee of the entity, a Form 2848 must be filed with the error report;

(3) For a mathematical calculation error, the specific calculation element(s) that the entity disputes and its proposed corrected calculation;

(4) For a rebate data error, the NDC for the drug to which it relates; a discussion of whether the data used in the preliminary fee calculation matches previously reported Form 8947 data on rebates; and, if the data used in the preliminary fee calculation does match the Form 8947 data, an explanation of why the Form 8947 data was erroneous and why the IRS should use the proposed corrected data instead;

(5) For the listing of an NDC for an orphan drug, the name and NDC of the orphan drug; a discussion of whether the data used in the preliminary fee calculation matches previously reported Form 8947 data on orphan drugs; and, if the data used in the preliminary fee calculation does match the Form 8947 data, an explanation of why the Form 8947 data was erroneous and why the IRS should use the proposed corrected data instead;

(6) For any other asserted error, an explanation of the nature of the error, how the error affects the fee calculation, an explanation of how the entity established that an error occurred, the proposed correction to the error, and an explanation of why the IRS or Agency should use the proposed corrected data instead;

(7) If an entity is using data to establish the existence of an error and that data was not reported on Form 8947 or contained in the notification of the preliminary fee calculation, a description of what the data is, how the entity acquired the data, and who maintains it; and

(8) Documentation of any rebate and orphan drug data, or other information used to establish the existence of any errors.

(d) *Form, manner, and timing of submission.* Each covered entity must submit its error report(s) in the form and manner that is prescribed in guidance published in the Internal Revenue Bulletin. This guidance will also prescribe the date by which each covered entity must submit its report(s).

§ 51.8T Notification and payment of fee (temporary).

(a) *Notification of final fee calculation.* No later than August 31st of each fee year, the IRS will send each covered entity its final fee calculation for that year. In any fee year, the IRS will base its final fee calculation on data provided to it by the Agencies as adjusted pursuant to the dispute resolution process. The notification to a covered entity of its final fee calculation will include—

(1) The covered entity's allocated fee;

(2) After the 2011 fee year, an adjustment amount calculated as described in § 51.5T;

(3) The covered entity's branded prescription drug sales, by NDC, by Program;

(4) The covered entity's branded prescription drug sales taken into account after application of § 51.5T(a)(3);

(5) The aggregate branded prescription drug sales taken into account for all covered entities; and

(6) The final determination with respect to error reports.

(b) *Differences in preliminary fee calculation and final fee calculation.* A covered entity's final fee calculation may differ from the covered entity's preliminary fee calculation because of changes made pursuant to the dispute resolution process described in § 51.7T. Even if a covered entity did not file an error report described in § 51.7T, a covered entity's final fee may differ from a covered entity's preliminary fee because of a change in data reported by the Agencies after resolution of error reports, including a change in the aggregate prescription drug sales figure. A change in aggregate prescription drug sales data can affect each covered entity's fee because each covered entity's fee is a fraction of the aggregate fee collected from all covered entities. A covered entity's final fee may also differ from its preliminary fee calculation because the data used in the preliminary fee calculation may have contained inaccurate branded prescription drug sales information that was corrected or updated at the conclusion of the dispute resolution process.

(c) *Payment of final fee.* Each covered entity must pay its final fee by September 30th of the fee year. For a controlled group, the payment must be made using the designated entity's EIN as reported on Form 8947. The fee must be paid by electronic funds transfer as required by § 51.6302–1T. There is no tax return to be filed for the fee.

(d) *Joint and several liability.* In the case of a controlled group that is liable for the fee, all covered entities within the controlled group are jointly and severally liable for the fee. Accordingly, if a covered entity's fee is not paid, the IRS will separately assess each covered entity in the group for the full amount of the controlled group's fee.

§ 51.9T Tax treatment of fee (temporary).

(a) *Treatment as an excise tax.* The fee imposed by section 9008 is treated as an excise tax for purposes of subtitle F of the Code (sections 6001–7874). Thus, references in subtitle F to ''taxes imposed by this title,'' ''internal revenue tax,'' and similar references, are also references to the fee imposed by section 9008. For example, the fee imposed by section 9008 is assessed (section 6201), collected (sections 6301, 6321, and 6331), enforced (section 7602), subject to examination and summons (section 7602), and subject to confidentiality rules (section 6103), in the same manner as taxes imposed by the Code.

(b) *Deficiency procedures.* The deficiency procedures of sections 6211–6216 do not apply to the fee imposed by section 9008.

(c) *Limitation on assessment.* The IRS must assess the amount of the fee for any fee year within three years of September 30th of that fee year.

(d) *Application of section 275.* The fee is treated as a tax described in section 275(a)(6) (relating to taxes for which no deduction is allowed).

§ 51.10T Refund claims (temporary).

Any claim for a refund of the fee must be made by the person that paid the fee to the government and must be made on Form 843, ''Claim for Refund and Request for Abatement,'' in accordance with the instructions for that form.

§ 51.11T Effective/applicability date (temporary).

Sections 51.1T through 51.10T apply to any fee on branded prescription drug sales that is due on or after September 30, 2011.

§ 51.12T Expiration date (temporary).

The applicability of §§ 51.1T through 51.10T expires August 15, 2014.

§ 51.6302–1T Method of paying the branded prescription drug fee (temporary).

(a) *Fee to be paid by electronic funds transfer.* Under the authority of section 6302(a), the fee imposed on branded prescription drug sales by section 9008 and § 51.5T must be paid by electronic funds transfer as defined in § 31.6302–1(h)(4)(i), as if the fee were a depository tax. For the time for paying the fee, see § 51.8T.

(b) *Effective/applicability date.* This section applies on and after *August 18, 2011.*

(c) *Expiration date.* The applicability of this section expires August 15, 2014.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 2.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 3.** In § 602.101, paragraph (b) is amended by adding the following entry in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where indentified and described	Current OMB Control No.
* * * * *	
51.8T	1545–2209
* * * * *	

Sarah Hall Ingram,

Deputy Commissioner for Services and Enforcement.

Approved: August 12, 2011.

Emily S. McMahon,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2011–21011 Filed 8–15–11; 11:15 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0760]

RIN 1625–AA87

Security Zone; Potomac River, Georgetown Channel, Washington, DC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone encompassing certain waters of the Potomac River, Georgetown Channel, in Washington, DC, in order to safeguard high-ranking public officials from terrorist acts and incidents. This action is necessary to ensure the safety of persons and property, and prevent terrorist acts or incidents. This rule prohibits vessels and people from entering the security zone and requires vessels and persons in the security zone to depart the security zone, unless specifically exempt under the provisions in this rule or granted specific permission from the Coast Guard Captain of the Port Baltimore.

DATES: This rule is effective from 6 a.m. until 6 p.m. on August 28, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0760 and are available online by going to *http://www.regulations.gov*, inserting USCG–2011–0760 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the 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, 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, call or e-mail Mr. Ronald L. Houck, at Sector Baltimore Waterways Management Division, Coast Guard; telephone 410–576–2674, e-mail *Ronald.L.Houck@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory 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 it is contrary to public interest to delay the effective date of this rule. The Coast Guard is establishing the security zone to protect high-ranking government officials, mitigate potential terrorist acts, and enhance public and maritime safety and security. The Coast Guard was unable to publish a NPRM due to the short time period between event planners notifying the Coast Guard of the event and publication of the security zone. Furthermore, delaying the effective date would be contrary to the security zone's intended objectives of protecting high-ranking government officials, mitigating potential terrorist acts and enhancing public and maritime safety security.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Due to the need for immediate action, the restriction of vessel traffic is necessary to protect life, property and the environment, therefore, a 30-day notice period is impracticable. Delaying the effective date would be contrary to the security zone's intended objectives of protecting high-ranking government officials, mitigating potential terrorist acts and enhancing public and maritime safety and security.

Background and Purpose

The President of the United States will be attending the Martin Luther King, Jr. National Memorial in Washington, DC dedication ceremony on August 28, 2011. The ceremony is located along the waterfront in Washington, DC, in close proximity to navigable waterways within the Captain of the Port's Area of Responsibility.

The Coast Guard has given each Coast Guard Captain of the Port the ability to implement comprehensive port security regimes designed to safeguard human life, vessels, and waterfront facilities while still sustaining the flow of commerce. The Captain of the Port Baltimore is establishing this security zone to protect high-ranking government officials, mitigate potential terrorist acts, and enhance public and maritime safety and security in order to safeguard life, property, and the environment on or near the navigable waters.

Discussion of Rule

Through this regulation, the Coast Guard will establish a security zone. The security zone will be in effect from 6 a.m. until 6 p.m. on August 28, 2011. The security zone will include all navigable waters of the Potomac River, Georgetown Channel, within 75 yards from eastern shore measured perpendicularly to the shore between the Theodore Roosevelt Memorial Bridge and the Arlington Memorial

Bridge, and within 150 yards from eastern shore measured perpendicularly to the shore from the Arlington Memorial Bridge to the George Mason Memorial Bridge (the most western bridge of the 5-span, Fourteenth Street Bridge Complex), including all waters of the Georgetown Channel Tidal Basin, located in Washington, DC. This location is entirely within the Area of Responsibility of the Captain of the Port Baltimore, as set forth at 33 CFR 3.25–15.

This rule requires that entry into, attempted entry into, or remaining in this security zone is prohibited unless authorized by the Coast Guard Captain of the Port Baltimore. Except for persons or vessels authorized by the Captain of the Port Baltimore, no person or vessel may enter or remain in the regulated area during the enforcement period. All vessels underway within the security zone at the time it is in effect are to depart the zone immediately. To seek permission to transit the area, the Captain of the Port Baltimore can be contacted at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Coast Guard vessels enforcing the security zone can be contacted on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). The Coast Guard will issue Broadcast Notices to Mariners to further publicize the security zone.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. Although this security zone restricts vessel traffic from transiting through the affected area, vessels may transit safely around the zone. Furthermore, the effect of this regulation will not be significant due to the limited size and duration that the regulated area will be in effect. In addition, notifications will be made to the maritime community via marine information broadcasts so mariners may adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this 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.

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 may affect the following entities, some of which might be small entities: The owners or operators of vessels intending to operate or transit through or within the security zone during the enforcement period. The security zone will not have a significant economic impact on a substantial number of small entities for the following reasons. The security zone is of limited size and duration. Vessel traffic may safely transit around the zone. Before the effective period, maritime advisories will be widely available to the maritime community.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

Collection of Information

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

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

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 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.

Taking of Private Property

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

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.

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.

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.

Energy Effects

We have analyzed this 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 energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

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

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 concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves establishing a temporary security zone. An environmental analysis checklist 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. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0760 to read as follows:

§ 165.T05–0760 Security Zone; Potomac River, Georgetown Channel, Washington, DC.

(a) *Location.* The following area is a security zone: All waters of the Potomac River, Georgetown Channel, within 75 yards from eastern shore measured perpendicularly to the shore between the Theodore Roosevelt Memorial Bridge and the Arlington Memorial Bridge, and within 150 yards from eastern shore measured perpendicularly to the shore from the Arlington Memorial Bridge to the George Mason Memorial Bridge (the most western bridge of the 5-span, Fourteenth Street Bridge Complex), including all waters of the Georgetown Channel Tidal Basin, located in Washington, DC.

(b) *Definitions.* As used in this section:

Captain of the Port Baltimore means the Commander, U.S. Coast Guard Sector Baltimore, Maryland.

Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Baltimore to assist in enforcing the security zone described in paragraph (a) of this section.

(c) *Regulations.* The general security zone regulations found in 33 CFR 165.33 apply to the security zone created by this temporary section, § 165.T05–0760.

(1) All persons are required to comply with the general regulations governing security zones found in 33 CFR 165.33.

(2) Entry into or remaining in this zone is prohibited unless authorized by the Coast Guard Captain of the Port Baltimore. All vessels underway within this security zone at the time it is implemented are to depart the zone.

(3) Persons desiring to transit the area of the security zone must first obtain authorization from the Captain of the Port Baltimore or his designated representative. To seek permission to transit the area, the Captain of the Port Baltimore and his designated representatives can be contacted at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Upon being hailed by a U.S. Coast Guard vessel, or other Federal, State, or local agency vessel, by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port Baltimore or his designated representative and proceed at the minimum speed necessary to maintain a safe course while within the zone.

(4) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zones by Federal, State, and local agencies.

(d) *Enforcement period.* This section will be enforced from 6 a.m. until 6 p.m. on August 28, 2011.

Dated: August 4, 2011.

Mark P. O'Malley,

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

[FR Doc. 2011–21027 Filed 8–17–11; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 111

First-Class Package Service

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service is revising *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®), 401, 402, 433, 434, 435, 436, 503, 507, 602, and 705 to introduce a new competitive product called First-Class Package Service, which will replace and remove First-Class Mail® commercial base and commercial plus parcels from the market-dominant product offering. First-Class Mail retail single-piece parcels remain a market-dominant product offering.

DATES: *Effective Date:* October 3, 2011.

FOR FURTHER INFORMATION CONTACT: Markes Lucius at 202–268–6140 or Bill Chatfield at 202–268–7278.

SUPPLEMENTARY INFORMATION: On February 24, 2011, the Postal Service filed a notice with the Postal Regulatory Commission to institute a new competitive product, then tentatively called ''Lightweight Commercial Parcels,'' and to remove First-Class Mail commercial base and commercial plus parcels from the market-dominant product offerings. The Commission completed its review on April 6, 2011.

In this final rule, the Postal Service provides a description of the conditions

for eligibility for the new competitive product, now called First-Class Package Service. First-Class Package Service parcels will receive the same service as First-Class Mail, however, parcels mailed at commercial base prices may not contain any content that meets the definition of 'letter' in 39 CFR 310.1 (for example, no personal correspondence is permitted). First-Class Package Service parcels mailed at commercial plus prices have no content restrictions, other than the generic restrictions on nonmailable matter.

Effective Dates and More Information

The Postal Service will begin to account for any First-Class Mail commercial base or commercial plus priced parcels as the competitive First-Class Package Service product on October 1, 2011. Mailers will retain the option to mail eligible items weighing 13 ounces or less at retail First-Class Mail single-piece parcel prices.

Mailers may begin using the new labeling and marking methods outlined in this final rule as of October 3, 2011, but will not be required to do so until May 2012.

The Postal Service adopts the following changes to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), which is incorporated by reference in the *Code of Federal Regulations.* See 39 CFR 111.1.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR Part 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR Part 111 is revised to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the following sections of *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

400 Commercial Parcels

401 Physical Standards

1.0 Physical Standards for Parcels

* * * * *

1.3 Maximum Weight and Size

[Revise the second sentence of 1.3 as follows:]

* * * Lower weight limits apply to parcels mailed at Priority Mail commercial plus cubic, Regional Rate Box, First-Class Package Service, Standard Mail, Parcel Select Regional Ground, and Bound Printed Matter prices. * * *

* * * * *

2.0 Additional Physical Standards by Class of Mail

* * * * *

[Revise the title of 2.3 as follows:]

2.3 First-Class Package Service Parcels

2.3.1 Weight

[Revise the text of 2.3.1 as follows:]

First-Class Package Service parcels cannot exceed 13 ounces, except for commercial plus parcels, which may exceed 13 ounces but must weigh less than 16 ounces.

2.3.2 Additional Physical Standards

[Revise the second sentence of the introductory text of 2.3.2 as follows:]

* * * First-Class Package Service parcels are eligible for Delivery Confirmation and Signature Confirmation services. A First-Class Package Service parcel is:

* * * * *

402 Elements on the Face of a Mailpiece

* * * * *

2.0 Placement and Content of Markings

* * * * *

[Revise the heading of 2.4 as follows:]

2.4 First-Class Package Service Markings

2.4.1 Placement and Content

Markings must be placed as follows:

[Revise the second sentence of item 2.4.1a as follows:]

a. * * * The basic required marking ''Presorted (or ''PRSRT'') First-Class Package'' (or ''PKG'') must be printed as part of; directly below; or to the left of the postage on presorted parcels. * * *

* * * * *

[Revise the second sentence of item 2.4.1b as follows:]

b. * * * In addition to the basic marking in 2.4.1a, First-Class Package Service parcels claiming commercial parcel prices must be marked as follows in a prominent location on the address side of the parcel:

[Revise items 2.4.1b1 and b2 as follows:]

1. Except for parcels with permit imprint postage, parcels claiming commercial base prices must be marked ''Commercial Base Price'' or ''ComBasPrice.''

2. All parcels claiming commercial plus prices must be marked ''Commercial Plus Price'' or ''ComPlsPrice.''

* * * * *

430 First-Class Package Service

433 Prices and Eligibility

[Revise the title of 1.0 as follows:]

1.0 Prices and Fees for First-Class Package Service

1.1 Price Application

[Add a new last sentence to item 1.1 as follows:]

* * * All prices and fees can be found in Notice 123–Price List.

* * * * *

[Revise the title and text of 1.2 as follows:]

1.2 Price Determination for First-Class Package Service Parcels

First-Class Package Service commercial base prices are the same price for the first three ounces, with additional prices per additional ounce or fraction thereof; any fraction of an ounce after the first three ounces is considered a whole ounce. The minimum postage per addressed piece is that for a piece weighing 3 ounces. First-Class Package Service commercial plus prices are not based on ounce increments but are flat rate prices at each sortation level for parcels weighing less than 16 ounces.

1.3 Commercial Base Parcel Prices

[Revise the text of 1.3 as follows:]

First-Class Package Service presorted parcels no more than 13 ounces in weight are eligible for commercial base prices. Nonpresorted First-Class Package Service parcels no more than 13 ounces in weight mailed under the following conditions are eligible for single-piece commercial base prices:

a. The residual portion of a presorted mailing prepared under 435.4.0.

b. Nonpresorted mailings paid by permit imprint, IBI meter, or PC Postage.

c. See 402.2.4 for marking requirements.

1.4 Commercial Plus Prices

[Revise the text of 1.4 as follows:]

First-Class Package Service machinable parcels less than 16 ounces and Merchandise Return Service parcels are eligible for commercial plus prices for customers that:

a. Establish a customer commitment agreement with the Postal Service to mail more than 5,000 First-Class Package Service machinable parcels (including those parcels returned using Merchandise Return Service) at commercial plus prices in a calendar year. Customers may contact their account manager or the manager, Shipping Support (see 608.8.0 for address) for additional information.

b. Pay for postage by using a permit imprint.

c. Enter a minimum of 500 pieces of mail for each presorted mailing, or a minimum of 200 pieces or 50 pounds of mail for each single-piece mailing, or receive parcels returned using Merchandise Return Services.

d. Use the Electronic Verification System (eVS) or submit an electronic postage statement with a computerized manifest.

e. Mark parcels under 402.2.4.

* * * * *

1.6 Presort Mailing Fee

[Revise the text of 1.6 as follows:]

Payment of a presort mailing fee is required once each 12-month period at each office of mailing by any person or organization entering mailings at automation or Presorted First-Class Mail or any First-Class Package Service prices. Payment of one fee allows a mailer to enter mail at all those prices. Persons or organizations paying this fee may enter mail of their clients as well as their own mail. The fee may be paid in advance only for the next 12 months and only during the last 60 days of the current service period. The fee charged is that which is in effect on the date of payment.

[Revise the title and text of 1.7 as follows:]

1.7 Computing Postage for First-Class Package Service

Affix postage to each piece or, for permit imprint mailings, multiply the number of pieces at each price increment by the corresponding postage price, add the *unrounded* products (amounts), and round off the total postage to the nearest whole cent.

* * * * *

[Revise the title of 2.0 as follows:]

2.0 Content Standards for First-Class Package Service Parcels

2.1 General

[Revise the text of 2.1 as follows:]

With the exception of restricted material described in 601.8.0, any mailable item may be mailed at First-Class Package Service commercial plus prices. Parcels mailed at First-Class Package Service commercial base prices are not sealed against inspection and may not contain documents or personal correspondence, except that such parcels may contain invoices, receipts, incidental advertising, and other documents that relate in all substantial respects to merchandise contained in the parcels.

[Revise the title and text of 2.2 as follows:]

2.2 Matter Required To Be Mailed as First-Class Mail

See 133.3.0 for a detailed description of matter required to be mailed as First-Class Mail (or Express Mail or Priority Mail). The following types of contents must be mailed as First-Class Mail (or Express Mail or Priority Mail):

a. Bills and statements of account.

b. Personal information.

c. Handwritten and typewritten material.

[Delete items 2.3 through 2.5 in their entirety and renumber current 2.6 as new 2.3 and revise the title and text as follows:]

2.3 Restricted Air Transportation

All First-Class Package Service parcels are subject to limitations for air transportation. See 601.10.0 for restrictions on air transportation.

[Revise the title of 3.0 as follows:]

3.0 Basic Standards for First-Class Package Service Parcels

3.1 Description of Service

[Revise the text of 3.1 as follows:]

First-Class Package Service parcels receive expeditious handling and transportation.

3.2 Defining Characteristics

3.2.1 Inspection of Contents

[Revise the text of 3.2.1 as follows:]

Parcels mailed at First-Class Package Service commercial plus prices are closed against postal inspection. Federal law and USPS regulations restrict both opening and reviewing the contents of First-Class Package Service commercial plus parcels by anyone other than the addressee.

[Revise the title and text of 3.2.2 as follows:]

3.2.2 Forwarding and Return Services

The postage price of First-Class Package Service parcels includes forwarding service to a new address for up to 12 months and return of undeliverable parcels to the sender.

[Delete current 3.2.3, Return Service, in its entirety and renumber current 3.2.4 as new 3.2.3 and revise as follows:]

3.2.3 Extra Services for First-Class Package Service Parcels

Extra services available for First-Class Package Service parcels are certificate of mailing service, Certified Mail service, COD service, Delivery Confirmation service, insured mail service (merchandise only), Registered Mail service, return receipt service, restricted delivery service, Signature Confirmation service, and special handling. See information regarding extra services in 503. See 508.7.0 for details about Hold for Pickup service.

[Delete current 3.2.5 and 3.2.6 in their entirety.]

[Revise the heading of 3.3 as follows:]

3.3 Additional Basic Standards for First-Class Package Service Parcels

All presorted First-Class Package Service parcels must:

[Delete current items 3.3a through 3.3e in their entirety; and replace as follows:]

a. Meet the applicable postage payment standards in 434 and 604.7.0.

b. Bear a delivery address that includes the correct ZIP Code or ZIP+4 code and that meets the address quality standards in 3.4 and 3.5.

[Delete 3.4, Presort Mailing Fee, in its entirety and renumber current 3.5 through 3.6 as new 3.4 through 3.5.]

* * * * *

[Revise the title of 4.0 as follows:]

4.0 Price Eligibility for Presorted First-Class Package Service Parcels

* * * * *

434 Postage Payment and Documentation

1.0 Basic Standards for Postage Payment

1.1 Postage Payment Options

[Revise the first sentence of 1.1 and add a new second sentence as follows:]

Postage for First-Class Package Service parcels must be paid with

affixed postage or permit imprint as specified below. Parcels mailed at commercial plus prices must be mailed with permit imprint postage.* * *

[Revise the title of 2.0 as follows:]

2.0 Postage Payment for Presorted First-Class Package Service Parcels

2.1 Permit Imprint Postage

[Revise the first sentence of 2.1 as follows:]

All First-Class Package Service parcels may bear permit imprint postage under 604.5.0. * * *

* * * * *

[Revise the title and text of 2.2 as follows:]

2.2 Affixed Postage for First-Class Package Service Parcels

Each First-Class Package Service parcel bearing affixed postage (not allowed for commercial plus parcels) must bear the full postage at the First-Class Package Service price for which it qualifies.

* * * * *

3.0 Mailing Documentation

* * * * *

3.2 Basic Documentation Standards

[Revise the text of 3.2 as follows:]

Supporting documentation (see 708.1.0) of postage is required for each mailing except for eVS mailings under 705.2.9, or unless the correct price is affixed to each piece or each piece is of identical weight and the pieces are separated by price when presented for acceptance.

* * * * *

[Delete current 3.5, Standard Format for Documentation, in its entirety (standards are in 708.1.0 referred to above) and renumber current 3.6 through 3.8 as new 3.5 through 3.7.]

* * * * *

435 Mail Preparation

1.0 General Information for Mail Preparation

* * * * *

1.3 Terms for Presort Levels

Terms used for presort levels are defined as follows:

[Revise the introductory line in 1.3a as follows:]

a. 5-digit scheme for First-Class Package Service parcels: * * *

* * * * *

3.0 Sack Labels

* * * * *

3.3 Line 2 (Content Line)

Line 2 (content line) must meet these standards:

* * * * *

[Revise 3.3b as follows:]

b. *Codes:* The codes shown below must be used as appropriate on Line 2 of sack labels. See 708.6.

[Revise the second row in the table in 3.3 and add a new third row as follows:]

Content type	Code
* * * * *	
First-Class Package Service Parcels	FC. PARCELS.
* * * * *	

* * * * *

[Revise the title of 4.0 as follows:]

4.0 Preparing Parcels

4.1 Basic Standards

[Revise the text of 4.1 as follows:]

Each Presorted First-Class Package Service mailing must be prepared in USPS-approved sacks and each parcel marked ''Presorted'' (or ''PRSRT'') and ''First-Class Package Service.'' All parcels must be sorted together and prepared under 4.3 and 4.4.

[Revise the title and text of 4.2 as follows:]

4.2 Single-Piece Mail

Single-piece (nonpresorted) First-Class Package Service parcels may be presented as a separate mailing or with a presorted mailing and reported on the same postage statement as follows:

a. The single-piece mail must be physically separated from other pieces.

b. The single-piece mail must bear no presorted price marking, or must be marked with the correction marking: ''Single-Piece'' or ''SNGLP'' under 402.2.4.

* * * * *

4.4 Sacking and Labeling

Preparation sequence, sack size, and labeling:

[Revise item 4.4a2 by changing ''FCM'' to ''FC'' as follows:]

a. * * * labeling:

* * * * *

2. Line 2: For 5-digit scheme sacks, ''FC PARCELS 5D SCH.'' For 5-digit sacks, ''FC PARCELS 5D.''

[Revise item 4.4b2 by changing ''FCM'' to ''FC'' as follows:]

b. * * * labeling:

* * * * *

2. Line 2: ''FC PARCELS 3D.''

[Revise item 4.4c2 by changing ''FCM'' to ''FC'' as follows:]

c. * * * labeling:

* * * * *

2. Line 2: ''FC PARCELS ADC.''

[Revise item 4.4d2 by changing ''FCM'' to ''FC'' as follows:]

d. * * * labeling:

* * * * *

2. Line 2: ''FC PARCELS WKG.''

* * * * *

436 Enter and Deposit

1.0 Deposit

[Delete 1.1, Service Objective, in its entirety (stated in 433), and renumber current 1.2 through 1.4 as new 1.1 through 1.3.]

1.1 Time and Location of Deposit

[Revise the text of renumbered 1.1 as follows:]

First-Class Package Service parcels must be deposited at locations and times designated by the postmaster. Metered mail must be deposited in locations under the jurisdiction of the licensing Post Office except under 604.4.5.3. Permit imprint mail must be deposited under 604.5.0 and 705.

1.2 Approved Collections

[Revise the introductory text of renumbered 1.2 as follows:]

The USPS may collect First-Class Package Service parcels at a mailer's facility if part of an approved collection service for other classes of mail; space is available on the transportation; and:

* * * * *

2.0 Verification

2.1 USPS Verification and Mailer Correction

[Revise the text of 2.1 as follows:]

Mailings are subject to USPS procedures to verify correct preparation and postage payment. If, at the acceptance unit, a mailing is found not to qualify for a First-Class Package Service presort price, the mailer must take corrective action or pay a single-piece price (see 2.3). The return of mailings to the mailer's facility for reworking is the mailer's responsibility.

* * * * *

2.3 Payment at Single-Piece Price Rather Than Correcting Errors

[Revise the text of 2.3 as follows:]

A mailer who pays a single-piece First-Class Package Service price rather than correcting presorting errors in a mailing paid with meter or precanceled stamps must either affix metered postage for the additional amount on each piece or pay the difference in cash (or by check) and present the receipt to the acceptance point before the mail may be released for processing. A mailer who makes the same choice for a permit imprint mailing must correct the postage statement to show the higher price.

* * * * *

500 Additional Mailing Services

503 Extra Services

* * * * *

2.0 Registered Mail

* * * * *

2.2 Basic Information About Registered Mail

* * * * *

2.2.2 Eligible Matter

[Revise the first sentence of 2.2.2 as follows:]

Only mailable matter prepaid with postage at the First-Class Mail, First-Class Package Service, or Priority Mail (excluding Critical Mail) prices may be sent as Registered Mail. * * *

* * * * *

3.0 Certified Mail

* * * * *

3.2 Basic Information

* * * * *

3.2.2 Eligible Matter

[Revise the text of 3.2.2 as follows:]

Only mailable matter prepaid with postage at the First-Class Mail, First-Class Package Service, or Priority Mail (excluding Critical Mail) prices may be sent as Certified Mail.

* * * * *

4.0 Insured Mail

* * * * *

4.2 Basic Information

* * * * *

4.2.2 Eligible Matter

The following types of mail may be insured:

[Revise the text of item 4.2.2a as follows:]

a. First-Class Mail, First-Class Package Service and Priority Mail (including Critical Mail), if it contains matter that is eligible to be mailed at Standard Mail or Package Services prices.

* * * * *

4.3 Mailing

* * * * *

4.3.5 Integrated Barcodes

The following options are available for mailers who print their own labels:

* * * * *

[Revise the first sentence of 4.3.5c as follows:]

c. Mailers must use an integrated barcode (see Exhibit 4.3.5c) when insurance is purchased online for Priority Mail and for parcels mailed at First-Class Mail, First-Class Package Service, Media Mail, Parcel Post, or Parcel Select prices. * * *

* * * * *

5.0 Certificate of Mailing

5.1 Certificate of Mailing Fees

[Revise the second sentence of 5.1 as follows:]

* * * The correct fee must be paid in addition to postage for mailings of identical pieces of First-Class Mail, First-Class Package Service (except for parcels mailed at commercial plus prices), Priority Mail (excluding Critical Mail), and Package Services. * * *

* * * * *

5.2 Basic Information

* * * * *

5.2.4 Eligible Matter—Bulk Quantities

[Revise the second sentence of 5.2.4 as follows:]

* * * This certificate is provided only for a mailing of identical pieces of First-Class Mail, First-Class Package Service (except for parcels mailed at commercial plus prices), Priority Mail (excluding Critical Mail), Standard Mail, and Package Services. * * *

* * * * *

6.0 Return Receipt

* * * * *

6.2 Basic Information

* * * * *

6.2.2 Eligible Matter

Return receipt service is available for:

* * * * *

[Revise the text of 6.2.2b as follows:]

b. First-Class Mail, First-Class Package Service, and Priority Mail (excluding Critical Mail) when purchased at the time of mailing with Certified Mail, COD, insured mail (for more than $200.00), or Registered Mail service.

* * * * *

7.0 Restricted Delivery

* * * * *

7.2 Basic Information

* * * * *

7.2.2 Eligible Matter

Restricted Delivery service is available for:

[Revise the text of 7.2.2a as follows:]

a. First-Class Mail, First-Class Package Service, and Priority Mail (excluding Critical Mail) when purchased at the time of mailing with Certified Mail, COD, insured mail (for more than $200.00), or Registered Mail service.

* * * * *

10.0 Delivery Confirmation

* * * * *

10.2 Basic Information

* * * * *

10.2.2 Eligible Matter

[Revise the first sentence of 10.2.2 as follows:]

Delivery Confirmation is available for First-Class Mail parcels and First-Class Package Service parcels; all Priority Mail pieces; Standard Mail Not Flat-Machinable pieces and machinable or irregular parcels (electronic option only); Package Services, Parcel Select, and Parcel Select Regional Ground parcels (electronic option only) under 401.1.0. * * *

* * * * *

11.0 Signature Confirmation

* * * * *

11.2 Basic Information

* * * * *

11.2.2 Eligible Matter

[Revise the first sentence of 11.2.2 as follows:]

Signature Confirmation is available for First-Class Mail parcels and First-Class Package Service parcels; all Priority Mail pieces; Standard Mail Not Flat-Machinable pieces and machinable or irregular parcels (electronic option only); Package Services, Parcel Select, and Parcel Select Regional Ground

parcels (electronic option only) under 401.1.0. * * *

* * * * *

12.0 Collect on Delivery (COD)

* * * * *

12.2 Basic Information

* * * * *

12.2.2 Eligible Matter

[Revise the introductory sentence of 12.2.2 as follows:]

COD service may be used for Express Mail, First-Class Mail, First-Class Package Service, Priority Mail (excluding Critical Mail), and any Package Services or Parcel Select sub-category if:

* * * * *

12.2.4 Registered COD Mail

[Revise the first sentence of 12.2.4 as follows:]

Sealed domestic mail of any class bearing First-Class Mail or First-Class Package Service postage may be sent as registered COD mail. * * *

* * * * *

13.0 Special Handling

* * * * *

13.2 Basic Information

* * * * *

13.2.2 Availability

[Revise the text of 13.2.2 as follows:]

Special handling service is available only for First-Class Mail, First-Class Package Service, Priority Mail (excluding Critical Mail), Package Services, and Parcel Select pieces.

* * * * *

13.2.4 Bees and Poultry

[Revise the text of 13.2.4 as follows:]

Unless sent at First-Class Mail, First-Class Package Service, or Priority Mail prices, special handling is required for parcels containing honeybees or baby poultry.

* * * * *

507 Mailer Services

1.0 Treatment of Mail

* * * * *

1.4 Basic Treatment

* * * * *

1.4.5 Extra Services

Mail with extra services is treated according to the charts for each class of mail in 1.5, except that:

* * * * *

[Revise the text of 1.4.5b as follows:]

b. All insured First-Class Mail. First-Class Package Service and Priority Mail pieces are forwarded and returned at no additional charge. All insured Standard Mail, Package Services, and Parcel Select pieces are forwarded or returned.

* * * * *

1.5 Treatment for Ancillary Services by Class of Mail

[Revise the title and the introductory text of 1.5.1 as follows:]

1.5.1 First-Class Mail, First-Class Package Service, and Priority Mail

Undeliverable-as-addressed First-Class Mail (including postcards), First-Class Package Service, and Priority Mail pieces are treated under Exhibit 1.5.1, with these additional conditions:

* * * * *

[Revise the text of 1.5.1d as follows:]

d. First-Class Mail, First-Class Package Service or Priority Mail pieces bearing Standard Mail markings and endorsements under 202 and 244.5.1 for letters, 302 and 344.5.1 for flats, and 402 and 444.4.1 for parcels receives forwarding, return, and address correction services for Standard Mail under 1.5.3.

e. ''Change Service Requested'' is not permitted for the following:

* * * * *

[Revise the text of items 1.5.1e2 and e3 as follows:]

2. First-Class Mail, First-Class Package Service, or Priority Mail pieces containing hazardous materials under 601.10.0.

3. First-Class Mail, First-Class Package Service or Priority Mail pieces with an extra service other than Delivery Confirmation or Signature Confirmation.

[Revise the introductory text of 1.5.1f as follows:]

f. Address Change Service under 4.0 is available for First-Class Mail, First-Class Package Service, and Priority Mail pieces with the ACS participant code for an authorized ACS participant and a valid ancillary service endorsement. Mailers participating in OneCode ACS under 4.2.6 may print an Intelligent Mail barcode on First-Class Mail automation letters instead of a participant code and endorsement. The only endorsements permitted on First-Class Mail, First-Class Package Service and Priority Mail valid ACS pieces are ''Address Service Requested'', ''Change Service Requested'' or ''Electronic Service Requested'' subject to the following:

* * * * *

[Revise the title of Exhibit 1.5.1 as follows:]

Exhibit 1.5.1 Treatment of Undeliverable First-Class Mail, First-Class Package Service and Priority Mail

* * * * *

[In the table for Change Service Requested, in the third column, last row, revise item (1)(b) as follows:]

(b) First-Class Mail and First-Class Package Service (excluding hazardous materials).

* * * * *

1.8 Returning Mail

* * * * *

[Revise the title and text of 1.8.3 as follows:]

1.8.3 Express Mail, Priority Mail, First-Class Mail, and First-Class Package Service

Mailpieces sent as Express Mail, Priority Mail, First-Class Mail, or First-Class Package Service that cannot be delivered as addressed or forwarded to a new address, unless otherwise requested by the sender, are returned to the sender at no additional charge. Excluding pieces containing live animals, the following are disposed of by the USPS:

a. Priority Mail pieces with a valid Address Change Service (ACS) participant code marked ''Perishable'' and endorsed ''Change Service Requested.''

b. First-Class Mail or First-Class Package Service pieces with a valid ACS participant code and endorsed ''Change Service Requested.''

* * * * *

1.9 Dead Mail

1.9.1 Basic Information

[Revise the introductory text of 1.9.1 as follows:]

Dead mail is matter deposited in the mail that is undeliverable and cannot be returned to the sender. A reasonable effort is made to match articles found loose in the mail with the envelope or wrapper and to return or forward the articles. The disposition of dead mail items is as follows:

* * * * *

[Revise the text of 1.91e as follows:]

e. Except for unendorsed Standard Mail, undeliverable Standard Mail and Package Services, and insured First-Class Mail or First-Class Package

Service pieces containing Standard Mail or Package Services enclosures, that cannot be returned because of an incorrect, incomplete, illegible, or missing return address is opened and examined to identify the sender or addressee.

* * * * *

2.0 Forwarding

* * * * *

2.2 Forwardable Mail

* * * * *

2.2.3 Discontinued Post Office

[Revise the text of 2.2.3 as follows:]

All Express Mail, Priority Mail, First-Class Mail, First-Class Package Service, Periodicals, and Package Services pieces addressed to a discontinued Post Office may be forwarded without added charge to a Post Office that the addressee designates as more convenient than the office to which the USPS ordered the mail sent.

2.2.4 Rural Delivery

[Revise the text of 2.2.4 as follows:]

When rural delivery service is established or changed, a customer of any office receiving mail from the rural carrier of another office may have all Express Mail, Priority Mail, First-Class Mail, First-Class Package Service, Periodicals, and Package Services pieces forwarded to the latter office for delivery without added charge, if the customer files a written request with the postmaster at the former office.

* * * * *

2.2.6 Mail for Military Personnel

[Revise the first sentence of 2.2.6 as follows:]

All Express Mail, First-Class Mail, First-Class Package Service, Periodicals, and Package Services mailpieces addressed to persons in the U.S. Armed Forces (including civilian employees) serving where U.S. mail service operates is forwarded at no added charge when the change of address is caused by official orders. * * *

* * * * *

2.3 Postage for Forwarding

* * * * *

[Revise the title and text of 2.3.3 as follows:]

2.3.3 Priority Mail, First-Class Mail, and First-Class Package Service

Priority Mail, First-Class Mail (including postcards), and First-Class Package Service mailpieces are forwarded without charge when postage is fully prepaid by the sender.

* * * * *

3.0 Premium Forwarding Service

* * * * *

3.3 Preparation

* * * * *

3.3.3 Mailpieces Requiring a Scan or Signature at Delivery

[Revise the introductory text of 3.3.3 and item 3.3.3a as follows:]

Mailpieces requiring a scan or signature at delivery, such as Express Mail or numbered insured mail, are scanned, and then rerouted immediately and separately to the temporary address, subject to the following:

a. Express Mail, Priority Mail, First-Class Mail and First-Class Package Service mailpieces are rerouted at no additional charge.

* * * * *

[Revise the title and text of 3.3.5 as follows:]

3.3.5 First-Class Mail, First-Class Package Service, and Periodicals Parcels Not Requiring a Scan or Signature at Delivery

First-Class Mail, First-Class Package Service, and Periodicals parcels not requiring a scan or signature at delivery and that do not fit into the weekly Priority Mail shipment are separately rerouted at no additional charge.

* * * * *

3.4 Enter and Deposit

3.4.1 Mailpieces Arriving Postage Due at the Primary Address

* * * Mailpieces arriving postage due are rerouted as follows:

[Revise 3.4.1a as follows:]

a. Postage due First-Class Mail and First-Class Package Service mailpieces are rerouted as First-Class Mail or First-Class Package Service postage due. Only the original postage due amount is collected. There is no additional charge for rerouting the mailpiece.

* * * * *

4.0 Address Correction Services

4.1 Address Correction Service

* * * * *

4.1.5 Other Classes

[Revise the text of 4.1.5 as follows:]

When possible, ''on-piece'' address correction is provided for Express Mail, Priority Mail, First-Class Mail, First-Class Package Service, Standard Mail, Package Services, and Parcel Select pieces. If the piece cannot be forwarded, it is returned with new address information or reason for nondelivery attached. When separate corrections are necessary, Form 3547 is mailed to the sender with the address correction fee charged and the mail is forwarded. This service is not available for mailpieces to be delivered by military personnel at any military installation, including APOs and FPOs.

* * * * *

5.0 Recall of Mail

5.1 Who May Recall Mail

* * * * *

5.1.3 Expenses and Postage

[Revise the first sentence of 5.1.3 as follows:]

The mailer must pay all expenses of recalling mail (including return postage for other than First-Class Mail or First-Class Package Service mailpieces). * * *

* * * * *

600 Basic Standards for All Mailing Services

* * * * *

602 Addressing

1.0 Elements of Addressing

* * * * *

1.3 Address Elements

[Revise the introductory text of 1.3 as follows:]

All mail not bearing a simplified address must bear a delivery address that contains at least the following elements in this order from the top line:

* * * * *

[Revise items 1.3e and 1.3e1 as follows:]

e. ZIP Code where required:

1. ZIP Codes are required on Express Mail, commercial First-Class Mail, First-Class Package Service, Periodicals, Standard Mail, Package Services and Parcel Select mailpieces, all mail sent to military addresses within the United States and to APO and FPO addresses, official mail, Business Reply Mail, and merchandise return service mail.

* * * * *

1.9 Additional Addressing Standards by Class

[Revise the text of 1.9 as follows:]

Basic addressing standards are in the Prices and Eligibility section for each class of mail.

* * * * *

604 Postage Payment Methods

* * * * *

4.0 Postage Meters and PC Postage Products (Postage Evidencing Systems)

4.1 Basic Information

* * * * *

4.1.5 Authorized Classes of Mail

[Revise the text of 4.1.5 as follows:]

Mailers may use postage evidencing systems to affix or apply indicia on any class of mail except First-Class Package Service commercial plus parcels, Periodicals, and Bound Printed Matter.

* * * * *

4.5 Mailings

4.5.1 Mailing Date Format

* * * The mailing date format used in the indicia is also subject to the following conditions.

a. Complete Date. Mailers must use a complete date for the following:

[Revise 4.5.1a1 as follows:]

1. All Express Mail, Priority Mail, First-Class Mail, and First-Class Package Service pieces.

* * * * *

5.0 Permit Imprint (Indicia)

5.1 General Standards

5.1.1 Definition

[Revise the text of 5.1.1 as follows:]

A mailer may be authorized to mail material without affixing postage when payment is made at the time of mailing from a permit imprint advance deposit account established with USPS. This payment method may be used for postage and extra service fees for Express Mail (''eVS'' only), Priority Mail, First-Class Mail, First-Class Package Service, Standard Mail, Package Services, and Parcel Select mailpieces. This method is not available for Periodicals.

* * * * *

5.3 Indicia, Design, Placement, and Content

* * * * *

[Revise the title and the first sentence of 5.3.6 as follows:]

5.3.6 Express Mail, Priority Mail, Critical Mail, First-Class Mail and First-Class Package Service Format

A permit imprint indicia on Express Mail, Priority Mail, Critical Mail, First-Class Mail, or First-Class Package Service mailpieces must show ''Express Mail,'' ''Priority Mail'' (or ''Priority''), ''Critical Mail,'' ''First-Class Mail,'' or ''First-Class Package'' (or ''First-Class Pkg'') as applicable; ''U.S. Postage Paid''; city and state; and permit number. * * *

* * * * *

700 Special Standards

* * * * *

705 Advance Preparation and Special Postage Payment Systems

* * * * *

8.0 Preparing Pallets

* * * * *

8.6 Pallet Placards

* * * * *

8.6.5 Line 2 (Content Line)

Line 2 (content line) must meet these standards:

* * * * *

[Revise the table in 8.6.5 by adding a new 7th row (between ''First-Class Mail'' and ''Flats'' with ''First-Class Package Service'' in the Content Type column and ''FC PKG'' in the Code column as follows:]

Content type	Code
* * * * *	
First-Class Package Service	FC PKG.

* * * * *

We will publish an appropriate amendment to 39 CFR Part 111 to reflect these changes.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 2011–21028 Filed 8–17–11; 8:45 am]

BILLING CODE 7710–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2010–1058; FRL–9453–2]

Approval and Promulgation of Implementation Plans; New York Reasonable Further Progress Plans, Emissions Inventories, Contingency Measures and Motor Vehicle Emissions Budgets

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving portions of a proposed State Implementation Plan revision submitted by New York that are intended to meet several Clean Air Act requirements for attaining the 0.08 part per million 8-hour ozone national ambient air quality standards. Specifically, EPA is approving into the SIP the following elements which are required by the Act: The 2002 base year and 2008 projection year emissions inventories, the 2008 motor vehicle emissions budgets used for planning purposes, the 2008 Reasonable Further Progress (RFP) plan, and the 2008 RFP Plan contingency measures as they apply to the New York portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT 8-hour ozone moderate nonattainment area. EPA is also approving the 2002 base year emissions inventory for the Poughkeepsie 8-hour ozone moderate nonattainment area and the state-wide 2002 base year ozone emissions inventory.

DATES: *Effective Date:* This rule is effective on September 19, 2011.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R02–OAR–2010–1058. All documents in the docket are listed on the *http://www.regulations.gov* Web site. 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 material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region II Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007–1866. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is 212–637–4249.

FOR FURTHER INFORMATION CONTACT: Raymond K. Forde, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10278, (212) 637–3716.

SUPPLEMENTARY INFORMATION:

I. Background

On March 31, 2011 (76 FR 17801), EPA proposed approval of the New York State Implementation Plan (SIP) submitted on February 8, 2008 and supplemented on December 28, 2009 and January 26, 2011. The SIP submittal addresses the requirements for the New York portion of the New York-Northern New Jersey-Long Island and Poughkeepsie 8-hour ozone moderate nonattainment areas. The New York portion of the New York-Northern New

Jersey-Long Island area is composed of the five boroughs of New York City and the counties of Nassau, Suffolk, Westchester and Rockland (referred to as the New York Metro Area). The Poughkeepsie area is composed of Dutchess, Orange and Putnam counties.

The following Clean Air Act (CAA) requirements were the subject of the March 31, 2011 proposal: The 2002 base year emissions inventory, the 2008 projection year emissions inventories, the 2008 motor vehicle emissions budgets used for planning purposes, the 2008 RFP plan, the 2008 RFP Plan contingency measures as they apply to the New York portion of the New York Metro ozone moderate nonattainment area, the 2002 base year emissions inventory for the Poughkeepsie 8-hour ozone moderate nonattainment area and the state-wide 2002 base year ozone emissions inventory.

With respect to the Poughkeepsie area, EPA has evaluated its air quality monitoring data and has determined the Poughkeepsie area has attained the 8-hour ozone standard. On December 7, 2009, EPA announced this determination in the **Federal Register** (74 FR 63993). Consistent with 40 CFR 51.918, this determination suspends the requirements for various SIP items, including, the requirement to submit an attainment demonstration, an RFP plan, and section 172(c)(9) contingency measures for the eight-hour ozone NAAQS for so long as the area continues to attain the ozone NAAQS. Therefore, EPA is not taking action on these proposed SIP elements for the Poughkeepsie area that are contained in the 8-hour ozone SIP proposal that was submitted to EPA on February 8, 2008. However, EPA is taking action on the 2002 base year emissions inventory for the Poughkeepsie Area.

A detailed discussion of the SIP revisions and EPA's rationale for approving them is contained in the March 31, 2011 proposal and will not be restated here. The reader is referred to the proposal for more details.

II. Public Notice

EPA received no comments in response to the March 31, 2011 proposal. Therefore, in this action, EPA is approving New York's plans.

III. Conclusion

EPA has evaluated New York's submittal for consistency with the Clean Air Act and Agency regulations and policy. EPA is approving into the SIP the following components for the New York portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT 8-hour ozone moderate nonattainment area which are required by the Act: the 2002 base and 2008 projection year emissions inventories, the 2008 motor vehicle emissions budgets used for planning purposes, the 2008 RFP plan, and the 2008 RFP Plan contingency measures. These components were submitted to EPA by New York in a package entitled ''New York SIP for Ozone—Attainment Demonstration for New York Metro Area,'' dated February 8, 2008 and supplemented on December 28, 2009 and January 26, 2011.

EPA is also approving the 2002 base year emissions inventory for the Poughkeepsie 8-hour ozone moderate nonattainment area and the state-wide 2002 base year emissions inventory. New York submitted these revisions to EPA for review and approval on February 8, 2008 in a package entitled, ''New York SIP for Ozone—Attainment Demonstration for Poughkeepsie, NY Area'' and supplemented on December 28, 2009 and January 26, 2011.

IV. Statutory and Executive Order Reviews

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

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

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 17, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference,

Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 4, 2011.

Judith A. Enck,

Regional Administrator, Region 2.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart HH—New York

■ 2. Section 52.1670 is amended by adding an entry to end of table in paragraph (e) to read as follows:

§ 52.1670 Identification of plan.

* * * * *

(e) * * *

Action/SIP element	Applicable geographic or nonattainment area	New York submittal date	EPA approval date	Explanation
*	*	*	*	*
2002 base year emissions inventory; 2008 projection year emissions inventories; 2008 motor vehicle emissions budgets used for planning purposes; 2008 ozone reasonable further progress (RFP) plan; and 2008 RFP Plan contingency measures.	New York portion of the New York-Northern New Jersey-Long Island 8-hour ozone nonattainment area.	2/8/2008 supplemented on 12/28/2009 and 1/26/2011	August 18, 2011.	
2002 base year emissions inventory.	Poughkeepsie 8-hour ozone moderate nonattainment area.	2/8/2008 supplemented on 12/28/2009 and 1/26/2011	August 18, 2011.	
2002 base year emissions inventory.	State-wide	2/8/2008 supplemented on 12/28/2009 and 1/26/2011	August 18, 2011.	

■ 3. Section 52.1683 is amended by adding paragraph (l) to read as follows:

§ 52.1683 Control Strategy: Ozone.

* * * * *

(l)(1) The following State Implementation Plan (SIP) elements are approved: The 2002 base year emissions inventory, the 2008 projection year emissions inventories, the 2008 motor vehicle emissions budgets used for planning purposes, the 2008 ozone reasonable further progress (RFP) plan, and the 2008 RFP Plan contingency measures as they apply to the New York portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT 8-hour ozone moderate nonattainment area. These elements are included in the package entitled ''New York SIP for Ozone-Attainment Demonstration for New York Metro Area,'' dated February 8, 2008 and supplemented on December 28, 2009 and January 26, 2011.

(2) The following SIP elements are approved: The 2002 base year emissions inventory for the Poughkeepsie 8-hour ozone moderate nonattainment area and the state-wide 2002 base year emissions inventory. These elements are included in a package entitled, ''New York SIP for Ozone-Attainment Demonstration for Poughkeepsie, NY Area,'' dated February 8, 2008 and supplemented on December 28, 2009 and January 26, 2011.

[FR Doc. 2011–21097 Filed 8–17–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1983–0002; FRL–9452–3]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Barceloneta Landfill Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region II is publishing a direct final Notice of Deletion of the Barceloneta Landfill Superfund Site (Site), located in Florida Afuera, Puerto Rico, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the Commonwealth of Puerto Rico, through the Puerto Rico Environmental Quality Board, because EPA has determined that all appropriate response actions under CERCLA, other than operation, maintenance, and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: This direct final deletion is effective October 3, 2011 unless EPA receives adverse comments by September 19, 2011. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–1983–0002, by one of the following methods:

- *http://www.regulations.gov.* Follow on-line instructions for submitting comments.
- *E-mail:* Luis E. Santos, Remedial Project Manager, *santos.luis@epa.gov.*
- *Fax:* 787–289–7104.
- *Mail:* Luis E. Santos, Remedial Project Manager, U.S. Environmental Protection Agency, Region II, Caribbean Protection Division, Centro Europa Building, Suite 417, Ponce de León

Ave., Stop 22, San Juan, Puerto Rico 00907–4127.

• *Hand delivery:* U.S. Environmental Protection Agency, Region II, Caribbean Protection Division, Centro Europa Building, Suite 417, Ponce de León Ave., Stop 22, San Juan, Puerto Rico 00907–4127. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SFUND–1983–0002. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://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 e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail 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.

Docket: All documents in the docket are listed in the *http://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 material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at:

U.S. Environmental Protection Agency, Region II, Superfund Records Center, 290 Broadway, 18th Floor, New York, NY 10007–1866, *Phone:* 212–637–4308, *Hours:* Monday to Friday from 9 a.m. to 5 p.m.

Or

U.S. Environmental Protection Agency, Region II, Caribbean Environmental Protection Division, Centro Europa Building, Suite 417, 1492, Ponce de León Ave., Stop 22, San Juan, Puerto Rico 00907–4127, *Phone:* (787) 977–5802, *Hours:* 8:30 a.m. to 4:30 p.m.—Monday through Friday (excluding holidays), *Contact:* Luis E. Santos.

FOR FURTHER INFORMATION CONTACT: Luis E. Santos, Remedial Project Manager, U.S. Environmental Protection Agency, Region II, telephone at (787) 977–5824; fax at 787–289–7104; or e-mail at *santos.luis@epa.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. NPL Deletion Criteria
III. Deletion Procedures
IV. Basis for Site Deletion
V. Deletion Action

I. Introduction

EPA Region II is publishing this direct final Notice of Deletion of the Barceloneta Landfill Superfund Site (Site), from the National Priorities List (NPL). The NPL constitutes Appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in 300.425(e) (3) of the NCP, sites deleted from the NPL remain eligible for Fund-financed remedial actions if future conditions warrant such actions.

Because EPA considers this action to be noncontroversial and routine, this action will be effective October 3, 2011 unless EPA receives adverse comments by September 19, 2011. Along with this direct final Notice of Deletion, EPA is co-publishing a Notice of Intent to Delete in the ''Proposed Rules'' section of the **Federal Register**. If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely withdrawal of this direct final Notice of Deletion before the effective date of the deletion, and the deletion will not take effect. EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments already received. There will be no additional opportunity to comment.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Barceloneta Landfill Superfund Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the state, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. all appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. the remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Pursuant to CERCLA section 121 (c) and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews even if a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Deletion Procedures

The following procedures apply to deletion of the Site:

(1) EPA consulted with the Commonwealth of Puerto Rico prior to

developing this direct final Notice of Deletion and the Notice of Intent to Delete co-published today in the ''Proposed Rules'' section of the **Federal Register**.

(2) EPA has provided the state 30 working days for review of this notice and the parallel Notice of Intent to Delete prior to their publication today, and the Commonwealth, through the Puerto Rico Environmental Quality Board, has concurred on the deletion of the Site from the NPL.

(3) Concurrently with the publication of this direct final Notice of Deletion, a notice of the availability of the parallel Notice of Intent to Delete is being published in a major local newspaper, El Norte y Puerto Rico Daily Sun. The newspaper notice announces the 30-day public comment period concerning the Notice of Intent to Delete the Site from the NPL.

(4) The EPA placed copies of documents supporting the proposed deletion in the deletion docket and made these items available for public inspection and copying at the Site information repositories identified above.

(5) If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely notice of withdrawal of this direct final Notice of Deletion before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments already received.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Site Deletion

The following summary provides the Agency's rationale for recommending deletion of the Barceloneta Landfill Superfund Site from the NPL:

Site Background and History

The Barceloneta Landfill, an inactive non-hazardous domestic and industrial waste disposal facility, is located in Barceloneta, Puerto Rico on the north coast of the island, approximately 20 miles due west of San Juan. The Landfill is about 4.5 kilometers south of the Town of Barceloneta in Florida Afuera Ward. The property which contains the Barceloneta Landfill is approximately 32.6 hectares (80.6 acres) in size and is owned by the Municipality of Barceloneta. The Landfill is surrounded by a tropical forest. The Quebrada Cimarrona, a tributary of the Rio Grande de Manatí, is located 0.8 kilometers north of the Landfill. A small residential area of approximately 150 residences in Barrio Bajura Adentro is located approximately one kilometer east of the Landfill. Approximately two kilometers north of the Landfill, in an area with more gentle topographic relief, there are a series of manufacturing facilities. The nearest village is Cruce Magueyes, located approximately two kilometers to north-west of the Landfill. The residences in the area of the Landfill are served by a public water supply system that uses ground water as a source.

The property contained three surface depressions which were used for waste disposal. These waste disposal areas are known as the northern, southern, and southeastern disposal areas. Each disposal area was located in a depression or ''sumidero'' (sinkhole) that is surrounded by conical limestone hills referred to as ''mogotes''. The three waste disposal areas cover about 15 acres. The northern disposal area is separated into two sections by an access road. The southern disposal area was also known as the Superfund disposal area or ''El Superfondo''. The northern and southern disposal areas were filled and inactive at the time of the 1996 Record of Decision (ROD). The southeastern disposal area remained active until December 31, 1998. Although the southern disposal area was known as the Superfund disposal area, all three disposal areas are covered by the Superfund National Priorities List (NPL) site listing and were addressed under CERCLA.

The Barceloneta Landfill is located in a belt of rugged karst topography that extends along the north coast from 30 kilometers (19 miles) east of San Juan to the west of the island. In the vicinity of the Site, this belt is located from about one kilometer south of the coast to about 20 kilometers (12 miles) inland. North (seaward) of this rugged karst region is a belt of relatively flat coastal plain sediments. South (landward), the rugged karst terrain transitions into the central mountainous core of the island. Features of this karst landscape include numerous sumideros, steep scarp cliffs on the mogotes and adjoining ridges which surround the sumideros, and a lack of surface streams or drainage features associated with individual sumideros.

The Site is underlain by the northern limestone province of Puerto Rico which consists of blanket deposits, the Aymamon Limestone, the Aguada Limestone, the Cibao Formation, and the Lares Formation. Groundwater exists under unconfined conditions in the Aymamon and Aguada Limestones and under confined conditions in the Cibao and Lares Formations. Groundwater flow is to the north.

Groundwater in this area of the northern province discharges to the Rio Grande de Manatí (river) and the Cano Tiburones (wetlands) which are 2.7 kilometers (1.7 miles) north of the Site. Groundwater also feeds the Ojo de Guillo spring located 1 kilometer (0.6 miles) northeast of the Site.

The property on which the Barceloneta Landfill is located was purchased by the Municipality of Barceloneta during the early 1970s. Preparation of the Site for landfill use began in April 1972, and the landfill operations commenced in August 1973. Reportedly, the Landfill was initially approved to receive both municipal and industrial waste, but was restricted to only municipal waste disposal in 1975. However, disposal of industrial wastes appears to have continued past 1975. Specific dates of active filling in each of the three disposal areas are difficult to determine given the lack of detailed record keeping. The Puerto Rico Environmental Quality Board (EQB) has information which indicates that the Landfill (all three disposal areas) was used in the late 1970's for disposal of wastes which contained hazardous substances. Personnel from EQB and the Department of Health conducted numerous inspections of the Site and listed various violations. These violations included: Insufficient cover material; allowing refuse to burn; the presence of flies, rats and mosquitoes; allowing unlimited access to the Landfill; and, allowing people to inhabit structures in the Landfill. The Site was proposed for inclusion on the NPL in December 1982 (47 FR 58476), and was subsequently approved and listed as an NPL site in September 1983 (48 FR 40658). No activities were conducted using EPA removal authority at this site. The site property consists mainly of forested areas which provide a habitat for various plant, insect and animal species. In order to protect the landfill cap, trees will not be allowed to grow on the capped area. However, grasses will be permitted to grow and it is expected that the landfill areas will be comparable to surrounding ecology. No reuse is planned for the site.

Remedial Investigation/Feasibility Study

In 1984, a Remedial Action Master Plan (RAMP) was prepared by an EPA contractor for the Site. Based on the RAMP, a Remedial Investigation and Feasibility Study (RI/FS) Work Plan was developed. In September 1990, Consent Order was signed in which ten Settling Defendents (SDs) agreed to perform the RI/FS for the Site. Pursuant to the Work Plan, sampling of subsurface soils, ground water and surface water was completed. The first phase of the RI was completed in 1992 and the second phase of the RI field work was completed in January 1994. A final RI report was received by EPA in March 1995 and the streamlined Risk Assessment was completed in May 1995. An abbreviated Final FS was conducted in accordance with EPA's Presumptive Remedy approach and was received by EPA in September 1995.

Consistent with EPA's Presumptive Remedy approach, EPA conducted a streamlined baseline Risk Assessment by comparing the levels of contaminants in ground water to MCLs. These levels were exceeded, indicating that the Landfill is a source of contamination to the ground water and therefore remedial measures are necessary to protect human health and the environment. EPA's Risk Assessment indicated that the levels of contaminants present in the ground water pose a relatively low long-term threat to the human health. However, if no action were to be taken with respect to the Landfill, the continued release of contaminants into ground water could potentially result in a greater risk at some point in the future. Therefore, based on the results of the Risk Assessment, it was determined that actual or threatened release of hazardous substances from this Site present a threat to public health, welfare, or the environment.

Selected Remedy

On July 5, 1996, the Regional Administrator signed a ROD. The following remedial action objectives were established for the Site:

- To prevent direct contact with waste material;
- To reduce or eliminate the potential for the Landfill disposal areas to release hazardous substances to ground water;
- To reduce or eliminate the potential for migration of hazardous substances to ground water downgradient of the Landfill;
- To prevent the migration of and control Landfill gas; and
- To minimize any potential future impacts of hazardous substances that may migrate into environmental media.

The major components of the selected remedy are as follow:

- Installing a low permeability cover system for the three Landfill cells meeting the requirements of the RCRA Subtitle D and Puerto Rico's Regulations Governing Landfill Closure. This cover system or landfill cap(s) will further reduce infiltration of precipitation water into the landfill and reduce leachate generation thus mitigating impacts to ground water.
- Regrading the Site and installing storm water management improvements at the Site to reduce infiltration of storm water into the Landfill and reduce leachate generation.
- Conducting long term ground water and surface water monitoring to evaluate the effectiveness of the cover system. It is anticipated that monitoring will be conducted on a quarterly basis for the first year, semi-annually for the next four years, and then annually. Monitoring will include the eight existing monitoring wells. Initially, the wells will be sampled for a broad parameter list. The list has been developed based on constituents detected above Safe Drinking Water Act Maximum Contaminant Levels in the Remedial Investigation and on the requirements of the RCRA Subtitle D and Puerto Rico's Regulation Governing Landfill Closure (RMNHSW). After the first five years, the parameter list would be reviewed and those parameters not detected above standards would be omitted. The exact long term ground water monitoring program will be further defined remedial design (RD).
- Conducting a landfill gas survey during predesign to determine the necessity of a landfill gas collection system. The appropriate type of system, if necessary, will be determined during RD.
- Implementing a long term operation and maintenance program for the cover system which will include inspection of the system and provision for repair.
- Recommending to appropriate authorities that institutional controls be emplaced. Institutional controls are recommended in order to protect the integrity of the landfill cover system and to reduce potential exposure to landfill contents. The institutional controls will include recommending that zoning restrictions be applied to the Site to limit future land use and recommending that a deed restriction be established to limit future land and ground-water use.
- Installing a perimeter fence with signs to restrict access.
- Reevaluating Site conditions at least once every five years to determine if a modification of the selected remedy is necessary.

Response Actions

A September 30, 1997 Consent Decree (CD) memorialized a settlement whereby ten parties agreed to implement the remedy which was selected in the ROD. The SDs hired M&S Ingenieria y Ciencia Asociados who prepared remedial design plans and specifications, which EPA approved on September 17, 1999. On December 16, 1999, EPA approved the Remedial Action Work Plan and M&S Ingenieria y Ciencia Asociados as the Settling Defendants proposed a remedial action contractor.

During the RD activities a new area of waste disposal was discovered at the Site outside the limits of the three waste cells delineated for closure in the ROD. The waste was located in a sinkhole which lies immediately to the east of the Superfund cell. In agreement with EPA & EQB, the SDs relocated this waste material and performed a clean closure. This waste was incorporated and capped with the waste in Superfund disposal area.

The gas venting system was constructed on the Site. The gas venting system is monitored by the PRPs' contractor and results reviewed by EPA. The system is functioning as intended and it is not a necessity landfill gas collection system.

The groundwater monitoring program was developed during the RD phase: The system included the eight existing monitoring wells. It was determined that groundwater sampling would be conducted quarterly for the first year, semi-annually for the next four years, and then conducted annually. It was determined that the wells would be sampled for a broad parameter list developed based on constituents detected above MCLs and SDWS in the RI, RCRA Subtitle D requirements, and Puerto Rico's Regulation Governing Landfill Closure. This initial list of parameters included:

- Volatile Organic Compounds of Concern (VOCs). Only l,l-dichloroethane was detected above MCLs during the RI. However, a more conservative approach that included the complete EPA Method Scan for volatile organic compounds was implemented.
- Metals of Concern include mercury, chromium, manganese and nickel. These were detected above MCLs and SDWS during the RI.

After the first five years, the parameter list would be reviewed and those parameters not detected above standards would be omitted; The O&M Plan, dated March 28, 2000, and approved by EPA, establishes the criteria used to reevaluate and modify

the number of wells and list of parameters sampled.

EPA approved early Remedial Actions to be carried out prior to the final approval of the Remedial Design Report. These activities included the excavation and stockpiling of clay and the excavation and relocation of waste from the discovered waste area. These activities were started on September 7, 1999. The Remedial Action on-site construction started in January 24, 2000 and was completed on August 30, 2000.

On September 5, 2000, EPA and the State conducted a prefinal inspection and notified the Settling Defendants to proceed with the development of the draft Remedial Action (RA) Report. Punch list items identified during the prefinal inspection will be addressed in the final inspection. On September 27, 2001, EPA approved the final RA Report.

The Municipality of Barceloneta has implemented the Institutional Controls at the Site. The Institutional Controls including zoning restrictions and a deed restriction are in place. These controls were implemented at Barceloneta Landfill Deed on February 22, 2010.

Cleanup Goals

The ROD called for conducting long-term groundwater monitoring to evaluate the effectiveness of the cover system, ensure that the concentrations of contaminants in the groundwater are decreasing over time, and monitor the natural attenuation of contaminants within the plume.

MW–3, has had only one parameter, 1,1-dichloroethene, exceeding MCLs during the two years of monitoring. However, on two consecutive monitoring periods (March 2003 and October 2003), the results for 1,1-dichloroethene were non-detect and 4.9 mg/l, respectively, and below the MCL of 7 mg/l. Based on the June 2004 groundwater monitoring report for the Site and according to the criteria in the O&M Plan, on September 2004, groundwater monitoring was reduced to five of the original eight wells and to the following parameters: mercury, chromium, manganese and nickel. These five wells are currently sampled annually. Mercury and chromium are monitored to ensure that levels remain below MCLs. Chromium was identified below the MCLs for three consecutive monitoring events it was omitted from the parameter list according to the O&M Plan, dated March 28, 2000. Since the ROD was signed, the MCL and MCLG were remanded for nickel. As a result, EPA no longer has an enforceable legal limit for nickel in drinking water. Therefore, mercury, nickel and manganese contaminant concentrations are still monitoring but there is no MCL threshold. The remaining five wells (MW–1, MW–4, MW–6, MW–7 and MW–8) are currently sampled annually.

Since 2004, the results of the Site Groundwater Analytical Results are summarized on a well by well basis below:

- MW–1, the background well, had concentrations below MCLs and SDWS for manganese, mercury and nickel during the Spring 2011 sampling event. These results showed similar concentrations to the last annual sampling event in March 2010.
- MW–4, located in the middle of the site, had concentrations of mercury below the MCL of 0.002 mg/L (0.00132 mg/L) during the Spring 2011 sampling event. These concentrations have decreased since 2004. Manganese and nickel were below SDWS during this sampling event.
- MW–6, a downgradient well, had concentrations of mercury below the MCL of 0.002 mg/L during the Spring 2011 sampling event. These concentrations have been consistently below the MCL since 2004. Nickel was found at a concentration of 0.192 mg/L. Concentrations of nickel at this well continue to decrease compared to previous sampling events. Manganese was detected above the SDWS and shows concentrations similar to the March 2010 sampling event.
- MW–7, a downgradient well, had concentrations of mercury, nickel and manganese below MCLs and SDWS. The last sampling event of March 2010 also showed concentrations similar to this sampling event.
- MW–8, a downgradient well, had concentrations of mercury, nickel and manganese below MCLs and SDWS. The last two sampling events, October 2009 and March 2010, show all parameters below MCLs and SDWS.

In summary, all wells monitored at the site show contaminants below MCLs. Although nickel and manganese are present in groundwater, these contaminants do not have an enforceable MCL and will continue to be monitored.

Operation and Maintenance

Currently, five groundwater monitoring wells are sampled and analyzed on an annually basis for mercury, manganese and nickel, and the results are compared to the Maximum Contaminant Levels or Secondary Drinking Water Standards identified in the Record of Decision. The five groundwater monitoring wells are designated MW–1, MW–4, MW–6, MW–7 and MW–8 will continue to be monitored by annual inspections and the five-year review process.

Five-Year Review

Hazardous substances were not remediated to levels that would allow for unlimited use and unrestricted exposure, therefore the five-year review requirement of Section 121(c) of CERCLA, as amended, is applicable. On August 2005 and 2010 respectively, two five-year reviews (FYR) were conducted. In August 2010, the FYR concluded that the remedy at the Barceloneta Landfill currently protects human health and the environment in the short term because all remedy components are functioning as intended and institutional controls are in place to prevent exposure to contaminated groundwater. In order for the remedy to be protective in the long term, the O & M plan should be reviewed to ensure that the appropriate monitoring wells are being sampled and the correct analytes are being reported.

Since the FYR was conducted, EPA requested the PRP to review the O & M plan to ensure that the appropriate monitoring wells are being sampled and the correct analytes are being reported. It was concluded that the correct monitoring wells are being sampled and the appropriate parameters are being evaluated and reported. However, because Chromium was identified below the MCL for three consecutive periods, it was omitted from the parameter list. The groundwater will continue to be monitored annually based on the criteria identified in the 2000 O&M Plan.

In addition, the ROD stated that surface water monitoring would be conducted. After the FYR was completed, it was concluded that surface water sampling would not be conducted because there was no surface waters present at the Site. The nearest surface water is the Ojo de Guillo, a spring located 1 kilometer (0.6 miles) northeast of the Site. Therefore, this recommendation was not implemented.

The next FYR will be completed on or before August 30, 2015.

Community Involvement

Public participation activities for this Site have been satisfied as required in CERCLA sections 113(k) and 117, 42 U.S.C. 9613(k) and 9617. Throughout the remedial process, EPA and the Puerto Rico Department of Environmental Quality have kept the public informed of the activities being conducted at the Site by way of public meetings, progress fact sheets, and the announcement through local newspaper advertisement on the availability of documents such as the RI/FS, Risk

Assessment, ROD, Proposed Plan and Five-Year Reviews.

Determination That the Site Meets the Criteria for Deletion in the NCP

EPA has determined that this Site poses no significant threat to public health or the environment because the landfill has been capped, removing direct contact exposure (*i.e.,* ingestion or dermal contact of soil) to the public. In addition, the Municipality of Barceloneta put in place deed restrictions for future land use and groundwater extraction. The potential impacts to the groundwater have been addressed and groundwater monitoring indicates MCLs are being met at the landfill unit boundary. Groundwater monitoring will continue to ensure groundwater protection continues to be achieved.

V. Deletion Action

The EPA, with concurrence of the Puerto Rico Environmental Quality Board, has determined that all appropriate response actions under CERCLA, other than operation, maintenance, monitoring and five-year reviews have been completed. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication. This action will be effective October 3, 2011 unless EPA receives adverse comments by September 19, 2011. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion, and it will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: August 8, 2011.

Judith Enck,

Regional Administrator, Region 2.

For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

■ 2. Table 1 of Appendix B to part 300 is amended by removing Barceloneta Landfill'', ''Florida Afuera, PR''.

[FR Doc. 2011–21123 Filed 8–17–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[PS Docket No. 06–229; WT Docket 06–150; WP Docket 07–100; FCC 11–6]

Implementing a Nationwide, Broadband, Interoperable Public Safety Network in the 700 MHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts an initial set of rules necessary to ensure the development of a nationwide interoperable public safety broadband network. The establishment of a common air interface for 700 MHz public safety broadband networks will create a foundation for interoperability and provide a clear path for the deployment and evolution of the nationwide network.

DATES: *Effective:* August 18, 2011, except § 90.1407(f) which contains information collections requirements that have not been approved by OMB. The Federal Communications Commission will publish a document in the **Federal Register** announcing the effective date. The incorporation by reference of certain publications listed in the rules is approved by the Director of the Federal Register as of August 18, 2011.

FOR FURTHER INFORMATION CONTACT: Jennifer Manner, Federal Communications Commission, Public Safety and Homeland Security Bureau, 445 12th Street, SW., Room 7–C761, Washington, DC 20554. Telephone: (202)–418–3619, e-mail: *jennifer.manner@fcc.gov.*

SUPPLEMENTARY INFORMATION: In the *Third Report and Order,* FCC 11–6, adopted January 25, 2011, and released January 26, 2011, the Commission adopted rules to promote development of a nationwide interoperable public safety broadband network. The Commission designated Long Term Evolution (LTE), in particular at least 3GPP Standard, Evolved Universal Terrestrial Radio Access (E–UTRA) Release 8 (LTE) and associated Evolved Packet Core (EPC), as the common technology platform for the nationwide network. The Commission also required that public safety broadband network operators submit to the Public Safety and Homeland Security Bureau a certification that their networks support required LTE interfaces. The Commission also stayed certain Part 90 rules that were designed to implement a mandatory public-private partnership that has not materialized. These rules include 47 CFR 90.1403(b)(1), (2), (3), (5), (8); 90.1405 through 90.1430; and 90.1435. The *Third Report and Order* is available at *http://www.fcc.gov/Daily_Releases/Daily_Business/2011/db0204/FCC–11–6A1.pdf.*

As required by the Regulatory Flexibility Act, the Commission certifies that the requirements of the *Third Report and Order* will not have a significant economic impact on a substantial number of small entities. The *Third Report and Order* contains new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under Section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the new or modified information collection requirements contained in this proceeding. The Commission shall send a copy of the *Third Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 90

Administrative practice and procedure, Business and industry, Civil defense, Common carriers, Communications equipment, Emergency medical services, Incorporation by reference, Individuals with disabilities, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

For the reasons discussed in the preamble, The Federal Communications Commission amends 47 CFR part 90 as follows:

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

■ 1. The authority citation for part 90 continues to read as follows:

Authority: Sections 4(i), 11, 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r), and 332(c)(7) unless otherwise noted.

■ 2. Section 90.7 is amended by adding definitions for ''Public Safety Broadband Network Operator'' and ''Service Availability'' and revising the definition for ''Upper 700MHz D Block license'' to read as follows:

§ 90.7 Definitions.

* * * * *

Public Safety Broadband Network Operator. A Public Safety Network Operator is a public safety entity that is authorized by lease or other permitted mechanism under the Public Safety Broadband License to operate a public safety broadband network in the 763–768 MHz and 793–798 MHz bands.

* * * * *

Service Availability. The use of a public safety broadband network on a day-to-day basis for operational purposes by at least fifty users.

* * * * *

Upper 700 MHz D Block license. The Upper 700 MHz D Block license authorizes services in the 758–763 MHz and 788–793 MHz bands.

* * * * *

■ 3. Section 90.203 is amended by adding paragraph (p) to read as follows:

§ 90.203 Certification required

* * * * *

(p) *Equipment certification for transmitters in the 763–769 and 793–799 MHz Bands.* Applications for all transmitters must show support for at least 3GPP TS 23.401, V8.8.0 (2009–12), ''3rd Generation Partnership Project; Technical Specification Group Services and System Aspects; General Packet Radio Service (GPRS) enhancements for Evolved Universal Terrestrial Radio Access Network (E–UTRAN) access (Release 8),'' December, 2009, which is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected at the Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554 or National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741– 6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies of the 3GPP Standard E–UTRA Release 8 can be obtained from 3GPP Mobile Competence Centre, c/o ETSI, 650, route des Lucioles, 06921 Sophia-Antipolis Cedex, France, Tel: +33 (0)4 92 94 42 00, Fax: +33 4 93 65 47 16, *http://www.3gpp.org.*

■ 4. Section 90.1407 is amended by adding paragraphs (d) through (f) to read as follows:

§ 90.1407 Spectrum use in the network.

* * * * *

(d) Public Safety Broadband Network Operators must use at least 3GPP TS 23.401, V8.8.0 (2009–12), ''3rd Generation Partnership Project; Technical Specification Group Services and System Aspects; General Packet Radio Service (GPRS) enhancements for Evolved Universal Terrestrial Radio Access Network (E–UTRAN) access (Release 8),'' December, 2009 (incorporated by reference). The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected at the Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554 or National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741– 6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies of the 3GPP Standard E–UTRA Release 8 can be obtained from 3GPP Mobile Competence Centre, c/o ETSI, 650, route des Lucioles, 06921 Sophia-Antipolis Cedex, France, Tel: +33 (0)4 92 94 42 00, Fax: +33 4 93 65 47 16, *http://www.3gpp.org.* Later versions of this standard may be employed by Public Safety Broadband Network Operators provided they are backwards-compatible with this version.

(e) Systems in the network must support the following interfaces: Uu–LTE air interface; S6a—Visited MME to Home HSS; S8—Visited SGW to Home PGW; S9—Visited PCRF to Home PCRF for dynamic policy arbitration; S10—MME to MME support for Category 1 handover support; X2—eNodeB to eNodeB; S1–u—between eNodeB and SGW; S1–MME—between eNodeB and MME; S5—between SGW and PGW; S6a—between MME and HSS; S11—between MME and SGW; SGi—between PGW and external PDN; Gx—between PGW and PCRF (for QoS policy, filter policy and charging rules); Rx—between PCRF and AF located in a PDN; Gy/Gz—offline/online charging interfaces.

(f) A Public Safety Broadband Network Operator must submit to the Chief of the Public Safety and Homeland Security Bureau prior to deployment of any Radio Access Network equipment a certification that it will be in compliance with paragraph (e) of this section prior to the date its network achieves service availability.

[FR Doc. 2011–20831 Filed 8–17–11; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 100804323–0569–02]

RIN 0648–XA617

Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries; Closure of the 2011 Trimester 2 Directed Loligo Squid Fishery

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces that 90 percent of the Trimester 2 *Loligo* squid (*Loligo*) quota is projected to be harvested by 0001 hours, August 23, 2011. Therefore, the directed *Loligo* fishery in the Exclusive Economic Zone (EEZ) will be closed as of 0001 hours, August 23, 2011, and vessels issued a Federal permit are prohibited from possessing or landing more than 2,500 lb (1.13 mt) of *Loligo* for the remainder of Trimester 2 (through August 31, 2011). The directed *Loligo* fishery will re-open for Trimester 3 on September 1, 2011. This action is necessary to prevent the fishery from exceeding its Trimester 2 allocation of 11,190,664 lb (5,076 mt), and to allow for effective management of this stock.

DATES: Effective 0001 hours, August 23, 2011, through 2400 hours, August 31, 2011.

FOR FURTHER INFORMATION CONTACT: Lindsey Feldman, Fishery Management Specialist, 978–675–2179, Fax 978–281–9135.

SUPPLEMENTARY INFORMATION: Regulations governing the *Loligo* fishery are found at 50 CFR part 648. The regulations require specifications for maximum sustainable yield, initial optimum yield, allowable biological catch, domestic annual harvest (DAH),

domestic annual processing, joint venture processing, and total allowable levels of foreign fishing for the species managed under the Atlantic Mackerel, Squid, and Butterfish Fishery Management Plan (FMP). The procedures for setting the annual initial specifications are described in § 648.21.

The 2011 specification of DAH for *Loligo* was set at 3,384 mt (76 FR 8306, February 14, 2011). Due to an under harvest of the Trimester 1 *Loligo* quota, on May 16, 2011, the Trimester 2 quota was increased to 5,076 mt. Section 648.22 requires NMFS to close the directed *Loligo* fishery in the EEZ when 90 percent of the Trimester 2 quota is projected to be harvested. NMFS is required to notify the Executive Directors of the Mid-Atlantic, New England, and South Atlantic Fishery Management Councils; mail notification of the closure to all *Loligo* permit holders at least 72 hr before the effective date of the closure; provide adequate notice of the closure to recreational participants in the fishery; and publish notification of the closure in the **Federal Register.**

The Administrator, Northeast Region, NMFS, based on dealer reports and other available information, has determined that 90 percent of the Trimester 2 *Loligo* quota for the 2011 fishing year will be harvested on August 23, 2011. Therefore, effective 0001 hours, August 23, 2011, Trimester 2 directed *Loligo* fishery is closed and vessels issued Federal permits for *Loligo* are prohibited from possessing or landing more than 2,500 lb (1.13 mt) of *Loligo* through August 31, 2011. The Trimester 3 *Loligo* fishery will open at 0001 hours, September 1, 2011.

Classification

This action is required by 50 CFR part 648, and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA (AA), finds good cause pursuant to 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment because it would be contrary to the public interest. This action closes the directed *Loligo* fishery until August 31, 2011, under current regulations. The regulations at § 648.21 require such action to ensure that *Loligo* vessels do not exceed the 2011 Trimester 2 quota. Data indicating the *Loligo* fleet will have landed at least 90 percent of the 2011 Trimester 2 quota have only recently become available. If implementation of this closure is delayed to solicit prior public comment, the quota for Trimester 2 will be exceeded, thereby undermining the conservation objectives of the FMP. The AA further finds, pursuant to 5 U.S.C. 553(d)(3), good cause to waive the 30-day delayed effectiveness period for the reasons stated above.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 15, 2011.

James P. Burgess,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2011–21109 Filed 8–17–11; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 76, No. 160
Thursday, August 18, 2011

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

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 273 and 276

RIN 0584–AD98

Supplemental Nutrition Assistance Program: Major System Failures

AGENCY: Food and Nutrition Service, USDA.

ACTION: Proposed rule.

SUMMARY: This rule proposes to amend Supplemental Nutrition Assistance Program (SNAP—formerly the Food Stamp Program) regulations to implement the Food, Conservation, and Energy Act of 2008, (''FCEA''). Section 4133, The ''Major System Failures'' section of the FCEA, amends the Food and Nutrition Act of 2008 (''the Act'') to require the United States Department of Agriculture (USDA) to determine when a systemic State error is resulting in the overissuance of benefits to a substantial number of SNAP households and the actions the Department may take if such a determination were made. This rule proposes criteria for determining if a State experienced a systemic error that resulted in the overissuance of benefits to a substantial number of households and specifies the steps that the Department may take to collect data, instruct the State to terminate claims collection from the affected households, and issue a bill to the State for the value of the over-issuances. It also identifies the review and appeal process for any such billing.

DATES: Comments must be received on or before October 17, 2011.

ADDRESSES: The Food and Nutrition Service invites interested persons to submit comments on this proposed rule. Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* Preferred method. Go to *http://www.regulations.gov*; follow the online instructions for submitting comments on Docket FNS–2009–0025.
- *Fax:* Submit comments by facsimile transmission to (703) 305–2486, attention: Lizbeth Silbermann.
- *Mail:* Send comments to Lizbeth Silbermann, Director, Program Development Division, Food and Nutrition Service, 3101 Park Center Drive, Room 810, Alexandria, Virginia 22302, (703) 305–2494.
- *Hand delivery or Courier:* Deliver comments to Lizbeth Silbermann at the above address. All comments on this proposed rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the comments publicly available on the Internet via *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: For further information concerning this proposed rule, you may contact Moira Johnston, Program Development Division, Supplemental Nutrition Assistance Program, 3101 Park Center Drive, Room 800, Alexandria, Virginia 22302 or via the Internet at *moira.johnston@fns.usda.gov.*

SUPPLEMENTARY INFORMATION: *Additional electronic filing information:* You may download a copy of this rule from *http://www.fns.usda.gov/SNAP*. You may also comment via the Internet at the same address. Please include ATTENTION RIN 0548–AD98 in the subject line and your name and address in the message. If you do not receive a confirmation that we have received your comment please call 703–305–2515.

Written Comments: Written comments on this rule should be specific, confined to issues pertinent to the rule, and should explain the reason for any change you recommend. Where possible, you should reference the specific section or paragraph of the rule you are addressing. We may not consider or include in the Administrative Record for the final rulemaking comments that we receive after the close of the comment period or comments delivered to an address other than that listed above. We will make available all comments for public inspection, including, name, address and other contact information of respondents. If you wish to request that we consider withholding your name, address, or other contact information from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your comment. We will honor requests for confidentiality on a case-by-case basis to the extent allowed by law. We will make available for public inspection in their entirety all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses.

Executive Order 12866

This rule has been determined to be not significant and was reviewed by the Office Management and Budget in conformance with Executive Order (E.O.) 12866.

Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612). It has been certified that this rule will not have a significant economic impact on a substantial number of small entities. State agencies that administer SNAP will be affected to the extent they implement major changes in program operations.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under Section 202 of the UMRA, the Department generally must prepare a written statement, including a cost/benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures to State, local, or tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) that impose costs on State, local, or tribal governments or to the private sector of $100 million or more in any one year. This rule is, therefore, not subject to the

requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

The SNAP is listed in the Catalog of Federal Domestic Assistance under No. 10.551. For the reasons set forth in the final rule in 7 CFR part 3015, Subpart V and related document published June 24, 1983 (48 FR 29114 for SNP; 48 FR 29115 for FSP), this Program is excluded from the scope of E.O. 12372, which requires intergovernmental consultation with State and local officials.

Federalism Impact Statement

E.O. 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of E.O. 13132. FNS has considered the impact of this rule on State and local governments and has determined that this rule does not have Federalism implications. This rule does not impose substantial or direct compliance costs on State and local governments. Therefore, under Section 6(b) of the E.O., a federalism summary impact statement is not required.

Prior Consultation With State Officials

After the FCEA was enacted on June 18, 2008, FNS held a series of conference calls with State agencies and FNS regional offices to explain the SNAP provisions included in the public law and to answer questions that State agencies had about implementing the changes to the program. On July 3, 2008, FNS issued an implementation memorandum that described each SNAP-related provision in the FCEA and provided basic information to assist State agencies in meeting statutorily-mandated implementation timeframes. FNS responded to additional questions that State agencies submitted and posted the answers on the FNS Web site. Another forum for consultation with State officials on implementation of the FCEA provisions included various conferences hosted by FNS regional offices, State agency professional organizations, and program advocacy organizations. During these conferences, held in the latter part of 2008 and early months of 2009, FNS officials responded to a range of questions posed by State agency officials related to implementation of FCEA provisions.

Executive Order 12988

This rule has been reviewed under E.O. 12988, ''Civil Justice Reform.'' This rule, when published final, is not intended to have preemptive effect with respect to any State or local laws, regulations, or policies that conflict with its provisions or that would otherwise impede its full implementation. This rule is not intended to have retroactive effect unless so specified in the ''Effective Date'' paragraph of the final rule. Prior to any judicial challenge to the provisions of this rule or the application of its provisions, all applicable administrative procedures must be exhausted. In SNAP, the administrative procedures are as follows: For program benefit recipients—State administrative procedures issued pursuant to 7 U.S.C. 2020(e)(10) of the Food and Nutrition Act of 2008 and regulations at § 273.15; for State agencies—administrative procedures issued pursuant to 7 U.S.C. 2023 of the Act and regulations at § 276.7 (for rules related to non-Quality Control liabilities) or 7 CFR part 283 (for rules related to Quality Control liabilities); or Program retailers and wholesalers—administrative procedures issued pursuant to 7 U.S.C. 2023 and 7 CFR part 279.

Civil Rights Impact Analysis

FNS has reviewed this rule in accordance with the Department Regulation 4300–4, ''Civil Rights Impact Analysis,'' to identify and address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, and the characteristics of SNAP households and individual participants, FNS has determined that an important impact of this rule will be to help relieve the adverse effects of errors in program operations on recipients, including protected classes. All data available to FNS indicate that protected individuals have the same opportunity to participate in SNAP as non-protected individuals. FNS specifically prohibits State and local government agencies that administer the Program from engaging in actions that discriminate based on race, color, national origin, gender, age, disability, marital or family status. SNAP non-discrimination policy can be found at 7 CFR 272.6(a). Where State agencies have options, and they choose to implement a certain provision, they must implement it in such a way that it complies with 7 CFR 272.6.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects 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. We are unaware of any current Tribal laws that could be in conflict with the proposed rule. We request that commenters address any concerns in this regard in their responses.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR part 1320) requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This proposed rule contains information collections that are subject to review and approval by OMB; therefore, FNS is submitting for public comment the changes in the information collection burden that would result from adoption of the proposals in the rule. Comments on this proposed rule must be received by October 17, 2011.

Send comments to Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for FNS, Washington, DC 20503. Please also send a copy of your comments to Lizbeth Silbermann, Director Program Development Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, VA 22302. For further information, or for copies of the information collection package, please contact Moira Johnston at the above address or via the Internet at *Moira.Johnston@fns.usda.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. For further information, or for copies of the information collection requirements, please contact Moira Johnston at the address indicated above.

Title: Major System Failures.

OMB Number: 0584–New.

Expiration Date: Not yet determined.

Type of Request: New Collection.

Abstract: Section 4133 of the FCEA, Major System Failures, amended the Act to require the United States Department of Agriculture (USDA) to determine when a systemic State error is resulting in the overissuance of SNAP benefits to a substantial number of SNAP households and the actions the Department may take if such a determination were made. To make this determination, the Department may require that States with potential Systemic Error situations to collect specific data concerning the systemic error. Such data may be obtained from the State's Information Management System or it may be necessary for the State to select and review a statistical (random) sample of cases and report the results to the Department.

Respondents: The 53 state agencies that administer SNAP.

Estimated Number of Annual Responses per Respondent: Based on experience from the past twenty years (1990–2010) and considering the need for replacement of legacy systems in many States, out of the 53 State Agencies FNS estimates that one state agency will experience one systemic error every other year. If this provision had been in effect (using the proposed definition for a systemic error and States' history of overissuance in SNAP), there were two or three instances between 1990 and 2010 in which the Department may have required States to provide additional data following implementation of a new information management system. While there is no hard data that would indicate an increase in the frequency of such situations, the implementation of new systems with new technology may introduce additional risk. FNS' estimate represents the highest number of systemic error situations that can be expected.

Estimated Total Annual Responses: One required response every year. Based upon the above estimate of one systemic error situation every other year, an individual State might be expected to be required to provide additional data under the authority of 7 CFR 273.19 about once every 53 years.

Estimated Total Annual Reporting Burden on Respondents: Proposed Section 273.19 requires States to provide the data specified by FNS when a systemic error that affects a substantial number of households occurs. Such data is expected to either be available from a State's Information Management System (IMS) or the State will be required to collect the information from reviewing a sample of its case files for the systemic error. As noted above it is expected that there would be one respondent once every year. The average number of staff days required per systemic error occurrence is expected to be 255 so the total annual burden would be 2040 hours.

The above estimate is based upon the following assumptions and calculations:

- *IMS data*—Production of a data file containing case level information and/or summary reports that would provide the necessary information concerning a systemic error should not require more than 80 hours given the growing sophistication of States' systems.
- *Sample of cases*—FNS believes that the number of sample cases required for Quality Control (QC) each year would be sufficient to measure the cost of a systemic error but would be needed for a 6-month period rather than annually. While this rule does not specify the number of cases a State will select for review, the maximum FNS would require based upon this rulemaking would be 500 over a 6-month period. Since the number required for a large State's QC sample is about 1,000 cases annually, FNS and the State would have 500 cases available from QC to measure a systemic error in a 6-month period and would need an additional 500 cases in a 6-month period to reach a sample size comparable to the QC sample. In the smaller States (14–16 States) the number would be between 300 and 400 additional cases. The QC reporting burdens have already been approved by OMB as shown in the following chart.

OMB Approval No.	*Expiration date*
OMB 0584–0303	12/31/2013
OMB 0584–0034	12/31/2012
OMB 0584–0074	4/30/2013
OMB 0584–0299	3/31/2013

It is estimated that it would take a State about 10 staff days to construct a sample frame, and select and assign the sample. An additional 20 staff days would be necessary to develop the review guidance and forms. Since desk reviews of case files together with some phone interviews with households and collateral contacts should provide sufficient information, each case review should require no more than one staff day to complete (for example, given an average of 450 case reviews, the average burden to complete the case reviews would be 450 staff days). Another 20 staff days would be needed to compile and report the results of the sample including examination of the cases originally selected for QC review. Based upon the above, the average requirement would the 500 staff days when a sample of cases is required.

Averaging the 80 hours (10 staff days) with the 500 staff days yields 255 days per systemic error if the frequency of using IMS data and reviews of case samples were equal (there is no information to suggest otherwise).

ATTACHMENT A: MAJOR SYSTEM FAILURES

[Affected Public: State and Local Agencies (including Indian Tribal Organizations and U.S. Territories]

Regulation section	Title	Number of potential respondents	Estimated annual report/ record filed	Total annual responses	Estimated hours per response	Estimated total burden hours
Reporting Burden Estimates						
272.19	States' State agencies	53	.019	1	2040	2040
Subtotal—Reporting		53	.019	1	2040	2040

ATTACHMENT A: MAJOR SYSTEM FAILURES—Continued

[Affected Public: State and Local Agencies (including Indian Tribal Organizations and U.S. Territories]

Regulation section	Title	Number of potential respondents	Estimated annual report/ record filed	Total annual responses	Estimated hours per response	Estimated total burden hours
Recordkeeping Burden Estimates						
		0	0	0	0	0
Grand Total		53	.019	1	2040	2040

E-Government Act Compliance

FNS is committed to complying with the E-Government Act of 2002 to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Background

Section 4133 of the FCEA amends Section 13 of the Act to provide the Secretary with the authority to define and determine when a State has overissued SNAP benefits to a substantial number of households in a fiscal year as a result of a major systemic error. If the Secretary made such a determination, the State agency could be prohibited from collecting these overissuances from some or all of the affected households and a claim would be established against the State for the value of the overissuances caused by the systemic error. States are required to provide the Secretary with information on which to base such a determination. The State has the right to appeal such a claim under the provisions of Section 14 of the Act. With many State's automated systems aging and the growing potential for replacement of those systems over the next several years, this provision provides a protection to households from claims collections if errors in the new system designs or their implementation result in systemic over-issuances to a substantial number of households.

What acronyms or abbreviations are used in this supplementary discussion of the proposed provisions?

In the discussion of the proposed provisions in this rule, we use the following acronyms or abbreviations to stand in for certain words or phrases:

Phrase	Acronym, abbreviation, or symbol
Code of Federal Regulations	CFR
Federal Register	FR
Federal Fiscal Year	FY
Food and Nutrition Act of 2008.	the Act
Food and Nutrition Service	FNS
Food, Conservation, and Energy Act of 2008.	FCEA
Quality Control	QC
U.S. Department of Agriculture.	the Department

What does the Food and Nutrition Act of 2008 say about State liability for major systemic errors?

The legislative language includes the following:

- The Secretary will define what constitutes a major systemic error that affects a substantial number of households.
- State agencies shall provide all information requested by the Secretary concerning the issuance of benefits to households by the State agency in the applicable fiscal year.
- The Secretary will make a final determination after reviewing relevant information provided by a State agency.
- The final determination will include whether the State agency overissued benefits to a substantial number of households as a result of a systemic error and the amount of the overissuance in the applicable fiscal year.
- The Secretary shall establish a claim against the State agency equal to the value of the overissuance caused by the systemic error.
- Administrative and judicial review, as provided in Section 14 of the Act, shall apply to the final determinations by the Secretary once the claim is established.
- The State agency shall, as soon as practical, remit to the Secretary the dollar amount specified in the claim if the determination of the Secretary is not appealed.
- When the determination of the Secretary is appealed, and after completion of the administrative or judicial review there is a finding of liability on the part of the State, it shall remit to the Secretary the dollar amount of the liability found in the administrative or judicial review. The payment shall be made by the State to the Secretary as soon as practical.
- The Secretary may reduce any amount due to the State agency under any other provision of the Act by the amount due if a State agency fails to make a payment within a reasonable period of time determined by the Secretary.

The FCEA language does not specifically define what constitutes a substantial number of households being overissued benefits or a major systemic error. The language is not specific to ''systems failures,'' and could be interpreted to include errors resulting from a variety of causes. Given the other authorities the Act provides to deal with error situations, the Department believes the intent of this provision is to focus on errors associated with automated eligibility systems and the effects of their implementation.

What is a major systemic error?

States have experienced technological and operational failures in the past when major systems were implemented before they were fully tested and staff fully trained in their use. The Department is proposing that a major systemic error be defined as an error resulting from a State's implementation of a new SNAP automated eligibility (data processing) system, reprogramming of an existing system, or adding new programming to an older system. While the legislative language does not limit the term systemic to ''systems'' errors, given the other authorities and remedies in the Act, the Department believes this is the most reasonable interpretation of this new authority (there is no practical utility relative to this proposed rulemaking in defining what might constitute a ''minor'' systemic error). The second criterion for use of the subject authority is that the systemic error affects a substantial number of households as discussed below.

What constitutes a ''substantial'' number of households?

The Department is particularly interested in comments on this aspect of the proposal. Clearly, defining ''substantial'' in the context of this rule is problematic. The Department considered using a specific number of households, but with the vast differences in States' caseload sizes, a single number could not be equitable between States. The better alternative is use of a percentage of States' caseloads that experience overissuances to define substantial. Since the national average *case error rate* has been around seven percent for several years and this number represents all of the errors made in the certification of households, it is reasonable to view this rate as ''substantial.'' Therefore, the Department proposes that when an average of 8 percent or more of a State's caseload receives overissuances due to a systemic error over a 6-month period, this would be considered a substantial number of households. The reason for specifying a minimum of 6 months is that if a systemic error that affected 8 percent of the caseload lasted less than 6 months, it could affect less than 4 percent of the State's case load on an annual basis.

Will States have the opportunity to take corrective action regarding the systemic error and avoid suspension of claims collection and the resulting liability?

States are required to take corrective action immediately when they are become aware of a potential systemic error and, if the action were effective, could prevent the error affecting 8 percent of its households over the 6-month period, thus avoiding liability under these provisions. However, once the systemic error has affected 8 percent of the caseload over the 6-month period, the Act does not provide for any consideration of a State's corrective action efforts. Even if a major systemic error was determined to exist, timely corrective action could reduce the State's exposure to additional months of liability.

Will FNS take the amount of the individual overissuances into account in determining the percentage of households affected by the systemic error?

The Department is proposing that the amount of the error be at least $21 per month for a case to be included in the calculation of a ''substantial'' number of households. The primary purpose of this proposed provision is to relieve households from payment of claims resulting from systemic errors. Since States have the option of establishing claims of less than $125 against those households that are no longer on the Program, households overissued less than $21 per month over a 6-month period would not reach $125 and may not be required to pay a claim even in the absence of this provision. Therefore, including cases with monthly loses of less than $21 in the count of households would not contribute to the purpose of this provision.

What authorities does USDA currently have when errors are made in a State's administration of SNAP?

This proposal does not represent a significant departure from the Department's policy in dealing with State error and compliance issues. FNS has long focused on working in partnership with States to prevent errors or develop strong corrective action measures through technical assistance and identifying promising State practices. While most States already test new automated eligibility systems extensively, this provision should help encourage all States to implement new systems using sound testing. The Act has four other primary authorities for billing States for the loss of Federal funds and non-compliance with Federal law and regulations. Each is based on a different set of concepts, but there is potential for overlap, depending on the nature of the error or compliance issue. None of these other authorities allow for prohibition of claims collection against households for overissuances.

Suspension/Disallowance of Administrative Funding

Section 11(g) of the Act, 7 CFR 276.4, specifies that if FNS determines that a State agency's administration of the Program is inefficient or ineffective, FNS may warn the State agency that a suspension and/or disallowance of administrative funds is being considered. After a State agency receives a warning, FNS may either suspend or disallow administrative funds if the problem is not corrected. Since this authority deals with administrative funds and the systemic error authority deals with overissued benefits, there can be no direct overlap between the claim amounts. In addition, while FNS could use the two authorities sequentially or simultaneously in dealing with a severe compliance issue, the suspension/disallowance authority is generally viewed as more appropriate to issues of non-compliance that affect program access or application processing.

Negligence

Section 11(h) of the Act, 7 CFR 276.3 specifies that FNS may determine that a State agency has been negligent in the certification of applicant households if a State agency disregards SNAP requirements or implements procedures that deviate from the Act, the regulations, or the FNS-approved State Plan of Operation without first obtaining FNS approval, and the result is a loss of Federal funds. In computing amounts of losses of Federal funds due to negligence, FNS may use actual, documented amounts or amounts which have been determined through the use of statistically valid projections. When a statistically valid projection is used, the methodology will include a 95 percent, one-sided confidence level.

If FNS makes a determination that there has been negligence or fraud on the part of a State agency in the certification of households for participation in the Program, FNS is authorized to bill the State agency for an amount equal to the amount of benefits issued as a result of the negligence or fraud.

While there are some structural similarities in terms of benefit loss and claim calculation, the systemic error authority does not require the State to ''disregard'' or ''deviate from'' a policy. There is potential for overlap in the use of the two authorities and to the extent that a State actually pays the Federal government for either a negligence billing or a systemic error billing under this authority, the second collection amount would be reduced.

Direct Liability

In accordance with Section 7(e) of the Act, 7 CFR 276.1(a)(2), FNS holds State agencies strictly liable for all losses that occur during issuance. This authority can only be used in cases of issuance errors. Since errors that fall outside of QC data are difficult to identify without review of States' issuance and certification files, FNS has employed data mining as necessary to determine if losses are occurring in the process of issuing benefits. It is possible that the systemic error in a States' operation could be in the issuance process so there is potential for overlap in the use of the two authorities and to the extent that a State actually pays the Federal government for both a strict liability billing and for a systemic error billing under this authority, the second collection amount would be reduced.

QC Sanctions

States' payment error rates are measured annually based on an in-

depth review of a sample of cases receiving SNAP benefits each month of the year. The review determines the amount of benefits cases should have been issued based on correct policy and verified household information relative to the amount that they were issued. The differences in the two amounts (over a threshold) constitute the error dollars that are divided by the total amount issued to the sample cases to calculate States' payment error rates. Because the sample is random and State-wide, these error rates represent the States' actual error rates. For a complete description of the QC process see Section 16(c) of the Act, 7 CFR 275.12, and QC Handbook 310 (may be found on the FNS Web site at *http://www.fns.usda.gov/snap/qc/default.htm*). Section 16(c)(1) of the Act specifies the process for determining when a State's payment error rate is excessive and State funds are subject to a liability. See § 275.23 for a complete description of the QC sanction provisions.

The key differences between the QC sanction and this authority is that the QC error rate is an index made up of errors with many different causes (potentially including certain systemic errors), QC liability amounts are not dollar-for-dollar relative to the over-issuances measured, and QC liability amounts are not necessarily repaid to the Federal government. To the extent that a State is billed by the Federal government for both a QC based liability and for a systemic error under this authority, the second collection amount would be reduced.

Could the Department invoke more than one of these authorities for the same error or compliance issue?

Yes. In certain situations the Department could use the systemic error authority and another authority to address different aspects of an issue in a State. However, any collections based on the same overissuance or direct liability loss would be offset in the second collection amount.

What is the relationship of this rule to the ''FCEA Testing Requirements Rule?''

Section 16(g) of the Act requires States designing new automated eligibility systems to thoroughly test and pilot such systems prior to full implementation. Through the advanced planning document process (7 CFR 277.18), FNS strives to work closely with States in their planning, and later, in their implementation of new systems. While it is not unusual for such potential errors to be present in the early stages of new software development and application, it is the purpose of the testing and piloting process to identify and correct such errors. A cautious and measured roll-out of new systems within a State also allows for identification and correction of any errors before they can affect the entire caseload. If a State complies with the required testing and piloting provisions of the Act and resulting regulations, deals effectively with issues identified in this process prior to rolling the new system out, and implements effectively in terms of case conversion and worker training, the potential for a systemic error that affects a substantial number of households is minimal.

However unlikely, it is possible that a State could experience a systemic error situation even if all precautions have been taken. While FNS would be reluctant to use the systemic error authority in this situation, the intent of the subject provision of the FCEA is to relieve the burden of reduced benefits by prohibiting claims collection for systemic overissuances to households. While the FCEA does give the Department discretion regarding the prohibition of collecting claims against households when a major systemic error occurs, it does not allow discretion regarding a State's liability for such an error; even when the State has been prudent in its planning and implementation. While such a situation would preclude a negligence billing, the Department would prohibit individual household claims collection and establish a liability against the State under this proposal.

Could the Department prohibit claims collection, but not bill the State for a systemic error?

No, the FCEA is clear that the determination that a systemic error has occurred will result in a claim against the State for the amount of the systemic error. This rule links the determination to prohibit claims collection for resulting overissuances to the mandate to bill the State. However, the Department has general discretionary authority under Section 13 of the Act to waive part or all of a claim against a State. If a State has adhered to the planning, testing, and piloting requirements of the Act and regulations, FNS would strongly consider recommending reduction or elimination of any claim against the State for a systemic error.

Will this authority only be used relative to computer programming problems that result in systemic errors?

No, the implementation of a new system or significant system changes may also require worker training, case conversion, sufficient server capacity, proper equipment and changes to the States' business processes in the local offices. If systemic errors arose from factors related to implementation, the Department could prohibit claims collection for the error and pursue a claim against the State.

How will the Department become aware of system problems that may result in the use of the systemic error authority?

The Department monitors States' implementation of new systems and their impact on program performance through on-site reviews and standard reports such as QC and participation reports. In addition, recipients, advocate groups and the media can provide indications of problems that FNS follows up on with inquires to the State, requests for additional data, and/or additional reviews of States operations. FNS can go further by using data mining techniques on States' data or analyzing QC data for error patterns that may have a systemic cause. Therefore, except in the most extreme circumstances, the process of identifying a systemic error would typically require a series of steps, within each of which FNS would be seeking to work with the State to correct the problem. If, upon State-wide implementation of a system, the systemic error was pervasive and readily identified, the process for using this authority to prohibit claims collection could be more immediate.

What data will States be required to provide to FNS?

FNS' data needs will be determined by the nature and timing of the systemic error. While the FCEA and this proposal requires States to provide all information requested by the Department, FNS will negotiate with the State on the data request to ensure that only the information needed to make a determination and calculate the proper amount of a claim would be required from the State. For example, FNS could use the authority of the FCEA to require States to conduct additional reviews of a sample of cases (similar to a QC review) to determine the extent of a potential systemic error, but would negotiate with the State on the extent of the review process, the timing of reviews and the size of the sample. States could also be required to provide data from their automated eligibility system. FNS will base its determination on whether there has been a systemic error that affected a substantial number of households on the data it gathers from the State. FNS would base its determination on the point estimate of

the sample data when sample data is used.

How will the Department notify States of the potential for prohibiting claims collection?

FNS will be in communication with any State that may be subject to this authority, but will notify the State that the State will have 10 days from the date of notification to stop claims collection against households affected by the systemic error.

How long will States have to provide required information to FNS?

Unless otherwise specified by FNS, States shall provide required information to FNS within 3 months of being notified of the data requirements.

How long will States have to implement the prohibition of recipient claims collection for overissuances based upon systemic errors?

States will have 10 business days after notification from FNS to stop claims collection against households affected by the systemic error.

Will States be required to return any claims resulting from the systemic error that are collected prior to the FNS notification prohibiting their collection?

Yes, claims resulting from the systemic error that are collected must be restored to households' Electronic Benefit Transfer (EBT) accounts.

When this authority is invoked, will claims be prohibited for all households?

No, claims establishment and collection would only be prohibited for the claims resulting from the systemic error(s) identified by FNS. States would be expected to continue to pursue claims against households that are overissued benefits in accordance with the Act, except those affected by the systemic error.

How long will recipient claims collection be prohibited under this provision?

Once FNS notifies a State that claims collection is to be prohibited for a systemic error, all claims in process and any claims that could be pursued for that error would be prohibited until the systemic error is determined by FNS to have been substantially corrected. For example, a State implements a major system change on March 1, and on August 1, FNS notifies the State to prohibit claims collection due to a systemic error in the certification process arising from that system change. The State takes corrective action to address the problem on October 1 and the State is notified on December 1 that FNS has determined that the systemic error has been eliminated. All claims against cases arising from systemic errors made between March 1st and December 1st would be prohibited, including benefits issued to such cases after December 1st until they are recertified. However, no claims resulting from an error occurring after December 1st could have claim collection prohibited.

What information will States be required to report on the prohibited claims collection?

While the State will be required to document the cases where overissuances are caused by the systemic error and claims are not being pursued, no additional reporting will be required.

How will FNS determine the claim amount against a State following prohibition of recipient claims collection?

FNS will use information from its standard reports together with the data it obtains from the State under the authority of this provision of the FCEA. QC data alone may be used or it may be used in conjunction with an additional sample of cases. Data mining techniques may be employed when QC data cannot provide the necessary information on the error. When FNS uses sample data, it will apply a 95 percent one-sided confidence level to determine the amount of a claim. The example of how this calculation will be made is provided in § 273.19(c)(5) as: the sample estimate of the major systemic error is 8 percent over a 6 month period, but based on a 95 percent confidence interval of 2 percentage points, the rate used would be 6 percent. Therefore the claim would be 6 percent of value of the State's total issuance over the 6 months.

What are the appeal procedures for claims against states?

The administrative appeal process for claims asserted under this authority is specified in § 276.7 and permits States to request an administrative review within 10 days of the date of delivery of the notice of claim. This proposed rule adds reference to billings based upon systemic errors into § 276.7(a)(1).

Can a State appeal the Department's decision to prohibit claims collection against households affected by a systemic error?

FNS' decision on prohibiting collection of recipient claims resulting from systemic error cannot be appealed. Only the related, but separate, claim against the State can be appealed.

If a State disagrees with the ruling of the SNAP appeals board, can it seek judicial review?

As specified in § 276.7(j), ''State agencies aggrieved by the final determination may obtain judicial review and trial de novo by filing a complaint against the United States within 30 days after the date of delivery of the final determination, requesting the court to set aside the final determination.''

If the State does not appeal the billing or there is a remaining liability amount after the administrative and or judicial review process, what are the next steps in the process?

As soon as practicable, the State would remit the claim amount as specified in the FNS billing. If a State agency fails to make a payment within a reasonable period of time, FNS would reduce the administrative funding due to the State agency by the amount of the claim.

List of Subjects

7 CFR Part 273

Administrative practice and procedure, Aliens, Claims, Employment, Grant programs—social programs, Income taxes, Reporting and recordkeeping requirements, Students, Supplemental Security Income.

7 CFR Part 276

State agency liabilities, Negligence or fraud, Suspension/disallowance of administrative funds, Injunctive relief, Good cause, Administrative review process.

Accordingly, 7 CFR parts 273 and 276 are proposed to be amended as follows:

PART 273—CERTIFICATION OF ELIGIBLE HOUSEHOLDS

1. The authority citation for part 273 and continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

2. Add § 273.19 to read as follows.

§ 273.19 Recipient claims resulting from major systemic errors.

(a) *Major systemic errors.* (1) Major systemic errors are overissuance errors that effect eight percent or more of a State's caseload over a 6 month period that result from the State's implementation of a new SNAP automated eligibility (data processing) system, reprogramming of an existing system, or adding new programming to an existing system.

(2) The causes of major systemic errors may include, but are not limited to: Incorrect computer programming, ineffective worker training, problems in case conversion, insufficient server capacity, improper equipment, and ineffective States' business processes in the local offices related to the systems change.

(b) *State reporting.* (1) When the Food and Nutrition Service (FNS) determines that major systemic errors may have occurred in a State, the State shall provide the information that FNS identifies as necessary to make its determination that a systemic error has, or has not, occurred. Based on the data FNS gathers from the State, FNS will determine whether there has been a systemic error that affected a substantial number of households. FNS' data needs will be determined by the nature and timing of the systemic error, but will generally cover at least a 6 month time period. FNS will only request the information necessary to make its determination and calculate the proper amount of any potential claim against the State. FNS may require States to conduct additional reviews of cases randomly sampled from the State's caseload to determine the extent of a potential systemic error. When sample data is used, FNS will base its determination on the point estimate of the sample data and negotiate with the State on the size of the sample. FNS may also require a State to provide data from its automated eligibility (data processing) system.

(2) Unless otherwise specified by FNS, States shall report to FNS within 3 months of being notified of the data requirements.

(c) *FNS determination.* (1) FNS shall base its determination of whether a major systemic error exists on the data it requires to be provided by the State and any data from Federal review sources including the USDA Office of Inspector General, the General Accounting Office, and FNS reviews. FNS may also validate data provided by a State.

(2) FNS will notify a State of its determination and, when a major systemic error is determined to exist, inform the State of the specifics of the error(s) and prohibit claims collection from the affected cases. FNS will establish and inform the State on the time period for which overissuances to the subject cases are not subject to recipient claims collection.

(3) When FNS determines that a major systemic error exists, FNS shall determine the amount of the overissuance caused by the major systemic error. FNS will calculate the claim amount based on the best information available and may require the State to provide information from its information management system or review a sample of cases.

(4) Error amounts below $20 in a given month shall not be included in the determination of a systemic error.

(5) When a sample is used, the claim shall be based on the lower boundary of a 95 percent confidence interval. Example of calculation based on information from a sample: The sample estimate of the major systemic error is 8 percent over a 6 month period, but based on a 95 percent confidence interval of 2 percentage points, the rate used would be 6 percent. Therefore the claim would be 6 percent of value of the State's total issuance over the 6 months.

(6) If any funds resulting from the systemic error caused overissuances are collected based on the negligence or quality control provisions of 7 CFR parts 276 and 275, the claim calculated under paragraph (c)(3) of this section would be reduced by the amount collected.

(d) *Action on recipient claims collection.* (1) When FNS determines that a major systemic error has occurred, the State will be notified that claims resulting from the systemic error overissuances shall not be collected. FNS will specify the beginning date of the major systemic error the time period in which the errors occurred.

(2) States shall have 10 days from the date of notification by FNS to stop collection of the claims resulting from the systemic error.

(3) Once FNS determines that the systemic error has been corrected to the extent that it no longer affects a substantial number of households, the State will be notified of the ending date for prohibition on collection of claims for overissuances resulting from the major systemic error and that claims shall again be collected for all overissuances.

(4) If claims are collected from households based on overissuances caused the major systemic error, the State shall return the claim amount collected to these households by restoring benefits to households EBT account.

(e) *Collection of liabilities and appeals.* FNS shall initiate collection action unless an administrative appeal relating to the liability is pending. Appeals include administrative appeals in accordance with the procedures specified in § 276.7 and judicial appeals. While the amount of a State's liability may be recovered through offsets to their letter of credit as identified in § 277.16(c) of this chapter, FNS shall also have the option of billing a State directly or using other claims collection mechanisms authorized under the Federal Claims Collection Act, depending upon the amount of the State's liability.

PART 276—STATE AGENCY LIABILITIES AND FEDERAL SANCTIONS

3. The authority citation for part 276 continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

4. In § 276.7, paragraph (a)(1) is revised to read as follows:

§ 276.7 Administrative review process.

(a) * * *

(1) Whenever FNS asserts a claim against a State agency, the State agency may appeal the claim by requesting an administrative review. FNS claims that may be appealed are billings resulting from financial losses involved in the acceptance, storage, and issuance of coupons (§ 276.2), billings based on charges of negligence or fraud (§ 276.3), billings based on over-issuances for systemic errors (§ 276.3) and disallowances of Federal funds for State agency failures to comply with the Food and Nutrition Act, regulations, or the FNS-approved State Plan of Operations (§ 276.4).

* * * * *

Dated: August 8, 2011.

Audrey Rowe,

Administrator, Food, Nutrition, and Consumer Services.

[FR Doc. 2011–20786 Filed 8–17–11; 8:45 am]

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DEPARTMENT OF ENERGY

10 CFR Part 431

[Docket No. EERE–2010–BT–NOA–0028]

RIN 1904–AC24

Energy Conservation Program for Consumer Products and Certain Commercial and Industrial Equipment: Statement of Policy for Adopting Full-Fuel-Cycle Analyses Into Energy Conservation Standards Program

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Statement of Policy.

SUMMARY: In its effort to adopt several National Academy of Sciences (the Academy) recommendations, the U.S. Department of Energy (DOE) intends to modify the methods it uses to estimate the likely impacts of energy

conservation standards for covered products on energy use and emissions and will work to expand the energy use and emissions information made available to consumers. Specifically, DOE intends to use full-fuel-cycle (FFC) measures of energy use and emissions, rather than the primary (or site) energy measures it currently uses. Additionally, DOE intends to work collaboratively with the Federal Trade Commission (FTC) to make readily available to consumers information on the FFC energy and greenhouse gas (GHG) emissions of specific products to enable consumers to make cross-class comparisons of product energy use and emissions.

ADDRESSES: The docket is available for review at *http://www.regulations.gov*, including the **Federal Register** notice of proposed policy, the public meeting attendee list and transcript, all comments received, and other supporting documents/materials. All documents in the docket are listed in the *http://www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

A link to the docket Web page can be found at: *http://www1.eere.energy.gov/buildings/appliance_standards/full_fuel_cycle_analyses.html.* The regulations.gov Web page will contain simple instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Summary of the Policy
II. Background
III. General Discussion and Discussion of Comments
A. Considering FFC Energy and Emission Impacts of Prospective Efficiency Standards
B. Using FFC Energy Efficiency Metrics in DOE's Assessment of Energy Conservation Standards Impacts
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I. Summary of the Policy

In its August 2010 Notice of Proposed Policy (referred to herein as ''Notice'' or ''NOPP'') (75 FR 51423), the U.S. Department of Energy (DOE) proposed to use full-fuel-cycle (FFC) measures of energy use and greenhouse gas (GHG) and other emissions in the national impact analyses and environmental assessments included in rulemakings for future energy conservation standards (referred to herein as ''energy conservation standards'' or ''energy efficiency levels''). DOE stated that using the FFC measure in these analyses will provide more complete information about the total energy use and GHG emissions associated with a specific energy efficiency level than the primary (or site) energy measures currently used by DOE. DOE also indicated that utilizing the FFC measure for environmental assessments and national impact analyses would not require alteration of the measures used to determine the energy efficiency of covered products (referred to herein as ''appliances and equipment'' or just ''appliances'') because the Energy Policy and Conservation Act (EPCA), as amended, requires that such measures be based solely on the energy consumed at the point of use. (42 U.S.C. 6291(4)–(6), 6311(3)–(4), (18)) However, the Notice stated that using the FFC measure in lieu of primary energy in environmental assessments and national impact analyses could affect the alternative standard levels that DOE considers before choosing an energy efficiency level in the future. A policy change to consider FFC impacts would increase the energy and emission reductions estimated to result from energy efficiency levels. This shift would, consequently, increase some of the estimated benefits of such standards.

The NOPP also proposed that DOE would significantly improve upon the Federal Trade Commission's (FTC) existing online databases of appliance site energy use and efficiency ratings by including FFC energy use and emissions data. DOE's Notice indicated that the improved databases could provide tools to enable users to easily compare a product's energy use, emissions, and costs to similar products, including products that are in different classes, have different features or use different fuels. DOE solicited public comment on whether such an online service would likely benefit consumers and, if so, the most effective way to present this information. DOE also solicited comments on the merits of providing GHG emissions and other product-specific comparative data on Energy Guide labels.

After consideration of the comments received on its NOPP, DOE has decided to use FFC measures of energy use and GHG and other emissions in the national impact analyses and environmental assessments included in future energy conservation standards rulemakings. DOE currently uses primary (or site) energy consumption for national impact analyses and environmental assessments using the National Energy Modeling System (NEMS) developed by DOE's Energy Information Administration (EIA). DOE will continue to rely upon NEMS-based estimates of primary energy and emission impacts, but intends to use conversion factors generated by the DOE Argonne National Laboratory (ANL) Greenhouse Gases, Regulated Emissions, and Energy Use in Transportation (GREET) model to convert these estimates into estimates of FFC energy and emission impacts. DOE also will, subject to the availability of funds, support efforts to make readily available to consumers and other users of regulated products information on the FFC energy use and emissions associated with specific products, and the means to compare this energy use and emissions to other comparable products, whether or not those other products use the same type of energy. The following sections more clearly state today's policy as it applies to the different issues raised in DOE's NOPP.

II. Background

Section 1802 of the Energy Policy Act of 2005 (EPACT 2005) directed DOE to commission a study with the National Academy of Sciences (the Academy) to examine whether the goals of energy conservation standards are best served by measurement of energy consumed, and efficiency improvements at, the actual point-of-use or through the use of the FFC, beginning at the source of energy production (Pub. L. 109–58). The FFC measure includes point-of-use energy, the energy losses associated with generation, transmission, and distribution of electricity, and the energy consumed in extracting, processing, and transporting or distributing primary fuels. The study, ''Review of Site (Point-of-Use) and Full-Fuel-Cycle Measurement Approaches to DOE/EERE Building Appliance Energy-

Efficiency Standards,'' (Academy report) was completed in May 2009 and included five recommendations. A copy of the study can be downloaded at: *http://www.nap.edu/catalog.php?record_id=12670.*

The Academy's primary recommendation is that ''DOE consider moving over time to use of a FFC measure of energy consumption for assessment of national and environmental impact, especially levels of GHG emissions, and to providing more comprehensive information to the public through labels and other means such as an enhanced Web site.'' [1] The Academy further recommended that DOE work with the FTC to consider options for making product specific GHG emissions estimates available to consumers. More specifically, the Academy recommended that DOE use the FFC measure of energy consumption for the environmental assessment and national impact analyses used in energy conservation standards rulemakings.

DOE's energy conservation program for consumer products and certain commercial and industrial equipment sets energy conservation standards to reduce U.S. energy consumption in residential and commercial buildings. DOE separates covered products into classes differentiated by energy source, technology, and capacity. EPCA, as amended, requires DOE to set energy conservation standards for covered products based on energy consumption at the point-of-use. (42 U.S.C. 6291(4)–(6), 6311(3)–(4), (18))

The point-of-use method for measuring energy consumption considers the use of electricity, natural gas, propane, and/or fuel oil by an appliance at the site where the appliance is operated. DOE uses point-of-use measures of energy consumption, usually presented in the physical units typically used for the relevant fuel (or electricity), for setting energy conservation standards. Before choosing an energy conservation standard, however, DOE performs several analyses to estimate the likely impacts of alternative standard levels. DOE impact analyses include a: life-cycle cost analysis, manufacturer impact analysis, national impact analysis, engineering analysis, screening analysis, environmental assessment, utility impact assessment, and employment impact assessment. For many years, DOE has used primary energy measures of energy consumption and related emissions in several of these analyses, including the national impact analysis and the environmental assessment, to estimate the total projected energy savings and emission impacts likely to result from the imposition of alternative standard levels. Primary energy includes energy consumed on-site, plus energy losses that occur in the generation, transmission, and distribution of electricity.

Based on the results of these various analyses, DOE then proposes (and, ultimately, adopts) the energy conservation standard that it determines achieves the maximum energy efficiency improvement that is technologically feasible and economically justified as required by EPCA, as amended. (42 U.S.C. 6295(o)(2)(A) Additionally, DOE must determine that the establishment of a new or amended energy conservation standard will result in significant energy conservation. (42 U.S.C. 6295(o)(3)(B))

III. General Discussion and Discussion of Comments

In response to DOE's Notice, DOE received comments from 41 entities. Comments were submitted by utilities, research facilities, consumer representatives, non-profit organizations, farmers and others. In the following sections, the comments received concerning this proposed change in policy are summarized and addressed, and DOE provides a statement of the resulting policy that it will apply in the development of future energy efficiency rules and related activities.

There were, however, a number of comments received in response to the Notice that are peripheral to the issues addressed in the Notice. For example, several comments indicated that the Department should not use estimates of the social cost of carbon in assessing the impacts of prospective energy conservation standards and others disagreed with the methods now used by DOE to estimate such cost. (See *e.g.,* NRECA, Public Comment, EERE–2010–BT–NOA–0028–0001, p. 3) These issues have been addressed in previous rulemakings, would not be affected by today's policy change to use FFC analyses, and were not the subject of the Academy's report.

American Public Power Association (APPA) commented that DOE should be noting the high degree of subjectivity involved in the monetary benefit of reduced carbon dioxide (CO_2) in the monetization of societal benefits. (APPA, Public Comment, EERE–2010–BT–NOA–0028–0033, p. 4) This comment on the treatment of the monetary benefits of reduced CO_2 emissions is outside the scope of the Notice and this final Policy Statement. However, DOE notes that DOE's analysis does identify such benefits separately in its life-cycle cost and net present value benefit calculations.

The Edison Electric Institute (EEI) indicated that the method used by DOE to derive estimates of primary energy inappropriately ''assigns'' a fossil fuel heat rate for electricity generated by renewable and nuclear resources. EEI indicated that this approach resulted in an inflated value for the national energy savings associated with the electricity demand reductions estimated by appliance efficiency standards analyses. (EEI, Public Comment, EERE–2010–BT–NOA–0028–0007, p. 3) Today's policy would not modify the methods used by DOE to calculate primary energy.

Michigan dairy farmers provided a comment concerning the final water heater energy conservation standard. (Weiss, Public Comment, EERE–2010–BT–NOA–0028–0009, p. 1) Comments on DOE directives made under previous energy conservation standards rulemakings are outside the scope of the Notice and are not addressed in this Statement of Policy.

A. Considering FFC Energy and Emission Impacts of Prospective Efficiency Standards

In its August 2010 Notice, DOE proposed to modify the methods it uses to estimate the likely impacts of energy conservation standards for covered products in order to use FFC measures of energy and related emissions in national impact analyses and environmental assessments, rather than the primary energy measures that DOE currently uses in these analyses. The NOPP also provided various tables with examples of the preliminary estimates of the conversion factors that DOE would use to shift its estimates of the primary energy savings and emission reductions likely to result from various energy efficiency levels to their FFC equivalents.

A few of the comments noted that existing law requires the development of efficiency standards based on the energy consumed by an appliance at its point-of-use (or site energy). While some commenters questioned whether this legal constraint was appropriate, no comments argued that DOE was not obligated by existing law to set its energy conservation standards using metrics derived from point-of-use (or site) energy. In a related comment, the American Council for an Energy-Efficient Economy (ACEEE) recommended that DOE make a statement indicating DOE's intention of keeping gas and electric appliances in separate product classes for energy

[1] Academy Report at p. 10.

conservation standards. (ACEEE, Public Comment, EERE–2010–BT–NOA–0028–0013, p. 1) The Consumer Energy Council of America (CECA) recommended that energy conservation standards continue to be fuel neutral, as they indicated was directed by EPCA, as amended, and that DOE should not identify or establish favored energy sources. (CECA, Public Comment, EERE–2010–BT–NOA–0028–0012, p. 2)

In response, DOE is confirming that it intends to continue to set energy conservation standards for covered products based on energy consumption at the point-of-use, as required by EPCA, as amended. (42 U.S.C. 6291(4)–(6), 6311(3)(4), (18)) DOE is also confirming that it will continue to consider comparable products that use different fuels in separate classes as required by 42 U.S.C. 6295(q)(1). However, DOE does not agree that EPCA, as amended, mandates fuel neutral energy conservation standards. In evaluating and establishing energy conservation standards, DOE divides covered products into classes based on the type of energy used, their size or capacity and other features that directly affect the product's energy use or efficiency. EPCA, as amended, specifically provides that energy conservation standards for different product classes can have higher or lower levels. (See 42 U.S.C. 6295(q)) DOE sets the energy conservation standard for each product class independently based upon the maximum energy efficiency improvement that is technologically feasible and economically justified, and that results in significant conservation of energy for each product class. (See 42 U.S.C. 6295(o)(2)(A)–(B) and (3)(B))

A number of comments focused on the primary issue raised by the Notice: Should DOE consider the FFC energy and emission impacts of prospective energy conservation standards in determining whether a particular standard should be selected? An appliance efficiency standard is chosen based on the results of various analyses—some of which EPCA, as amended, directs DOE to perform and some of which DOE performs under the discretionary provisions of EPCA. (42 U.S.C. 6295(o)(2)(B)) EPCA, as amended, does not mandate the use of point-of-use measures in these analyses, although the ultimate energy conservation standard chosen must be expressed as a point-of-use measure. (42 U.S.C. 6291(4)–(6), 6311(3)–(4), (18))

Several commenters supported DOE's proposal to begin considering the FFC energy and emission impacts of prospective energy conservation standards. The American Gas Association (AGA) indicated their support by stating, ''Current efficiency standards and appliance labels rely on incomplete energy consumption and emission measurements.'' (AGA, Public Comment, EERE–2010–BT–NOA–0028–0004, p. 1) Also in support, the National Propane Gas Association commented that the FFC approach will enable ''a more comprehensive analysis of total energy and environmental impacts of energy efficiency standards.'' (NPGA, Public Comment, EERE–2010–BT–NOA–0028–0034, p. 2)

The Air-Conditioning, Heating, and Refrigeration Institute (AHRI) expressed their concern that the use of FFC factors would lengthen the rulemaking process by sidetracking discussions of important aspects of a rulemaking, such as benefits to the consumer. (AHRI, Public Comment, EERE–2010–BT–NOA–0028–0017, p. 3)

DOE does not believe that the incorporation of FFC energy and emission impact analyses will substantially alter the focus of public review and comment on DOE's energy conservation standards rulemakings. DOE already conducts and presents the results of analyses on a broad range of criteria other than the direct impacts of appliance efficiency standards on the users of the covered product, as required by statute. While new impact analyses or methods often receive considerable attention when they are introduced, over time, public comments tend to focus on those elements of DOE's analysis that have the greatest impact on the identification and selection of the minimum standard level that is ultimately adopted. DOE does not believe that the use of FFC factors in the national impacts analysis and environmental assessment will significantly impact the selection of the minimum standard level adopted.

Other commenters also opposed such a change to the use of FFC factors. CECA and EEI both stated that considering FFC impacts would push the analysis used to set energy conservation standards beyond what is economically feasible and technically justified. EEI also questioned whether DOE had a sufficiently reliable basis for estimating FFC energy and emission impacts. (CECA, Public Comment, EERE–2010–BT–NOA–0028–0042, p. 7; EEI, Public Comment, EERE–2010–BT–NOA–0028–0007, p. 2) Specifically, EEI commented that ''there is significant disagreement'' as to the appropriate FFC and primary energy factors for the same energy source among different entities. (EEI, Public Comment, EERE–2010–BT–NOA–0028–0037, pp. 5–6)

Under today's policy, DOE will continue to use EIA estimates of primary energy and emission impacts as the basis for its impact analyses and the GREET model will be used simply to convert these primary energy values to their FFC equivalents. This approach avoids making any changes to the methods long used by DOE's EIA (and by DOE's appliance efficiency standards program) to convert energy end-use values to primary energy values, which are the source of many of the disagreements referenced by EEI. DOE's ANL has, in the past, compared different life-cycle assessment methods and found that the results are consistent with those generated by GREET when the same critical input parameters are used. This analysis will be cited in future standards rulemakings, as appropriate.

The statute specifically directs DOE to set appliance efficiency standards at levels that achieve the maximum energy savings that is technologically feasible and economically justified; DOE must also determine that the establishment of the chosen standard will result in significant energy conservation. (42 U.S.C. 6295(o)(2)–(3)) DOE does not believe that the consideration of the FFC energy and emission impacts in the national impacts analysis and environmental assessment of a standard under consideration is in conflict with this statutory directive. In practice, the consideration of FFC energy and emission impacts is likely to have comparatively small effects on DOE's analysis of the economic justification of specific alternative appliance efficiency standards. As indicated by the illustrative tables included in the NOPP that provided preliminary estimates of FFC conversion factors, the estimated energy savings likely to result from efficiency levels under consideration using the FFC method could increase by approximately seven to fifteen percent for gas or oil-fired appliances and two to fifteen percent for electric appliances, relative to the estimates of primary energy savings used currently. These relative increases were based on the ratio of FFC energy use and primary energy use, which were estimated by the GREET model. This increase in energy savings would not affect the estimated value or cost of the resulting energy savings, nor the estimated net present value of consumer life-cycle costs savings, since all energy costs savings are based on DOE estimates of the energy costs (derived from retail energy prices) paid directly by energy users. As a result of a change to consider FFC impacts, there also would be a

comparable increase in the CO_2 emission reductions and in the estimated monetary value of such emission reductions. DOE believes that these adjustments in the estimated energy savings and in the value of the benefits associated with reduced CO_2 emissions would enhance, rather than distort, DOE's analyses by more fully representing the total energy and emissions associated with the delivery of energy to consumers.

While estimates of the additional energy use and emissions resulting from the FFC methodology will add some new uncertainties to DOE's impact analyses, these new uncertainties are small relative to the total additional energy and emission impacts being estimated and are comparable to the uncertainties associated with previous DOE analyses. Since FFC-based estimates will more fully reflect the total energy and emission reductions associated with the imposition of energy conservation standards and are not significantly less reliable than current methods, DOE has concluded that such estimates should be used in future impact analyses.

Policy Statement: In the national impacts analyses and environmental assessments of future energy conservation standards rulemakings, DOE intends to include impact estimates based on FFC energy and emissions, rather than the previous practice of estimating such impacts based on the likely effects on primary energy and emissions.

B. Using FFC Energy Efficiency Metrics in DOE's Assessment of Energy Conservation Standards Impacts

In the NOPP, DOE proposed to use FFC measures of energy use and related emissions in the national impact analyses and environmental assessments included in future energy conservation standards rulemakings, but did not propose to create or use extended site or FFC measures of energy efficiency in its rules or regulatory impact analyses.

For rulemakings for covered products for which there is a choice of fuel, AGA noted the Academy's third recommendation that ''efficiency ratings should be calculated using the extended site (source) measure of energy consumption until the Department can consider and complete a transition to the use of a full fuel-cycle measure of consumption.'' AGA recommended that DOE make ''side-by-side comparisons of the calculated energy savings from proposed efficiency standard for each appliance'' as part of its analysis of the likely impacts of prospective standards. While recognizing that DOE does not have the statutory authority to use FFC energy efficiency metrics as the basis for DOE conservation standards, AGA recommended that DOE create and use such metrics as part of its analysis of the likely impacts of prospective energy conservation standards. (AGA, Public Comment, EERE–2010–BT–NOA–0028–0035, pp. 4–5)

DOE has the statutory authority to create and consider extended site or FFC energy efficiency metrics as part of its analysis of the likely impacts of prospective energy conservation standards. (See 42 U.S.C. 6295(o)(2)(B)(i)(VII)) Extended site or FFC energy efficiency metrics would provide DOE with a rough indication of the likely energy impacts of a shift in the market of products using different fuels (*i.e.,* fuel switching) that might result from the imposition of alternative energy conservation standards under consideration. If DOE's analysis indicated that a particular standard level under consideration would likely lead to a shift in consumer purchases from products with higher FFC efficiency to products with lower FFC efficiency, then DOE decision-makers would be alerted that such a shift would likely undercut the energy savings (and emission reductions) resulting from that standard level.

For this reason, DOE carefully considered whether it should establish a policy to calculate and use in future rulemakings such extended-site or FFC efficiency metrics for appliances for which there is a fuel choice. DOE concluded, however, that the use of extended site or FFC energy efficiency metrics would only provide a rough indicator of the impacts of possible fuel switching on total energy savings and emissions and, therefore, would not enhance current DOE estimates of the direct impacts of alternative standard levels on fuel choice, energy savings, emissions and other factors. On the other hand, such FFC energy efficiency metrics may prove to be a useful mechanism for conveying complex information to consumers. The issue of consumer information is discussed further in Section E of this notice.

Policy Statement: After careful consideration, DOE has concluded that calculating and comparing efficiency ratings on an FFC basis is not likely to significantly enhance the considerable information already available on the likely impacts of prospective energy conservation standards on total energy use, emissions and other factors. Consequently, DOE does not intend to create or use such metrics in the development of future appliance efficiency standards. While DOE already accounts for the potential impacts of fuel switching in its energy conservation standards analyses (where appropriate), it will make the methodologies and results of fuel switching more explicit in all rulemakings in which fuel switching might occur.

C. Estimated Impacts From Expansion of Considered GHG Emissions

As part of its rulemaking analyses, DOE currently estimates the impacts of alternative standard levels on emissions of Carbon Dioxide (CO_2), Sulfur Dioxide (SO_2), Nitrogen Oxide (NO_X) and Mercury. Of these, CO_2 is the only GHG addressed in DOE's rulemaking analyses. In the NOPP, DOE proposed to add estimates of the impact of alternative energy conservation standards on the emissions of two other types of GHGs, methane (CH_4) and nitrous oxide (N_2O), as part of the environmental assessments included in future rulemakings. These estimates would be provided both as physical units of the emissions of these gases and as CO_2 equivalents of these emissions based on their climate forcing effects (using generally accepted conversion factors). Although not directly addressed in the Academy's report, such emissions have a direct association with the production and use of energy and adding reduction estimates of these gases will allow DOE to provide a more comprehensive assessment of the impact of standards on GHG emissions. These two gases are included in national GHG emissions inventories worldwide and, according to the EPA, they are among the principle GHGs that enter the atmosphere due to energy production. Addition of reduction estimates of these gases to the environmental assessments of future energy efficiency rulemakings could increase the estimated impacts of alternative standard levels on CO_2-equivalent GHG emissions by approximately five to seventeen percent, as indicated by the preliminary estimates provided in the NOPP.

Southern Company agreed in their comments that it is reasonable to use estimates of the CO_2-equivalent emissions of these two gases in environmental assessments, stating that the addition would provide ''useful, more complete information on the environmental impacts of appliance use.'' They also noted ''that most leakage of methane from natural gas comes from distribution systems, and electric generation generally receives direct service from natural gas transmission systems without using gas distribution systems. Therefore the

methane-related global warming impact for electric generation should be much less than the adjustment for methane leakage for direct consumer use of natural gas, which does use natural gas distribution systems.'' (Southern, Public Comment, EERE–2010–BT–NOA–0028–0027, p. 4)

DOE notes that, for electricity generation from natural gas, the GREET model includes methane leakage associated with gas transmission systems, but not leakage associated with gas distribution from city gate to households. Also, methane leakage in gas production is accounted for in the natural gas fuel cycle in GREET.

NEEA questioned whether the flaring of natural gas and other gases during oil production, and methane from coal mining, is included in the FFC emissions analysis. (NEEA, Public Comment, EERE–2010–BT–NOA–0028–0021, p. 3) The emissions from both flaring and venting of gas in oil production are accounted for in GREET simulations. Methane released into the atmosphere during the production of oil or gas, or during coal mining, is also considered as an emission.

DOE did not receive any comments opposing the addition of these gases.

Policy Statement: DOE intends to add estimates of the impacts of alternative energy conservation standards on emissions of CH_4 and N_2O, two significant GHGs, to future environmental assessments. These impact estimates will be provided in the physical units of these gases, as well as their CO_2-equivalent values. These values, however, will not be used to develop estimates of the monetary value of reductions in CO_2 emissions until such time as the methodology used to calculate the social cost of carbon is explicitly modified to cover such gases.

D. Methodology for Estimating FFC Energy and Emission Impacts

DOE proposed to use the GREET model in energy conservation standards rulemakings to convert primary energy and emission impacts, including CH_4 and N_2O, to FFC energy and emission impacts. The GREET model was originally developed in 1995 and is routinely updated with support from several DOE programs. It includes more than 100 fuel production pathways, including those addressed by the FFC methodology to be used for product standards rulemakings. The model and its technical documentation are available at the GREET Web site (*http://greet.es.anl.gov/*). At present, there are more than 15,000 registered GREET users worldwide.

In the NOPP, for each alternative energy conservation standard under consideration, DOE proposed to first estimate the primary energy and related emission impacts by using the same methodologies and NEMS projections that DOE's conservation standards program has traditionally used. Second, for each alternative energy conservation standard under consideration, DOE proposed to use the energy conversion factors that are generated using the GREET model to convert primary energy use and emission impacts to FFC energy use and emission impacts.

EEI asked which version of the GREET model was used to derive the preliminary conversion values shown in Tables 1 and 2 of the Notice. (EEI, Public Comment, EERE–2010–BT–NOA–0028–0037, p. 5) The most recent version of the GREET model available at the time, version 1.8d, was used to calculate the values in Tables 1 and 2. There will be a new version of GREET released in 2011. The latest version of GREET will be used when the FFC is calculated in future energy conservation standards rulemakings.

Southern Company commented that DOE's proposal to use existing methodologies and NEMS, together with conversion factors generated by the GREET model, was a reasonable approach. (Southern, Public Comment, EERE–2010–BT–NOA–0028–0027, p. 3) Both AGA and the Natural Gas Supply Association (NGSA) commented in support of the GREET model, stating that GREET provides ''an adequate modeling platform for the calculation of energy consumption and greenhouse gas emissions data as part of the Department's energy conservation standards program.'' (AGA, Public Comment, EERE–2010–BT–NOA–0028–0035, p. 3; NGSA, Public Comment, EERE–2010–BT–NOA–0028–0019, p. 2)

The American Public Gas Association (APGA) commented that it is important that DOE use a transparent process to ensure that stakeholders understand how the GREET model would be used to calculate FFC energy and GHG emissions impacts as part of energy conservation standards rulemakings. The National Association of Home Builders expressed concern about the level of technical documentation and verifiable data provided in the Notice. (APGA, Public Comment, EERE–2010–BT–NOA–0028–0024, p. 5)

The methods, data and assumptions used in the GREET model were subject to public review and comment under separate Federal and State rulemakings. When the current GREET model, or a new version of the model, is used in future DOE rulemakings, the methods, data and assumptions will again be fully documented and subject to public review and comment.

The Northwest Energy Efficiency Alliance (NEEA) commented that the conversion factors and other GREET model estimates presented in the Notice appeared frozen in time, yielding minimal changes for most fuels analyzed from 2010 to 2030. (NEEA, Public Comment, EERE–2010–BT–NOA–0028–0021, p. 1) The NEMS and GREET models both forecast or simulate changes in energy use and emissions over time. The small changes in the conversion factors in Tables 1 and 2 of the Notice reflect the fact that large, long-lived capital stocks dominate the energy production and transport sector, and change slowly over time. New facilities or processes replace existing facilities and processes only gradually over many decades. Retrofitting of existing facilities to alter the fuels used or substantially reduce emissions can result in more rapid changes, and there are efforts to continually improve the ability of the GREET model to capture these types of changes.

Additionally, NEEA asked how to interpret the analyses as they apply to nuclear-fueled electricity, noting that the energy returned on energy invested (EROEI) for nuclear electricity is likely different than the two EROEI values reflected in the current DOE ANL estimates of the FFC factors for this source of energy. (NEEA, Public Comment, EERE–2010–BT–NOA–0028–0021, p. 2) GREET simulations for energy input versus output are based on fossil energy input only. This may be the reason why the imputed EROEI from the GREET model appears higher than some other estimates. The FFC factors are not the same as the EROEI values, since EROEI cannot separate use of different types of energy sources, which is necessary for FFC and GHG emission estimation. Details of the nuclear electricity pathway used in GREET are documented in a paper published in 2007 and posted at the GREET Web site.

EEI commented that the values in Tables 1 and 2 of the Notice are stochastic and do not include all aspects of energy production (such as energy used for oil drilling or to produce chemicals used in the natural gas hydraulic fracturing process). In addition, the tables do not show the range of values in the GREET model for different energy production methods. (EEI, Public Comment, EERE–2010–BT–NOA–0028–0037, p. 5)

DOE agrees that the values generated by the GREET model reflect industry averages that are the product of widely variable processes and practices. DOE

also agrees that the values do not represent all emissions associated, either directly or indirectly, with the production and delivery of energy to end-users, although DOE believes that the values generated by the GREET model will enable DOE to use estimates of energy and emission impacts that are a close approximation of the definition of FFC analysis recommended by the Academy. More specifically, while the current GREET model does not include energy use and emissions of oil exploration, it does include the impacts of upstream oil operations (including recovery and drilling). In addition, the energy and emission impacts of shale gas production will be added to the 2011 update of the GREET model.

Details of the estimates used for specific technology pathways (such as residual oil production, natural gas production, electricity generation) are provided in the GREET model and the methods, data and assumptions underlying these estimates are provided in the GREET documentation, both of which are available at *http://greet.es.anl.gov/.*

APPA commented that the GREET model is susceptible to multiple forms of error because of its large set of base assumptions. APPA also stated that the model is subject to manipulation. (APPA, Public Comment, EERE–2010–BT–NOA–0028–0033, p. 3) APPA is correct that the GREET model, like any life-cycle assessment (LCA) model, is based on a multitude of assumptions. The data supporting these assumptions come from Federal and State databases, as well as data provided by industry. The public can view the model, its assumptions, and the data. This transparency helps produce reliable estimates of FFC impacts.

CECA commented that: ''A simple conversion factor from site energy to full fuel cycle is not adequate. There are myriad criteria for determining full-fuel-cycle analysis and reaching agreement on a satisfactory procedure would likely be beyond DOE/EERE's time and resources.'' CECA also cited environmental externalities such as those in the European Commission's ExternE model. The ExternE model includes not just energy costs but societal concerns such as environmental impacts, global warming, accidents, energy security, employment impacts, and depletion of non-renewable resources. (CECA, Public Comment, EERE–2010–BT–NOA–0028–0012, p. 3) The State of California developed a model for transportation fuels which defines a ''Full Fuel Cycle Assessment'' as evaluating and comparing the full environmental and health impacts of each step in the life-cycle of a fuel, which include, but are not limited to, feedstock extraction, transport, storage, fuel production, distribution, vehicle operation, refueling, combustion, or conversion and evaporation. (California Energy Commission, Development of the State Plan for Alternative Transportation Fuels, AB 1007, 3/2/2007) These and other models, in addition to GREET, are cited in the Academy's report. Other entities had similar concerns regarding other available models. (AHRI, Public Comment, EERE–2010–BT–NOA–0028–0017, p. 3) AHRI also noted that the GREET model was not ''specifically designed for use in DOE efficiency standard rulemakings.''

Today's Policy Statement addresses the energy use and associated emissions directly used in, or emitted from, the point of primary fuel production to the point of end-use, as specified in the recommendations of the Academy's report. Consequently, the scope of FFC, as this term is used in this Policy Statement, is limited. Other social and environmental impacts, such as the indirect energy and emission impacts associated with the manufacture of covered appliances and equipment, or the manufacture of the equipment used in fuel production and refining, as well as other impacts on health or the environment, are not within the scope of the FFC estimates referenced in this Policy Statement.

In its evaluation of alternative transportation fuels under AB 1007, the California Energy Commission uses GREET and a fuel-cycle definition that is very similar to the FFC approach proposed for use in the development of DOE energy conservation standards.

DOE acknowledges that the GREET model was not specifically designed to generate the factors necessary to convert the primary energy and emission values now used in DOE's energy conservation standards impact analyses into FFC values. DOE is not aware of any model that was specifically designed for this purpose. Nevertheless, DOE has concluded that the GREET model can be appropriately used for this purpose and that the resulting values will be sufficiently reliable to significantly improve the usefulness of the resulting energy and emission impact estimates. The GREET model has been previously used to support certain Federal and State regulatory actions on GHG emissions (such as the EPA's Renewable Fuel Standard development and California's low-carbon fuel standard development) and Federal vehicle fuel efficiency labeling by EPA and DOE. It has already been subject to considerable public review and comment. For these reasons, DOE concludes that GREET is the best model to use for the purposes of today's Policy Statement.

Policy Statement: In future energy conservation standards rulemakings, DOE intends to calculate FFC energy and emission impacts by applying conversion factors generated by the GREET model to the NEMS projections currently used by DOE. When DOE uses the GREET factors in a rulemaking, the factors will be subject to public review and comment. These factors will be used to convert the primary energy and emission values generated by methodologies that have been traditionally used by DOE in its appliance efficiency standards rulemakings to their FFC equivalents. The GREET model will also be used to generate estimates of the FFC emissions of methane and nitrous oxides.

From time to time, DOE will review alternative approaches to estimating these factors and may decide to use a model other than GREET to estimate the FFC energy and emission impacts in any particular future appliance efficiency standards rulemaking. For example, DOE is aware that a future version of the NEMS model may provide the detail necessary to estimate FFC energy and emission impacts. Whether DOE uses the GREET model or another model identified in the future, the model and FFC energy and emission impacts will be subject to public review and comments within an energy conservation standards rulemaking.

E. Consumer Information on FFC Impacts of Specific Covered Products

The Academy recommended that DOE work with the FTC to initiate a project to consider the merits of providing consumers with information about FFC energy use and GHG emissions of individual appliances so that the public can make more informed purchasing decisions. In particular, the Academy recommended that DOE and FTC should initiate a project to consider the merits of adding to the Energy Guide label an indicator of how an appliance's total energy consumption might affect levels of GHG emissions.[2] The FTC has statutory authority over Energy Guide labels.

DOE indicated in its NOPP that the FTC maintains online databases of the site energy use and efficiency ratings of appliances currently on the market. These databases do not, however, include FFC energy use or any energy cost or emissions-related data. While it is possible to compare the site energy

[2] Academy report at p. 12.

use and efficiency ratings of different products using these databases, such comparisons are often difficult, especially if they involve products that have different features. Furthermore, comparing products that use different fuels is often not feasible because of differences in the measures of energy use or efficiency of products that use different fuels.

In response to the Academy's recommendations, DOE proposed to significantly improve upon the FTC's existing on-line databases by making FFC energy use and emissions data (and possibly annual energy cost data) available to the public. The improved databases could enable users to easily compare a product's energy use, associated emissions, and costs to similar products, including products that are in different classes because they have different features or use different fuels. Additional energy, emissions, and cost data could be included by updating FTC's online database with the emissions factors developed with the GREET model and estimated annual energy use and/or energy cost data reported by manufacturers on appliance Energy Guide labels. This proposed action was also supported by comments from the Natural Resources Defense Council. (NRDC, Public Comment, EERE–2010–BT–NOA–0028–0030, p. 2)

Regarding the Energy Guide label, DOE stated in the NOPP that it is not clear to DOE that including additional label disclosures, such as the GHG emissions indicator mentioned by the Academy, would be valuable to customers unless they could easily compare the GHG emissions associated with one product to other comparable products or other common energy uses. DOE indicated in its proposal that because the GHG emissions associated with a particular class of products using the same fuel would be directly proportional to that class of products' estimated annual energy costs, simply comparing an individual product to products of the same class using the same fuel would add little useful information to the label. DOE also stated that providing comparisons to the energy use, costs or emissions associated with other comparable products with different features or that use different fuels on the Energy Guide label may increase the complexity of the label, making the label more difficult to understand and decreasing the utility of the basic annual operating cost information already on the label.

AGA supported the inclusion of emissions information on Energy Guide labels to allow customers to better understand the emissions implications of their appliance choices. AGA commented that ''any concerns regarding the complexity and utility of any particular Energy Guide label can and should be addressed in a rulemaking proceeding by the FTC to revise the labels. The potential that some labels may be perceived by some users as less than clear should not be a basis for denying consumers the emissions information they need to make environmentally sound appliance choices.'' (AGA, Public Comment, EERE–2010–BT–NOA–0028–0004, pp. 3–4)

DOE will make available to the FTC the FFC energy and emission factors that it generates for use in rulemakings. DOE still has some concerns that using these factors to provide FFC information to consumers via the Energy Guide Label is likely to increase the complexity of the label and, therefore, may decrease its effectiveness. However, DOE believes that other means of providing this information to consumers could be as or more effective.

The Institute for Policy Integrity disagreed with DOE's concerns about adding GHG emissions to the Energy Guide labels. The Institute pointed out that other labels are far more complex, which indicates that consumers are accustomed to relatively complex labels, and encouraged DOE to work with the FTC on label modifications. (Institute, Public Comment, EERE–2010–BT–NOA–0028–0032, pp. 5–6)

In contrast, EEI commented that providing consumers with accurate product-specific GHG emissions data associated with electricity use would likely be extremely complex because each utility has its own distinct GHG emission mix. As a result, national or even regional average data can be very misleading. If product-specific GHG emissions data was made available, EEI, along with others, indicated that it supported the use of a website providing such information as opposed to including the information on Energy Guide labels. (EEI, Public Comment, EERE–2010–BT–NOA–0028–0007, p. 3)

EEI and CECA Solutions commented that DOE's proposal to provide customers with energy use and emissions data back to the point of extraction of fossil fuels would lead consumers to incorrectly believe that they will save more energy than is the case and could harm the ability of consumers to make smart purchasing decisions. (EEI, Public Comment, EERE–2010–BT–NOA–0028–0007, p. 2; CECA, Public Comment, EERE–2010–BT–NOA–0028–0012, p. 2)

Similarly, NRECA stated that consumers will not accurately understand the amount of energy being utilized by their appliances and providing this information would burden manufacturers, possibly resulting in higher costs for the consumer. (NRECA, Public Comment, EERE–2010–BT–NOA–0028–0002, p. 3)

In response, DOE emphasizes that it is not proposing to provide consumers with information that might lead them to conclude that the benefits associated with the reduction of FFC energy or emissions would be reflected in additional consumer cost savings. DOE does not believe that providing consumers with information about the FFC impacts of appliances on GHG emissions would mislead consumers about the actual energy use of their appliances, nor that providing such information would place a significant new cost on manufacturers that would increase product costs. However, DOE agrees that providing this type of information in a meaningful way, given the large regional variations in the electric sector, may well be difficult.

NRECA went on to comment that ''the analysis and cost effectiveness of the efficiency standard must be based upon costs and savings that the customers experience.'' They indicated that they believe that ''placing source energy consumption on a label for the customer is misleading at best, and very confusing. Customers could choose the ''highest'' efficiency unit on the label but find their utility bills increasing because the appliance would not be operating on the most efficient energy source at the site.'' (NRECA, Public Comment, EERE–2010–BT–NOA–0028–0002, p. 3)

DOE agrees that energy conservation standards should continue to be based, in large part, on the costs and savings that user's experience. However, EPCA, as amended, and other laws direct DOE to consider a range of other factors as well, including the energy resource and environmental impacts of alternative standard levels. While ongoing changes in the electric sector sometimes may make this type of analysis complex and less certain, DOE believes that such analyses are nevertheless possible and, ultimately, useful to government decision-makers and many consumers. Regarding the information made available to consumers, DOE agrees that information on energy costs and life-cycle costs should continue to be emphasized. However, DOE also believes that consumers should be given ready access to better information on the energy resource and environmental impacts of their appliance choices. DOE believes that this objective can be achieved, at least in part, through web-

based information tools, although DOE will also work collaboratively with the FTC to determine if changes to Energy Guide labeling requirements would be beneficial to consumers.

DOE agrees with NEEA's comment that the difference between primary energy use estimates and FFC energy use estimates is relatively small. (NEEA, Public Comment, EERE–2010–BT–NOA–0028–0021, p. 2) However, to date, consumers have not had ready access to information on either the primary or FFC energy and emission impacts of products. Making such information available in a manner that would enable consumers to make cross-fuel and cross-class comparisons of comparable products could provide consumers with significant new information.

The Consumer's Union commented that the Energy Guide labels must increase consumer awareness of GHG emissions to effectively educate consumers and engage them in energy and climate change policy. Such labels should ''address regional variation of electricity fuel mixes and provide consumers guidance on how to interpret the data given their region or particular utility.'' (Consumers, Public Comment, EERE–2010–BT–NOA–0028–0028, p. 5) DOE agrees that consumers should be given ready access to better information on the energy resource and environmental impacts of their appliance choices and how to provide this information in a meaningful way will be a significant issue for DOE and the FTC to consider.

Policy Statement: Subject to the availability of funds, DOE will work with other Federal agencies to make readily available to consumers improved information on the energy use, life-cycle cost and associated emissions of comparable products, even if those products use different forms of energy. Consumers should be able to easily identify the likely energy use, life-cycle costs and associated emissions of individual products (based on their local energy costs and utility system characteristics), but should also be able to compare those attributes to a range of other products providing similar utility. In developing betters ways of conveying such information to consumers, DOE will explore the possible role of common efficiency metrics for products using different fuels or energy, and will, as appropriate, solicit further public review and comment on the mechanisms developed to make available this information to consumers.

Any updates to Energy Guide labels will be promulgated by the FTC, which has statutory authority over Energy Guide labels.

IV. Procedural Issues and Regulatory Review

A. Review Under the National Environmental Policy Act of 1969

DOE has determined that this Policy Statement falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this Policy Statement describes methods for data analysis and how DOE plans to incorporate such data analysis into future energy conservation standards. For this reason, and because the Policy Statement does not establish an energy conservation standard or take any action that might have an impact on the environment, it is covered by the Categorical Exclusion A9 under 10 CFR part 1021, subpart D. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

B. Review Under the Information Quality Bulletin for Peer Review

In consultation with the Office of Science and Technology Policy (OSTP), OMB issued on December 16, 2004, its ''Final Information Quality Bulletin for Peer Review'' (the Bulletin). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal government, including influential scientific information related to agency regulatory actions. The purpose of the Bulletin is to enhance the quality and credibility of the government's scientific information. Under the Bulletin, the Academy recommendations and GREET model are ''influential scientific information,'' which the Bulletin defines as ''scientific information that the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.'' 70 FR 2664, 2667 (Jan. 14, 2005). The Academy recommendations have been peer reviewed pursuant to section II.2 of the Bulletin. The GREET model, which is in the public domain, has been reviewed through its development and applications over the past 16 years.

V. Approval of the Office of the Assistant Secretary

The Assistant Secretary of DOE's Office of Energy Efficiency and Renewable Energy has approved publication of this final policy.

Issued in Washington, DC, on August 10, 2011.

Roland J. Risser,

Program Manager, Building Technologies Program, Energy Efficiency and Renewable Energy.

[FR Doc. 2011–21078 Filed 8–17–11; 8:45 am]

BILLING CODE 6450–01–P

FARM CREDIT ADMINISTRATION

12 CFR Part 615

RIN 3052–AC50

Funding and Fiscal Affairs, Loan Policies and Operations, and Funding Operations; Investment Management

AGENCY: Farm Credit Administration.

ACTION: Proposed rule.

SUMMARY: The Farm Credit Administration (FCA, Agency, us, our, or we) proposes to amend our regulations governing investments held by institutions of the Farm Credit System (FCS or System). We propose to strengthen our regulations governing investment management, interest rate risk management, and association investments; revise the list of eligible investments to ensure it is limited only to high-quality, liquid investments; reduce regulatory burden for investments that fail to meet eligibility criteria after purchase or are unsuitable; and make other changes that will enhance the safety and soundness of System institutions. In this proposal, we also seek comments on compliance with section 939A of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act or DFA), which requires us to remove all references to and requirements relating to credit ratings and to substitute other appropriate standards of creditworthiness. We also seek comment on other issues.

DATES: You may send us comments by November 16, 2011.

ADDRESSES: We offer a variety of methods for you to submit comments on this proposed rule. For accuracy and efficiency reasons, commenters are encouraged to submit comments by e-mail or through the Agency's Web site. As facsimiles (fax) are difficult for us to process and achieve compliance with section 508 of the Rehabilitation Act, we are no longer accepting comments submitted by fax. Regardless of the method you use, please do not submit your comment multiple times via different methods. You may submit comments by any of the following methods:

• *E-mail:* Send us an e-mail at *reg-comm@fca.gov.*

• *FCA Web site: http://www.fca.gov.* Select ''Public Commenters,'' then ''Public Comments,'' and follow the directions for ''Submitting a Comment.''

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

• *Mail:* Gary K. Van Meter, Director, Office of Regulatory Policy, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

You may review copies of all comments we receive at our office in McLean, Virginia, or on our Web site at *http://www.fca.gov.* Once you are in the Web site, select ''Public Commenters,'' then ''Public Comments,'' and follow the directions for ''Reading Submitted Public Comments.'' We will show your comments as submitted, but for technical reasons we may omit items such as logos and special characters. Identifying information that you provide, such as phone numbers and addresses, will be publicly available. However, we will attempt to remove e-mail addresses to help reduce Internet spam.

FOR FURTHER INFORMATION CONTACT: Timothy T. Nerdahl, Senior Financial Analyst, Office of Regulatory Policy, Farm Credit Administration, McLean, VA 22102–5090, (952) 854–7151 extension 5035, TTY (952) 854–2239; or Jennifer A. Cohn, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4020.

SUPPLEMENTARY INFORMATION:

I. Objectives

The objectives of this proposed rule are to:

• Ensure that Farm Credit banks [1] hold sufficient high-quality, readily marketable investments to provide sufficient liquidity to continue operations and pay maturing obligations in the event of market disruption;

• Strengthen the safety and soundness of System institutions;

• Discuss the requirements of section 939A of the Dodd-Frank Act;

• Reduce regulatory burden with respect to investments that fail to meet eligibility criteria after purchase or are unsuitable; and

• Enhance the ability of the System to supply credit to agriculture and aquatic producers by ensuring adequate availability to funds.

II. Background

Congress created the System as a Government-sponsored enterprise (GSE) to provide a permanent, stable, and reliable source of credit and related services to American agriculture and aquatic producers. Farm Credit banks obtain funds used by System banks and associations to provide credit and related services primarily through the issuance of System-wide debt securities.[2] If access to the debt market becomes temporarily impeded, Farm Credit banks must have enough readily available funds to continue operations and pay maturing obligations.

Subpart E of part 615 imposes comprehensive requirements regarding the investments of System institutions (primarily Farm Credit banks).[3] Section 615.5134(a) of FCA regulations requires each Farm Credit bank to maintain a specified liquidity reserve.[4] This liquidity reserve may only be funded from cash and eligible investments.[5]

We adopted our last major revisions to our investment regulations in 1999 and amended them in a more limited manner in 2005. Since 1999, the marketplace pertaining to investments has changed significantly. Innovations in investment products have led to their increasing complexity, and investors need to have greater expertise to fully understand them. In addition, the financial crisis that began in 2007 resulted in numerous investment downgrades and the loss of billions of dollars by financial institutions.

While System banks suffered considerably less stress during the crisis than many other financial institutions, they did experience numerous downgrades and some losses on individual investments. In 2010, we issued a bookletter that provides clarification and guidance regarding our regulations and expectations with respect to the key elements of a robust investment asset management framework that institutions should establish to prudently manage their investments in changing markets.[6] The issuance of this bookletter was an interim measure towards strengthening our investment regulations.

In July 2010, the President signed into law the Dodd-Frank Act to strengthen regulation of the financial industry in the wake of the financial crisis that unfolded in 2007 and 2008. As discussed in greater detail below, section 939A of the DFA requires each Federal agency to revise all of its regulations that refer to or require reliance on credit ratings to assess creditworthiness of an instrument to remove the reference or requirement and to substitute other appropriate creditworthiness standards.

We now propose amendments that would strengthen our investment regulations. In addition, in certain areas, including compliance with section 939A of the DFA, we seek comments but propose no specific regulatory revisions. In these areas, we will likely have to propose revisions before we will be able to adopt revisions as final. We will consider all comments received in this or future rulemakings, as appropriate.

III. Section-by-Section Description of the Proposed Rule

Following is a section-by-section description of the proposed revisions to our rules.

A. Section 615.5131—Definitions

We propose to amend § 615.5131 to add two new definitions to reflect clarifications we propose to make to § 615.5140, as discussed below. We propose adding a definition for *Government agency,* which we would define as the United States Government or an agency, instrumentality, or corporation of the United States Government whose obligations *are* fully and explicitly insured or guaranteed as to the timely repayment of principal and interest by the full faith and credit of the United States Government. We also propose adding a definition for *Government-sponsored agency.* We would define this term as an agency, instrumentality, or corporation chartered or established to serve public purposes specified by the United States Congress but whose obligations *are not* explicitly insured or guaranteed by the full faith and credit of the United States Government. This definition would include GSEs such as the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac), as well as Federal agencies, such as the

[1] Section 619.9140 of FCA regulations defines Farm Credit bank to include Farm Credit Banks, agricultural credit banks, and banks for cooperatives.

[2] Farm Credit banks use the Federal Farm Credit Banks Funding Corporation (Funding Corporation) to issue and market System-wide debt securities. The Funding Corporation is owned by the Farm Credit banks.

[3] Section 615.5142 authorizes associations to hold eligible investments with the approval and oversight of their funding banks, for specified purposes. Associations that hold investments, as well as service corporations that hold investments, are subject to our investment management regulation at § 615.5133.

[4] We expect to propose revisions to § 615.5134 in an upcoming rulemaking.

[5] § 615.5134(a).

[6] FCA Bookletter BL–064, *Farm Credit System Investment Asset Management* (December 9, 2010). This Bookletter may be viewed at *http://www.fca.gov.* Under Quick Links, click on Bookletters.

Tennessee Valley Authority, that issue obligations that are not explicitly guaranteed by the Government of the United States' full faith and credit.

B. Section 615.5132—Investment Purposes

In 2005, we modified § 615.5132 to increase the permissible level of investments that Farm Credit banks may hold from 30 to 35 percent of total outstanding loans. The reason for the increase was to provide the banks with additional flexibility to meet their liquidity needs and accomplish their asset/liability management strategies in varying economic conditions. At this time, we continue to believe that the investment maximum of 35 percent of total outstanding loans provides the banks adequate flexibility to maintain their liquidity reserve at an appropriate amount. However, as discussed below, we solicit public comments on this issue.

In this discussion, we emphasize the proper application of a provision of this regulation. We also discuss a proposed revision and an area where we specifically seek the views of commenters.

1. Permissible Investment Purposes

Section 615.5132 permits each Farm Credit bank to hold eligible investments for the purposes of maintaining a liquidity reserve, managing surplus short-term funds, and managing interest rate risk. These purposes do not authorize Farm Credit banks to accumulate investment portfolios for arbitrage activities or to engage in trading for speculative or primarily capital gains purposes.[7] Realizing gains on sales before investments mature is not a regulatory violation as long as the profits are incidental to the specified permissible investment purposes. Farm Credit banks must ensure that their internal controls, required under §§ 615.5133(e) and 618.8430, ensure that eligible investments listed in § 615.5140(a) are limited to those that are appropriate under § 615.5132.

2. Excluding Investments Pledged To Meet Margin Requirements for Derivative Transactions

Section 615.5132 permits Farm Credit banks to hold eligible investments, for specified purposes, in an amount not to exceed 35 percent of its total outstanding loans. We propose to permit banks to exclude investments pledged to meet margin requirements for derivative transactions (collateral) when calculating the 35-percent investment limit. We note that investments that are pledged as collateral do not count toward a Farm Credit bank's compliance with its liquidity reserve requirement.[8] Derivatives are used as a hedging tool against interest rate risk and liquidity risk. Farm Credit banks use derivative products as an integral part of their interest rate risk management activities and as a supplement to the issuance of debt securities in the capital markets. We recognize that banks are required to post collateral to counterparties resulting from entering into derivative transactions, and we believe banks should not be discouraged from implementing appropriate risk management practices.

3. Treasury Securities and the 35-Percent Investment Limit

Historically, Farm Credit banks have invested in instruments that generate yield in excess of the cost of funds (positive carry). Since the recent financial crisis, however, the banks have experienced decreased liquidity with these instruments at times, and they have turned to United States Treasury securities because of their high liquidity.[9] Treasury securities generally have yields that are lower than the cost of the underlying Farm Credit debt that would fund such securities, and this negative carry has an adverse impact on bank earnings.

Under our existing 35-percent investment limit, holding Treasury securities reduces the maximum amount of investments that Farm Credit banks may hold in other eligible securities. Thus, the banks must choose between greater liquidity but a negative carry, or a positive carry but reduced liquidity.[10] Banks would be able to avoid making this choice if they were permitted to exclude a portion of or all Treasuries or to apply a discount to Treasury securities when calculating the 35-percent limit.

We currently believe that the 35-percent limit continues to provide sufficient flexibility for Farm Credit banks to maintain adequate liquidity. However, we have received a request from a System workgroup asking us to consider treating Treasury securities as cash for purposes of this provision.

Consequently, we seek comment on whether and how to address the situation Farm Credit banks face in holding Treasury securities. Are Farm Credit banks able to purchase sufficient Treasury securities to enhance liquidity, while remaining within the constraint that total investments may not exceed 35 percent of total outstanding loans? Or should the percentage be raised and, if so, to what level and why? Should Treasuries be excluded from total investments when calculating the percentage of total investments to total loans outstanding? Would it be appropriate to exclude a portion of Treasury securities from the calculation? Would it be appropriate to apply a discount to Treasuries? What would be the basis for such a calculation change?

C. Section 615.5133—Investment Management

Effective investment management requires financial institutions to establish policies that include risk limits, approved mechanisms for identifying, measuring, and reporting exposures, and strong corporate governance. The recent crisis and its lingering effects have re-emphasized the importance of sound investment management, and we believe that strengthened regulation would further ensure the safe and sound management of investments. Accordingly, we are proposing significant changes to § 615.5133, which governs investment management.[11]

In addition, we propose minor technical, clarifying, and non-substantive language changes to this section that we do not specifically discuss in this preamble.

1. Proposed § 615.5133(a)—Responsibilities of Board of Directors

We propose enhancements to the responsibilities of each board of directors set forth in § 615.5133(a). The existing regulation requires the board to review its investment policies annually and to make any changes that are needed. We believe that depending on the situation, this review may need to occur more than once a year. We would continue to require a review at least annually but, to reduce unnecessary regulatory burden, we propose to permit a designated board committee to conduct this review and to validate the

[7] FCA has consistently taken this position. *See, e.g.,* 70 FR 51587, August 31, 2005; 58 FR 63039, November 30, 1993.

[8] Under § 615.5134(b), all investments that a bank holds for the purpose of meeting the liquidity reserve requirement must be free of lien.

[9] A System workgroup has recommended the establishment of a minimum level of cash and/or investments in Treasury securities as part of the liquidity reserve requirement of Farm Credit banks. FCA expects to propose revisions to § 615.5134, governing this liquidity reserve requirement, in an upcoming rulemaking.

[10] Cash, which is also held for liquidity, also has a negative carry, but it is not subject to the 35-percent investment limit, and so it does not pose the same challenge.

[11] This rule would supersede the guidance contained in Bookletter BL–064.

sufficiency of the investment policies, provided that the board must adopt any changes to the policies.

2. Proposed § 615.5133(b)—Investment Policies—General Requirements

Section 615.5133(b) lists the items that a board's investment policy must address, but it currently does not include every requirement of § 615.5133. For example, existing § 615.5133(e) requires an institution to establish internal controls, and existing § 615.5133(f) requires specified securities valuation, but existing § 615.5133(b) does not require these items to be addressed in the investment policy. Our proposal would require that the investment policy address every requirement of § 615.5133. This revision would clarify our expectations as to the appropriate content of the board's policies.

We would also require that investment policies must address the means for reporting, and approvals needed for, exceptions to established policies. Because the investment policies are established by the board, we believe it is important for the board's policies to address how exceptions to those policies will be handled. We believe exceptions to a policy should be rare, because frequent exceptions call into question the adequacy of the policy.

In addition, we propose that institutions must document in their records or board minutes any analyses used in formulating policies or amendments to the policies. An accurate record of the analysis used to formulate investment policies documents appropriate governance. It also provides a trail for future directors and managers to review to fully understand how previous boards of directors arrived at their decisions and why they approved the policy in the form they did.

3. Proposed § 615.5133(c)—Investment Policies—Risk Tolerance

Our proposed changes are intended to make the investment policies' risk tolerance discussion more robust. In addition to the existing requirements of this section, investment policies would have to establish concentration limits for the various types and sectors of eligible investments and for the entire investment portfolio. We propose to delete the requirement that investment policies must establish diversification requirements, because the new concentration limit requirement would necessarily lead to diversification.

a. Proposed § 615.5133(c)(1)—Credit Risk

Existing § 615.5133(c)(1)(i) provides that investment policies must establish credit quality standards, limits on counterparty risk, and risk diversification standards that limit concentrations based on a single or related counterparty(ies), a geographical area, industries, or obligations with similar characteristics. We propose to clarify that concentration limits be based on either a single or related counterparty(ies). Further, concentration limits must also be based on a geographical area, industries or sectors, asset classes, or obligations with similar characteristics. We believe this amendment would ensure that diversification is more thoroughly considered by System institutions.

Existing § 615.5133(c)(1)(ii) requires investment policies to establish criteria for selecting securities firms. It requires the board annually to review the criteria for selecting securities firms and determine whether to continue existing relationships. To reduce unnecessary regulatory burden, we propose to permit a designated committee of the board to review the criteria and to determine whether to continue existing relationships, but the board must approve any changes to the criteria and any changes to the existing relationships. This change would permit a designated committee to use its technical expertise to assist the board in carrying out its responsibilities.

Existing § 615.5133(c)(1)(iii) requires investment policies to establish collateral margin requirements on repurchase agreements. We propose to require institutions to regularly mark the collateral to market and ensure appropriate controls are maintained over collateral held. We believe it is prudent for institutions to manage potential counterparty risk and to establish appropriate counterparty margin requirements based on the quality of the collateral and the terms of the agreement.

b. Proposed § 615.5133(c)(2)—Market Risk

We propose changes to § 615.5133(c)(2), which relates to market risk. Specifically, we propose to link this regulation to our stress-testing requirements contained in proposed § 615.5133(f)(2), our interest rate risk requirements contained in § 615.5135, and other policies and guidance. These changes clarify our expectations that the board consider all aspects of market risk.

4. Proposed § 615.5133(e)—Internal Controls

We propose to modify our internal controls requirements in § 615.5133(e). In § 615.5133(e)(2), we propose adding additional personnel to the list of personnel whose duties and supervision should be separated from personnel who execute investment transactions. These additional personnel are those who post accounting entries, reconcile trade confirmations, and report compliance with investment policy. We believe this additional separation is a best practice that System institutions should have in place to ensure controls are sufficient and appropriate.

We also propose a new § 615.5133(e)(4). This provision would require each institution to implement an effective internal audit program to review, at least annually, investment controls, processes, and compliance with FCA regulations and other regulatory guidance. The internal audit program would specifically have to include a review of the processes used for ensuring all investments, at the time of purchase, are eligible and suitable for purchase under the board's investment policies and for ensuring investments continue to meet all applicable generally accepted accounting principles even if they are no longer part of the liquidity portfolio.

Existing § 618.8430 requires each institution's board to adopt an internal control policy that provides direction to the institution in establishing effective control over, and accountability for, operations, programs, and resources. Our regulations do not, however, discuss the internal audit of the investment function specifically. However, FCA Bookletter BL–064 provides guidance on FCA expectations in this area. We now propose to strengthen this guidance by adding it as a regulatory requirement in § 615.5133(e)(4).

As we stated in FCA Bookletter BL–064, under § 618.8430 an institution's board is responsible for ensuring that sound systems and controls are in place to manage investment risks. Senior management is responsible for implementing an effective control environment to manage risk in an institution's investment portfolio, as well as to ensure compliance with applicable laws and regulations. Internal audit is a critical function that ensures appropriate internal controls are in place. Accordingly, our proposal would require System institutions to establish internal controls to ensure that an independent review over investment practices and controls, including

specifically the process for determining eligibility and suitability, is conducted.

An institution's audit plan must include a risk assessment, at least annually, of the investment function by the internal audit department or by an outside vendor if the expertise in-house does not exist. Moreover, an institution must conduct an internal audit of the investment function at least annually. As we stated in FCA Bookletter BL–064, the frequency and scope of review should be based on the complexity and size of the investment portfolio. In addition, auditors should be rotated to obtain alternate views of investment operations. Outside audits of the portfolio should be conducted periodically as necessary to ensure an objective evaluation of practices and controls by qualified auditors.

5. Proposed § 615.5133(f)—Due Diligence To Determine Eligibility, Suitability, and Value of Investments

We propose to add a new § 615.5133(f). This provision would cover the due diligence institutions must perform to determine eligibility, suitability, and value of investments. This provision would combine in one location the requirements governing securities valuation and those governing stress testing that are now in existing § 615.5133(f) and § 615.5141, respectively. Our proposed revisions would make these requirements more robust and less burdensome.

a. Proposed § 615.5133(f)(1)—Eligibility and Suitability for Purchase

In new § 615.5133(f)(1), we propose that before an institution purchases an investment, it must conduct sufficient due diligence to determine whether the investment is eligible under § 615.5140 and suitable for purchase under the investment policies of the institution's board. We propose to retain from existing § 615.5133(f)(1) the requirement that the institution must verify the value of the investment (unless it is a new issue) with a source that is independent of the broker, dealer, counterparty, or other intermediary to the transaction. We also propose to require that an institution's investment policies must fully address the extent of pre-purchase analysis that management must perform for various classes of investments and that the institution must document its assessment of eligibility and suitability, including the information used in its assessment. The provision would permit the institution to use all available sources, including third party sources, to assess the investment. Finally, the provision would require that the institution's assessment of each investment at the time of purchase must at a minimum include an evaluation of credit risk, liquidity risk, market risk, and interest rate risk, and an assessment of the cash flows and the underlying collateral of the investment.

This proposed regulation builds on our expectations for institutions to conduct proper due diligence, which we conveyed in FCA Bookletter BL–064. System institutions must conduct due diligence prior to purchasing a security. The degree of due diligence that an institution conducts must be commensurate with the complexity of the security. The need to evaluate and make a decision on a transaction quickly does not obviate the due diligence requirement. FCA expects that institutions must thoroughly understand the risks and cash flow characteristics of their investments, particularly for products that have unusual, leveraged, or highly variable cash flows. System institutions must identify and measure risks prior to acquisition. In general, institutions should conduct and document due diligence analyses separately for each investment security. Modeling cash flows and assumptions at the time of purchase provides insight into the changing risks certain investments present.

We believe that documentation of the analysis conducted is a critical component for assessing and verifying eligibility and suitability. Investment policies must require that an adequate level of analysis be conducted on the various classes of investments purchased. Under this proposed regulation, System institutions that engage in investment activity will need to strengthen their due diligence process and improve their documentation as to why the investment was purchased.

We expect that institutions will evaluate each investment they purchase using various sources available to them, including third parties if warranted, to assess whether an investment meets the eligibility requirements. Institutions may not, however, rely exclusively on third parties to justify the purchase of a security. Institutions must always conduct their own due diligence, because management and the board are ultimately responsible for any decisions. Moreover, because of the particular concerns surrounding the accuracy of credit ratings, institutions must be especially cautious if they choose to consider them.

b. Proposed § 615.5133(f)(2)—Pre-Purchase and Quarterly Stress Testing

We propose moving our investment stress-testing requirements into § 615.5133(f)(2), as part of our due diligence and security valuation requirements, and removing existing § 615.5141 as a stand-alone, stress-testing regulation. We propose this change because stress-testing is a key component of due diligence. It is used to assess the risk presented by an investment and the changes in valuation that may be experienced from movements in interest rates. In addition, we propose changes to the substance of the stress-testing requirements.

Existing § 615.5141 requires pre-purchase and quarterly interest rate stress testing for mortgage securities. It provides that mortgage securities are not eligible investments unless they pass a stress test, and it requires divestiture of a mortgage security that no longer complies with the stress-testing requirements.

In the preamble to the 1999 final rule, in which we adopted the existing stress-testing requirements, we stated that we believed stress-testing was an essential risk management practice because even highly rated mortgage securities may expose investors to significant interest rate risk.[12] We therefore stated that ''each System institution needs to employ appropriate analytical techniques and methodologies to measure and evaluate interest rate risk inherent in mortgage securities. More specifically, prudent risk management practices require every System institution to examine the performance of each mortgage security under a wide array of possible interest rate scenarios.'' [13]

Because of the importance of stress testing and the increasing complexity of investments, we propose in a new § 615.5133(f)(2) that all investments—not just mortgage securities, and including Treasury securities—must be stress tested before purchase and on a quarterly basis. This new requirement would enable System institutions to gain insight into the price movements of all securities they purchase. We understand that stress-testing for investments that have indexed rates that reprice at intervals of 12 months or less or have extremely short terms (such as Fed Funds and certain commercial paper) may be viewed as unnecessary. However, we believe that all investments must be stress tested to build a robust stress-testing environment that provides for a comprehensive and consistent analytical framework from which to evaluate the risks in the investment portfolio. It is also an important part of

[12] *See* 64 FR 28893, May 28, 1999.

[13] *Id.*

due diligence and the ongoing evaluation process.

Existing § 615.5141 provides two stress-testing options. In the first option, we set forth a standardized, three-pronged stress test that includes an average life test, an average life sensitivity test, and a price sensitivity test. In the second prong, we permit institutions to use alternative stress-test criteria and methodologies to evaluate the price sensitivity of mortgage securities.

We now propose to eliminate the standardized stress test. Since we first allowed the alternative stress test, we believe that every Farm Credit bank that invests in mortgage securities has moved to the alternative test and that none continue to use the standardized test. We discuss new stress-testing requirements, set forth in § 615.5133(f)(2)(iii), below.

To reduce regulatory burden, we propose in new § 615.5133(f)(2)(i) that an institution may purchase, with board approval, an investment that exceeds the stress-test parameters defined in its board's policies. We believe this flexibility is necessary because the financial markets continue to be very dynamic and a particular investment may not meet a board's parameters but may nevertheless provide additional liquidity or interest risk protection.

We propose in new § 615.5133(f)(2)(ii) that at the end of each quarter, each institution must stress test its entire investment portfolio, including a stress test of each individual investment, in accordance with paragraph (f)(2)(iii), as defined in its board policy. An investment that exceeds the board-defined stress parameters would not become ineligible and would not need to be divested. Rather, the board policy defining the stress tests would have to specify what actions the institution would take if its portfolio (but not an individual investment) exceeded the quarter-end, stress-test parameters defined in the policy, including the development of a plan to bring the portfolio back into compliance with those parameters.

We believe that stress testing the entire investment portfolio at each quarter-end will provide significant insight into the risks associated with the investment portfolio. We also believe that requiring the stress testing of individual investments on a quarterly basis is just a component of understanding how each individual investment affects the entire portfolio. Should an institution's entire portfolio exceed its board's stress-testing policy parameters it would have to develop a plan to bring the portfolio back into compliance. This plan should specify how the institution would bring the portfolio back into compliance and what timeframes are involved.

As discussed below, in § 615.5133(g)(2) we propose to require an institution to provide immediate notification to the board or a designated board committee if its stress test for the entire portfolio exceeds its board's policy parameters. We believe that a portfolio stress test that exceeds board parameters discloses a serious situation that could threaten the safety and soundness of the institution and that directors should be notified and a plan developed to reduce portfolio risk.

Proposed § 615.5133(f)(2)(iii) sets forth the requirements for pre-purchase and quarter-end stress tests. These requirements are for the most part unchanged from our existing requirements in § 615.5141 governing the alternative stress test. We discuss the differences below.

Proposed § 615.5133(f)(2)(iii) would require that the pre-purchase and quarter-end stress tests be defined in a board approved policy and include defined parameters for the types of securities an institution purchases. The stress tests would have to be comprehensive and appropriate for the risk profile of the institution. At a minimum, the stress tests would have to be able to measure the price sensitivity of investments over different interest rate/yield curve scenarios. The methodology that the institution uses to analyze investment securities would have to be appropriate for the complexity, structure, and cash flows of the investments in its portfolio.

The stress tests would have to enable the institution to determine at the time of purchase and each subsequent quarter-end that its investment securities, either individually or on a portfolio-wide basis, do not expose its capital, earnings, or liquidity to excessive risks. Also, the stress tests would have to enable the institution to evaluate the overall risk in the investment portfolio and compare it with defined board policy limits.

Two of the new requirements in this proposal—the requirement that all securities, not just mortgage securities, must be stress tested; and the requirement that securities must be stress tested on a portfolio-wide basis—are discussed above. The other new requirement is that stress tests would have to enable an institution to determine that its investment securities do not expose it to excessive liquidity risk. We propose this requirement because we believe an institution should have insight into the amount of cash it could obtain through the sale of investments, if necessary.

In conducting its stress tests, an institution would have to rely, to the maximum extent practicable, on verifiable information to support all of its assumptions, including prepayment and interest rate volatility assumptions, when applying its stress tests. An institution would have to document the basis for all assumptions used to evaluate a security and its underlying collateral, and it would also have to document all subsequent changes in its assumptions.

In this proposal, we specifically seek comment on several areas related to stress testing. Should FCA retain a standardized stress-testing option for institutions that do not wish to or do not have the capability of defining their own stress tests? Given that the Dodd-Frank Act requires us to eliminate credit ratings as a criterion for the eligibility of investments, would allowing System institutions to develop their own standards result in a variety of investment portfolios that exhibit substantially different risk profiles? Could this result in an inappropriate amount of risk in some investment portfolios? Also, should our regulations require stress-testing on all investments at the time of purchase? If not, on which investments should we require stress-testing, and why? Should institutions be required to stress test their individual investments and their entire investment portfolio on a quarterly basis? Why or why not?

c. Proposed § 615.5133(f)(3)—Ongoing Value Determination

We propose to redesignate existing § 615.5133(f)(2) as § 615.5133(f)(3). We propose to revise the last sentence of this provision to require an institution to evaluate the credit quality and price sensitivity of each investment in its portfolio and of its whole investment portfolio to the change in market interest rates. This change would clarify the meaning of this provision. We also propose to make other non-substantive changes to this provision.

d. Proposed § 615.5133(f)(4)—Presale Value Verification

We propose to redesignate existing § 615.5133(f)(3) as § 615.5133(f)(4) and to change the word ''security'' to ''investment.''

6. Proposed § 615.5133(g)—Reports to the Board of Directors

We propose revisions to § 615.5133(g), which specifies information that management must report to the board or a board committee each quarter.

Proposed § 615.5133(g)(1) would retain the general quarterly reporting requirements but would add to and modify them to strengthen the overall reporting requirements. Proposed § 615.5133(g)(2) would add a special reporting requirement.

Proposed § 615.5133(g)(1) would require management to report to the board of directors or a designated board committee at least quarterly on the following:

- Plans and strategies for achieving the board's objectives for the investment portfolio;
- Whether the investment portfolio effectively achieves the board's objectives;
- The current composition, quality, and liquidity profile of the investment portfolio;
- The performance of each class of investments and the entire investment portfolio, including all gains and losses that the institution incurred during the quarter on individual investments that it sold before maturity and why they were liquidated;
- Potential risk exposure to changes in market interest rates as identified through quarterly stress testing and any other factors that may affect the value of the institution's investment holdings;
- How investments affect the institution's capital, earnings, and overall financial condition;
- Any deviations from the board's policies (must be specifically identified); and
- The results of the institution's quarterly stress test.

We believe that these reporting requirements are best practices and are items that boards of directors or a designated board committee must know to exercise proper governance. We also believe that the use of the investment plan discussed below would be an important tool and an effective way to report to the board on the requirements above. Presenting an investment plan and its results to the board or designated board committee would provide assurances that all required reporting takes place.

Proposed § 615.5133(g)(2) would add a special reporting requirement. It would require an institution to provide immediate notification to its board of directors or to a designated board committee if its portfolio exceeded the quarterly stress-test parameters defined in the board policy required by proposed § 615.5133(f)(2)(ii). We propose this requirement because exceeding board policy parameters could lead to serious risk exposures for the institution.

7. Investment Plan and Investment Oversight Committee

Although not a regulatory requirement, each System institution that maintains an investment portfolio should develop an investment plan and establish a formal investment oversight committee. These practices enable management to implement the investment direction provided by the institution's board. In addition, as discussed above under reporting, management's presentation of an investment plan to the board or designated board committee, along with the investment portfolio results, would provide assurances that required reporting takes place.

An institution's senior management should develop a sufficiently detailed investment plan to appropriately execute the board's approved investment strategies and achieve business plan goals of the institution. The plan should be approved by senior management or an appropriate management committee. The investment plan should help provide for effective guidelines and control over the investment portfolio. The plan should be a working document that can deal with changes in market conditions. Investment plans should describe:

- The target portfolio composition given the board's investment policy, current market conditions, and projected liquidity needs;
- The rebalancing activities needed to achieve the target portfolio; and
- The performance measures that will be used to measure portfolio performance. Such measures should include target portfolio spread given the target portfolio composition and anticipated various spreads in relation to the institution's cost of funds.

To effectively implement the investment plan, each institution should consider establishing a formal investment committee to provide additional expertise and to serve as an additional control over investment management. In the past, the asset/liability management committees, which oversee the management of investment portfolios in most System institutions, have generally provided sufficient oversight of these portfolios. However, the importance, volume, and growing complexity of System investments may warrant additional expertise in the form of a more specialized investment committee. In addition to providing additional expertise, the investment committee would also provide for separation of duties between allocation and risk strategies and the actual traders. This committee could also provide appropriate monitoring and governance as well as provide structure or formalization of many of the informal processes.

D. Section 615.5135—Management of Interest Rate Risk

Interest rate risk management is an important part of the overall financial management of a Farm Credit bank. The potentially adverse effects that interest rate risk may have on net interest income and the market value of equity is of particular importance.

We believe that strong policy direction from a Farm Credit bank's board of directors is essential to an effective interest rate risk management program. Existing § 615.5135 requires a bank's board to adopt an interest rate risk management section of an asset/liability management policy. Our proposed revisions to this rule would strengthen a bank's interest rate risk management program. The existing requirements would remain. In addition, the revisions would require the interest rate risk management section of the asset/liability management policy to establish policies and procedures for the bank to:

- Address the purpose and objectives of interest rate risk management;
- Consider the impact of investments on interest rate risk based on the results of the stress testing required under proposed § 615.5133(f)(2); [14]
- Describe actions needed to obtain its desired risk management objectives;
- Identify exception parameters and approvals needed for any exceptions to the requirements of the board's policies;
- Describe delegations of authority;
- Describe reporting requirements, including exceptions to limits contained in the board's policies; and
- Consider the nature and purpose of derivative contracts and establish counterparty risk thresholds and limits for derivatives used to manage interest rate risk.

Boards of directors set policy direction for the institution. Bank management carries out this direction and is responsible for reporting back to

[14] Existing § 615.5135 already requires Farm Credit banks to include investments in their interest rate shock analysis. Farm Credit banks may wish to review an advisory on interest rate risk management, issued by certain other agencies in January 2010, that discusses stress testing. *See, Advisory on Interest Rate Risk Management,* issued by the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the National Credit Union Administration, the Office of the Comptroller of the Currency, the Office of Thrift Supervision, and the Federal Financial Institutions Examination Council State Liaison Committee (January 6, 2010).

the board on its implementation of board direction and results. Consequently, we would expect that many of the above requirements would be carried out by management or a committee comprised of management and directors.

In addition, our proposal would require that management of each Farm Credit bank must report at least quarterly to its board of directors, or to a designated committee of the board, describing the nature and level of interest rate risk exposure. Any deviations from the board's policy on interest rate risk must be specifically identified in the report and approved by the board or a designated committee of the board.

Finally, we propose several minor technical and clarifying amendments, such as changing ''shall'' to ''must''.

E. Section 615.5136—Emergencies Impeding Normal Access of Farm Credit Banks to Capital Markets

This section provides that an emergency shall be deemed to exist whenever a financial, economic, agricultural, or national defense crisis could impede the normal access of Farm Credit banks to the capital markets. Whenever FCA determines, after consultations with the Funding Corporation, that such an emergency exists, the FCA Board shall, in its sole discretion, adopt a resolution that increases the amount of eligible investments that banks are authorized to hold pursuant to § 615.5132, and/or modifies or waives the liquidity reserve requirement in § 615.5134.

We propose revisions to provide additional flexibility to the resolution that the FCA Board may adopt. First, in recognition that events such as the 2008 market turmoil may not allow for the deliberation contemplated by this regulation, we propose to clarify that the Funding Corporation consultation should occur only ''to the extent practicable.'' Second, the proposed rule would provide that FCA ''may'', rather than ''shall'', adopt a resolution. Third, rather than permitting the resolution to increase the authorized amount of eligible investments, the proposed rule would permit the resolution to modify the amount, qualities, and types of authorized, eligible investments. Finally, we propose to expressly permit the resolution to authorize other actions as deemed appropriate.

F. Section 615.5140—Eligible Investments

We last revised our listing of eligible investments, at § 615.5140, in 1999.[15] Those amendments expanded the list of eligible investments and relaxed or repealed certain restrictions that had previously been in the regulation. As a result, those amendments allowed System institutions to purchase and hold a broader array of high-quality and liquid investments. Those revisions reflected changes in the financial markets and helped fulfill our objective of developing a regulatory framework that could more readily accommodate innovations in financial products and analytical tools.

The recent financial crisis resulted in substantial turmoil in the financial markets. Overall, System institutions weathered this crisis better than many other regulated financial institutions. We believe this is due in part to the limited scope of authorized investments. Even so, some System institutions did experience losses on certain types of investments.

Based on this experience, we now propose amendments that would clarify which investments are eligible, eliminate certain investments, and reduce portfolio limits where appropriate. In addition, we ask questions about the most effective way to comply with section 939A of the DFA. As discussed in greater detail below, that provision requires each Federal agency to revise all regulations that refer to or require reliance on credit ratings to assess creditworthiness of an instrument to remove the reference or requirement and to substitute other appropriate creditworthiness standards.

1. Proposed Revisions to § 615.5140(a)

a. Proposed § 615.5140(a)—Introductory Paragraph

We propose revisions to the language in the introductory paragraph of § 615.5140(a). The existing language authorizes institutions to hold only the eligible investments that are listed and prohibits institutions from purchasing investments that are not listed. It also prohibits them from holding investments that were eligible when purchased but that subsequently became ineligible.

Like our existing regulation, our proposal would permit institutions to purchase only those investments that satisfy the eligibility criteria in § 615.5140. An investment that does not satisfy the eligibility criteria would not be eligible for purchase and would be subject to the divestiture requirements of proposed § 615.5143(a) if it were purchased.[16]

In a change from our existing approach, however, eligibility would be determined only at the time of purchase. An investment that satisfies the eligibility criteria at the time of purchase but that subsequently failed to satisfy the eligibility criteria would not become ineligible and would not have to be divested. Instead, it would be subject to the requirements of proposed § 615.5143(b), which would permit an institution to retain the investment subject to certain conditions.[17] As discussed below, in our discussion of our proposed amendments to § 615.5143, we believe this change would reduce regulatory burden without creating safety and soundness concerns.

In addition, existing § 615.5140(a) states that all investments must be denominated in United States dollars. We propose to relocate this language to § 615.5140(b).

b. Proposed § 615.5140(a)(1) and (a)(2)—Obligations of the United States and Obligations of Government-Sponsored Agencies

Existing § 615.5140(a)(1) lists ''Obligations of the United States'' as an eligible asset class. Under that heading three items are listed: Treasuries; agency securities (except mortgage securities); and other obligations fully insured or guaranteed by the United States, its agencies, instrumentalities, and corporations. We believe this listing is confusing and does not appropriately differentiate among obligors. Although the heading reads ''Obligations of the United States'', the second and third items are intended to include debt securities and other non-mortgage obligations of GSEs such as Fannie Mae and Freddie Mac, which are not obligations of the United States.[18]

[15] *See* 64 FR 28884 (May 28, 1999).

[16] In this context, ''purchase'' would include an acquisition such as a swap of one security in exchange for another. It would not include an acquisition through a merger or consolidation of institutions. This interpretation is consistent with our interpretation of the existing rule.

[17] Investments that do not meet our eligibility criteria that are acquired through a merger or consolidation would also be subject to the requirements of § 615.5143(b).

[18] We use the term ''Obligations of the United States'' to refer to obligations that are fully and explicitly insured or guaranteed by the full faith and credit of the United States. Although the United States Government placed Fannie Mae and Freddie Mac in conservatorship in September 2008 and has taken certain actions to effectively provide protection to the holders of obligations issued and guaranteed by the GSEs, these obligations are not explicitly insured or guaranteed by the United States Government's full faith and credit.

Accordingly, we propose to split this listing into two categories. We do not intend any substantive changes with this proposed revision. We intend only to clarify the existing language.

The first listing, under § 615.5140(a)(1), would be headed ''Obligations of the United States'', and it would include only non-mortgage obligations, including but not limited to Treasuries, that are fully insured or guaranteed by a *Government agency* (which by definition means they are backed by the full faith and credit of the United States).[19] The second listing, under § 615.5140(a)(2), would be headed ''Obligations of Government-Sponsored Agencies'', and it would include debt securities and other non-mortgage obligations of GSEs, as well as of Federal agencies, such as the Tennessee Valley Authority, that issue obligations that are not explicitly insured or guaranteed by the full faith and credit of the United States.[20]

Proposed § 615.5140(a)(2) would permit institutions to purchase obligations of Government-sponsored agencies only if the obligations are senior debt securities. We believe that limiting permissible investments in this manner helps to ensure that institutions maintain only the highest quality investments in their portfolios.

c. Proposed § 615.5140(a)(3)—Municipal Securities

Existing § 615.5140(a)(2) places no investment portfolio limits for general obligation municipal securities. We propose to modify this provision (redesignated as § 615.5140(a)(3)) to impose a 15-percent investment portfolio limit on these securities. We propose this limit because we believe that a portfolio solely comprised of general obligation municipal securities would not provide sufficient liquidity in the event of a crisis in that particular market. We note that this limit is consistent with our existing revenue bond municipal securities investment portfolio limit.

d. Proposed § 615.5140(a)(4)—International and Multilateral Development Bank Obligations

Existing § 615.5140(a)(3) places no final maturity limit and no investment portfolio limit on international and multilateral development bank obligations. In redesignated § 615.5140(a)(4), we propose imposing a 10-year maturity limit and a 15-percent investment portfolio limit, to ensure a more diversified and liquid portfolio. We believe that a portfolio containing longer term obligations or comprised of an excess of these obligations would not provide sufficient liquidity in the event of a crisis in that particular market. We note that System institutions have invested in these obligations only on a limited basis.

e. Proposed § 615.5140(a)(5)—Money Market Instruments

Existing § 615.5140(a)(4) permits institutions to invest in repurchase agreements that satisfy specified conditions. If the counterparty defaults, the regulation requires the institution to divest non-eligible securities in accordance with the divestiture requirements of § 615.5143. Under our proposal, (redesignated § 615.5140(a)(5)) as discussed above, an eligible investment could not become ineligible, and would not be required to be divested. Accordingly, we propose to delete this divestiture requirement.

f. Proposed § 615.5140(a)(6)—Mortgage Securities

Existing § 615.5140(5) requires stress testing of all mortgage securities. As discussed above, proposed § 615.5133(f) would require stress testing on all investments held in an institution's portfolio. Accordingly, we propose to delete the specific stress-testing requirement for mortgage securities (which would be listed in redesignated § 615.5140(a)(6)).

The first category listed in existing § 615.5140(a)(5) is mortgage securities that are issued or guaranteed by the United States. In redesignated § 615.5140(a)(6), we propose to revise this category to refer to mortgage securities that are fully guaranteed or fully insured by a Government agency.[21] This change makes clear that this category includes only mortgage securities that are fully backed by the full faith and credit of the United States. If the United States Government issues a mortgage security that is not fully guaranteed or fully insured by the full faith and credit of the United States Government, it is not eligible under this category.

The second category listed in existing § 615.5140(a)(5) is Fannie Mae and Freddie Mac mortgage securities. As discussed above, the United States Government placed these two housing GSEs in conservatorship in September 2008, and their future remains uncertain. As long as they remain in conservatorship, we believe the existing 50-percent investment portfolio limit is appropriate. Accordingly, we propose no changes to this category (which would be included in redesignated § 615.5140(a)(6)) at this time. Depending on what happens to these GSEs in the future, a portfolio limit reduction or other restriction may become warranted. We invite your comments regarding revisions you believe we should make to this category of investments.

The third category listed in existing § 615.5140(a)(5) is non-Agency securities that comply with 15 U.S.C. 77d(5) or 15 U.S.C. 78c(a)(41). For the purpose of clarification, in redesignated § 615.5140(a)(6), we propose to replace the term ''non-Agency'' with a reference to securities that are not fully insured or guaranteed by a Government agency, Fannie Mae, or Freddie Mac. We intend no substantive change with this clarification. Furthermore, in this preamble we continue the shorthand reference to these securities as non-Agency mortgage securities.

Under proposed § 615.5140(a)(6), a position in a non-Agency mortgage security would be eligible only if it is the senior-most position at the time of purchase. The FCA considers a position in a non-Agency mortgage security to be the senior-most position only if it currently meets both of the following criteria:

- No other remaining position in the securitization has priority in liquidation. Remaining positions that are the last to experience losses in the event of default and which share those losses pro rata meet this criterion.
- No other remaining position in the securitization has a higher priority claim to any contractual cash flows. Remaining positions that have the first priority claim to contractual cash flows (including planned amortization classes), as well as those that share on a pro rata basis a first priority claim to cash flows meet this criterion.

Institutions should be aware that the tranche that is the senior-most position at the time they are considering

[19] As discussed above, in § 615.5131 we propose to define *Government agency* as ''the United States Government or an agency, instrumentality, or corporation of the United States Government whose obligations are fully and explicitly insured or guaranteed as to the timely repayment of principal and interest by the full faith and credit of the United States.''

[20] As discussed above, in § 615.5131 we propose to define *Government-sponsored agency* as ''an agency, instrumentality, or corporation chartered or established to serve public purposes specified by the United States Congress but whose obligations are not explicitly insured or guaranteed by the full faith and credit of the United States Government, including but not limited to any Government-sponsored enterprise.''

[21] As discussed above, in § 615.5131 we propose to define *Government agency* as ''the United States Government or an agency, instrumentality, or corporation of the United States Government whose obligations are fully and explicitly insured or guaranteed as to the timely repayment of principal and interest by the full faith and credit of the United States.''

purchase is not necessarily the same tranche that was in the senior-most position at the time of issue. Institutions should also be careful not to be misled by the labeling of tranches as ''super senior'' or ''senior'' in a prospectus (or on market reporting services). Institutions may purchase non-Agency mortgage-backed securities (MBS) only if the securities satisfy the above two criteria at the time of purchase. Any security that would not satisfy the eligibility criteria after purchase because of the terms of the contract or because of structural issues would not be eligible.

In addition, we propose to reduce the investment portfolio limit for non-Agency mortgage securities from 15 to 10 percent to reduce the exposure in MBS that are not fully insured or guaranteed by the United States. We believe reducing exposure in this area of uninsured securities would result in a more diversified and liquid portfolio.

We note that the Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, United States Securities and Exchange Commission, Federal Housing Finance Agency, and Department of Housing and Urban Development (collectively, the other agencies) have proposed a rule to implement the credit risk retention requirements of section 15G of the Securities and Exchange Act of 1934, as added by section 941 of the DFA.[22] If this proposed rule of the other agencies is finalized, it could change the risk characteristics of investments that System institutions invest in. Consequently, FCA may consider further revisions to portfolio limits at that time.[23]

Finally, we propose to eliminate commercial mortgage-backed securities, which are included in existing § 615.5140(a)(5), from the list of eligible investments. We believe that these securities pose undue risk due to the nature of the collateral underlying these securities.

g. Proposed § 615.5140(a)(7)—Asset-Backed Securities

Existing § 615.5140(a)(6) authorizes investments in asset-backed securities with a 20-percent investment portfolio limit. In redesignated § 615.5140(a)(7), we propose to reduce the investment portfolio limit from 20 to 15 percent, with no more than 5 percent of the investment portfolio in any one type of collateral. We propose this change because we believe that certain asset-backed securities, such as home equity loans and manufactured housing loans, present appreciable, albeit manageable, risk. We believe this reduction will help limit the exposure of System institutions in investments such as manufactured housing and home equity loans that experienced considerable stress during the financial crisis.

h. Proposed § 615.5140(a)(8)—Corporate Debt Securities

Existing § 615.5140(a)(7) authorizes investments in corporate debt securities, subject to a 20-percent investment portfolio limit. The provision also prohibits investments in securities that are convertible to equity securities.

In redesignated § 615.5140(a)(8), we propose to add a requirement that the securities must be senior debt securities to be eligible for purchase. We would leave the portfolio limit the same, but we would create additional diversification by requiring that no more than 10 percent of the investment portfolio be in any one of the 10 industry sectors as defined by the Global Industry Classification Standard (GICS).[24]

i. Proposed § 615.5140(a)(9)—Diversified Investment Funds

We propose to clarify our expectations for diversified investment funds contained in our existing § 615.5140(a)(8). We believe the term ''diversified investment funds'' could include closed-end funds, which are typically exchange-traded. We propose to add language stating that only open-end funds are eligible, in order to reduce the possibility that investments are purchased for potentially speculative purposes.

In addition, the existing rule imposes no investment portfolio limitation, as long as shares in each investment company comprise 10 percent or less of an institution's portfolio. Our proposal would impose a 50-percent total investment portfolio limit, with no more than 10 percent in any single fund. We believe this proposal would provide for more appropriate diversification across an institution's investment portfolio.

2. Dodd-Frank Act Compliance

In July 2010, to strengthen regulation of the financial industry in the wake of the financial crisis that unfolded in 2007 and 2008, the President signed into law the Dodd-Frank Act. Section 939A of the DFA requires the following:

- Each Federal agency must review (i) all of its regulations that require the use of an assessment of the creditworthiness of a security or money market instrument, and (ii) any references to or requirements in its regulations regarding credit ratings.
- Each Federal agency must modify its regulations to remove any reference to or requirement of reliance on credit ratings and to substitute in the regulations such standards of creditworthiness as the agency determines is appropriate. In making this determination, the agency must seek to establish, to the extent feasible, uniform standards of creditworthiness.

We have completed our review of FCA regulations that impose creditworthiness requirements or that refer to or require the use of credit ratings. Existing § 615.5140(a) is one such regulation; it requires minimum NRSRO[25] credit ratings for many categories of investments—including municipal securities, certain money market instruments, non-Agency mortgage securities, asset-backed securities, and corporate debt securities—in order for them to be eligible.

There are a number of different ways to assess creditworthiness, and we are considering which approach or combination of approaches would be most appropriate in this context. It may well be that we would want to propose several of these approaches in concert with one another. In the discussion below, we explore various approaches that could be considered for assessing creditworthiness as a determinant of eligibility for purposes of § 615.5140(a).[26]

First, our regulation could specify financial measurements, benchmark indexes, and other measurable criteria against which institutions could evaluate the creditworthiness of their investments. The regulation could

[22] *See* 76 FR 24090 (April 29, 2011).

[23] Future revisions could include changes to the portfolio limits for asset-backed securities contained in proposed § 615.5140(a)(7), as well as to changes to the portfolio limits for non-Agency mortgage securities contained in proposed § 615.5140(a)(6).

[24] GICS was developed by Morgan Stanley Capital International and Standards and Poor's. The GICS is an industry analysis framework for investment research portfolio management and asset allocation. The GICS structure consists of 10 sectors, 24 industry groups, 68 industries, and 154 sub-industries. More information can be found at *http://www.mscibarra.com/products/indices/gics.*

[25] Nationally recognized statistical rating organization.

[26] In addition, existing § 615.5140(b), which we propose to redesignate as § 615.5140(c), provides that whenever the obligor or issuer of an eligible investment is located outside the United States, the host country must maintain the highest sovereign rating for political and economic stability by an NRSRO. The DFA requires us to replace that NRSRO standard with an appropriate substitute. The following discussion also applies to that provision.

specify factors and standards of criteria for various classes of investments. Institutions would need to ensure that these criteria were met in order for an investment to be eligible or suitable at the time of purchase. Some of the factors that could be considered as criteria to ensure a high quality, highly liquid investment portfolio include:

- Credit spreads (*i.e.*, whether it is possible to demonstrate that a position in certain investments is subject to a minimal amount of credit risk based on the spread between the security's yield and the yield of Treasury or other securities, or based on credit default swap spreads that reference the security);
- Default statistics (*i.e.*, whether providers of credit information relating to securities express a view that specific securities have a probability of default consistent with other securities with a minimal amount of credit risk);
- Inclusion on an index (*i.e.*, whether a security, or issuer of the security, is commonly included as a component of a recognized index of instruments that are subject to a minimal amount of credit risk);
- Priorities and enhancements (*i.e.*, the extent to which a security includes credit enhancement features, along with an evaluation of the relative strength of the enhancements, such as overcollateralization and reserve accounts, or has priority under applicable bankruptcy or creditors' rights provisions);
- Price, yield and/or volume (*i.e.*, whether the price and yield of a security or a credit default swap that references the security are consistent with other securities that are subject to a minimal amount of credit risk and whether the price resulted from active trading); and
- Asset class-specific factors (*e.g.*, in the case of structured finance products, the risk characteristics of the specific underlying collateral).

Is this approach one that FCA should consider, and are there other criteria that should be included? Should the creditworthiness standard include specific standards for probability and loss given default? If so, why, and where could the Agency source such data to derive such probabilities? Also, should this vary by asset class and/or type of investment? Finally, would it be appropriate to combine this approach with one or more of the other approaches, and if so, which ones, and why?

Second, our regulation could require System institutions to develop their own internal assessment process for evaluating the creditworthiness of investments. We believe that the level of due diligence needed to validate such a system could require significant effort on the part of System institutions. In addition, the internal evaluation system would need to be validated and might need to be frequently recalibrated based on changes in the marketplace. Institutions would need to be able to demonstrate to FCA that the probability of default characteristics and loss given default characteristics are verifiable and accurate. Any internal assessment would also have to consider an investment's marketability, liquidity, and pricing risk for determining eligibility and suitability.

The System has developed a standardized 14-point risk rating summary that institutions use to classify their loan portfolios. Similar criteria could possibly be used in the assessment of whether an investment is eligible or suitable for the portfolio. However, additional validation would likely be needed to ensure appropriate recognition of the critical factors present in investments.

Is this second approach one that we should consider? Do System institutions have the capability of validating an internal assessment system for investments, and is it appropriate to allow institutions to develop their own internal model for assessing creditworthiness of investments? If so, what standards of creditworthiness should be included, and why? If we consider an internal model approach, what would be the criteria for eligibility, and why? Also, should an assessment of creditworthiness link directly to a bank's loan rating system and if so, how should differences in classifications pertaining to eligibility be handled? Finally, would it be appropriate to combine this approach with one or more of the other approaches and, if so, which ones, and why?

Third, FCA could develop regulations that would require institutions to use third party assessments to assess creditworthiness. Organizations other than NRSROs may have the capability to evaluate creditworthiness, and this evaluation could be considered in an institution's eligibility and suitability assessment. We also believe that the DFA does not prohibit System institutions from looking to the NRSROs as a tool for assessing creditworthiness. Institutions that do so, however, should evaluate the quality of third party assessments by considering whether issuers or investors pay the rating fees. Moreover, as we have seen in the recent crisis, reliance on third party analysis can be problematic and cannot be used in isolation. Accordingly, if we were to require this approach, it would likely be in concert with one or more of the other approaches.

Is this third approach one that we should consider? What reliable third party sources exist? Would it be appropriate to combine this approach with one or more of the other approaches and if so, which ones, and why?

Fourth, FCA could develop a set of clearly defined criteria from which we would create a scale that ranks creditworthiness. We would then require System institutions to conduct due diligence to ensure that an investment they purchase actually complies with the criteria. The criteria could be as follows:

Highest Standard—Obligations must be of the highest quality with minimal credit risk. Issuers must have an extremely strong capacity to meet its long-term financial obligations and a superior ability to repay short-term debt obligations.

High Standard—Obligations must be of a high quality and subject to very low credit risk. Issuers must have a very strong capacity to meet its long-term financial obligations and a strong ability to repay short-term debt obligations.

We recognize that these standards may be viewed differently by different System institutions. This approach would require significant due diligence and controls in place to ensure consistency. It could also result in one institution determining an investment is eligible while another may determine an investment is not eligible at the time of purchase.

Is this fourth approach one that we should consider and, if so, what definitional criteria should be used? Would it be appropriate to combine this approach with one or more of the other approaches and, if so, which ones, and why?

In considering the requirements of the Dodd-Frank Act and the reasons for its enactment, do the above approaches allow for too much subjectivity and inconsistency? Alternatively, is there an approach that would allow for objective criteria that would lead to consistency in assessing eligibility? We are also considering how difficult and costly in practice any of the potential approaches or combination of approaches would be. In addition, we are considering whether there are other approaches to assessing creditworthiness that would be more appropriate. Finally, as a related matter, we are interested in what specific methods and standards an institution should be required to apply to appropriately assess the political and economic stability of a foreign country

that hosts the obligor or issuer of an eligible investment.

3. Changes to Remainder of § 615.5140

As discussed above, we propose to relocate to § 615.5140(b) the requirement, currently contained in the introductory paragraph of § 615.5140(a), that all investments must be denominated in United States dollars.

We propose to delete our existing § 615.5140(c), which requires that all eligible investments, except money market instruments, must be marketable. We expect that in an upcoming rulemaking, we will propose to include that requirement in § 615.5134.

We propose to reduce to 15 percent the 20-percent obligor limit contained in our existing § 615.5140(d)(1). We believe this reduction is appropriate because it helps to ensure diversification among obligors.

We also propose to clarify, consistent with the amendments to terminology that we propose in § 615.5140(a) and (b), that the obligor limit does not apply to obligations that are issued or guaranteed as to interest and principal by Government agencies or Government-sponsored agencies (rather than to obligations that are issued or guaranteed as to interest and principal by the United States, its agencies, instrumentalities, or corporations). We intend no substantive change with this clarification.

Obligations that are not fully insured or fully guaranteed by a Government agency or Government-sponsored agency present relatively greater risk than do obligations that are so insured or guaranteed. We also believe that money market instruments generally present more limited risk. We seek comment on whether an overall combined portfolio limit—including all obligations except for money market instruments and those fully insured or fully guaranteed by Government agencies and Government-sponsored agencies—would be appropriate. Should we implement such a limit and, if so, what should the limit be? In addition, in light of the concentration that can occur in the housing sector, should we consider implementing a housing sector limit? Why or why not?

G. Section 615.5141—Stress Tests for Mortgage Securities

Because we propose to relocate our stress-testing requirements to § 615.5133(f), we also propose to remove this stand-alone, stress-testing section from our regulations.

H. Section 615.5142—Association Investments

Section 615.5142 implements sections 2.2(10) and 2.12(18) of the Act, which require each funding bank to supervise and approve the investment activities of its affiliated associations. Section 615.5142 authorizes an association to hold eligible investments, listed in § 615.5140, with the approval of its funding bank, for the purposes of reducing interest rate risk and managing surplus short-term funds. Each bank must review annually the investment portfolio of every association that it funds.

Although funding banks are required to supervise and approve the investment activities of an association, when we adopted this regulation in 1999, we emphasized that bank oversight does not absolve an association's board and managers of their fiduciary duties to manage investments in a safe and sound manner. We stated that the fiduciary responsibilities of association boards obligate them to develop appropriate investment management policies and practices to manage the risks associated with investment activities. We also stated that each association's investment managers must fully understand the risks of its investments and make independent and objective evaluations of investments prior to purchase.[27]

In addition, we emphasized that each association with a nonagricultural investment portfolio is required to develop an investment policy that is based on its unique characteristics and that is commensurate with the nature of its investment activities and portfolio. An association must comply with all the requirements in § 615.5133 if the level or type of its investments could expose its capital to material loss.[28]

This guidance is still valid today. However, we believe additional clarification and a regulatory revision are appropriate.

As a point of clarification, although § 615.5142 permits association investments for the purpose of, in pertinent part, reducing interest rate risk, the interest rate risk of most associations is managed by their respective funding banks. Accordingly, interest rate risk at the association level is generally minimized although not completely eliminated. The use of investments for reducing interest rate risk should be commensurate with the actual interest rate risk exposure of the association. Furthermore, associations that engage in investment activities must ensure that their investments do not increase interest rate risk.

Section 615.5142 also permits associations to invest surplus short-term funds. We are concerned that an association could draw on its line of credit with its funding bank to obtain ''surplus'' short-term funds that it would invest in an investment with a longer term or repricing characteristics than the term and repricing characteristics of the funding. Funding a longer term investment with short-term funds creates the potential for interest rate risk. Because of this potential risk, associations must carefully manage their investments of surplus short-term funds.

Accordingly, we propose to add paragraph (b) to § 615.5142. Paragraph (b) would require that before an association purchases an eligible investment for the purpose of managing surplus short-term funds, it must ensure that the investment's repricing and maturity characteristics match the characteristics of the surplus short-term funds to be invested.

In addition, although we do not propose this as a requirement at this time, we believe that in order for an investment to be made for the purpose of managing surplus ''short-term'' funds, the funds generally should be invested in instruments that are ''overnight'' or that have maturities of 30 days or less. We seek comment on whether we should define surplus short-term funds and if so how. Further, is our belief that surplus short-term funds should only be invested in overnight investments or in investments with maturities of 30 days or less appropriate? Lastly, is our proposed limitation on the permissible characteristics of investments purchased for the purpose of managing surplus short-term funds appropriate for associations, or does it unreasonably restrict an association's ability to properly hold and manage investments?

I. Section 615.5143—Management of Ineligible and Unsuitable Investments

Existing § 615.5143 requires an institution to dispose of an investment that is ineligible (under the § 615.5140 criteria) within 6 months unless we approve, in writing, a plan that authorizes the institution to divest the instrument over a longer period of time. An acceptable divestiture plan must require the institution to dispose of the ineligible investment as quickly as possible without substantial financial loss. Until the institution actually disposes of the ineligible investment, the institution's investment portfolio managers must report on specified

[27] *See* 64 FR 28885–28886 (May 28, 1999).

[28] *Id.*

matters to the board of directors at least quarterly.

During the financial crisis of the past few years, we have received numerous divestiture plans from System institutions seeking our permission to continue to retain ineligible investments. Nearly all of these plans have involved investments that have become ineligible due to credit ratings downgrades.[29] Typically, the analyses in the divestiture plans have indicated that holding the instruments until maturity or until market conditions improve would minimize losses, compared with incurring a substantial loss with a sale in the then-current market. Moreover, the investments have not materially affected the financial capacity of the institution. Accordingly, we have approved all investment plans that we have received in at least the last 5 years.

The automatic 6-month divestiture requirement, with FCA approval needed for a longer divestiture period, has proven to be inefficient and unnecessary. The existing regulation requires institutions to expend time and effort to develop a divestiture plan, requires FCA staff to expend time and effort reviewing the plan and developing a recommendation, and requires the FCA Board to expend time and effort determining whether to approve the plan.

Accordingly, to reduce the regulatory burden on System institutions and to improve efficiency, proposed § 615.5143(b) would permit an institution to retain an investment that no longer satisfies the eligibility criteria set forth in § 615.5140 (that satisfied the criteria when purchased), without the need for FCA approval, subject to specified requirements that are summarized below.

Section 615.5143(b) would also permit an institution to retain an investment that satisfies the § 615.5140 eligibility criteria but that is not suitable because it does not satisfy the risk tolerance established in the institution's board policy pursuant to § 615.5133(c), subject to the same specified requirements.

The specified requirements that would have to be satisfied in order to retain an investment that no longer satisfies the § 615.5140 eligibility criteria or that is unsuitable are as follows:

1. The institution must notify FCA promptly in writing upon determining that the investment no longer satisfies the § 615.5140 eligibility criteria or is unsuitable;

2. The investment must not be used to fund the liquidity reserve requirement in § 615.5134;

3. The institution must include the investment in the § 615.5132 investment portfolio limit;

4. The institution must include the investment as collateral under § 615.5050 and net collateral under § 615.5301(c) at the lower of cost or market value; and

5. The institution must develop a plan to reduce risk arising from the investment.

The first requirement, regarding FCA notification, is necessary so that we can evaluate whether the institution is responding appropriately to the situation. The second and fourth requirements, regarding exclusion from the liquidity reserve and inclusion in collateral and net collateral, are warranted by safety and soundness concerns. The third condition, regarding inclusion in the investment portfolio limit under § 615.5132, is simply an express statement that we find no basis to exclude these investments from that limit. And the final requirement, regarding the development of a risk reduction plan, is necessary for safety and soundness purposes.

Proposed § 615.5143(a) provides that an investment that does not satisfy the § 615.5140 eligibility criteria at the time of purchase is ineligible. Institutions must not purchase ineligible investments. An institution that purchases an ineligible investment must notify us promptly, in writing, and must divest of the investment no later than 60 calendar days after determining that the investment is ineligible unless we approve, in writing, a plan that authorizes divestiture over a longer period of time.[30]

Although it is not stated in the regulation, we clarify here that an acceptable divestiture plan must require an institution to dispose of the investment as quickly as possible without substantial financial loss. The plan must also contain sufficient analysis to support continued retention of the investment, including its impact on the institution's capital, earnings, liquidity, and collateral position. Our decision will not be based solely on financial loss.

Until the institution divests of the investment:

1. It must not be used to fund the liquidity reserve requirement in § 615.5134;

2. It must be included in the § 615.5132 investment portfolio limit; and

3. It must not be included as collateral under § 615.5050 or net collateral under § 615.5301(c).

We believe each institution should exercise sufficient due diligence to ensure it does not purchase ineligible investments. Such a purchase would indicate weaknesses in an institution's internal controls and due diligence, and the institution should expect greater examination scrutiny if this occurs. We expect such a purchase to be extremely rare.

Proposed § 615.5143(c) would require each institution to report to its board at least quarterly on the following:

1. The status and performance of each investment that is ineligible; was eligible when purchased but now does not meet the eligibility criteria; or is unsuitable because it does not fit the institution's risk tolerance;

2. The impact that the investments described above may have on the institution's capital, earnings, liquidity, and collateral position; and

3. The terms and status of any required divestiture plan or risk reduction plan.

This reporting allows the institution's board to exercise appropriate oversight over investments that are ineligible, unsuitable, or otherwise problematic.

Finally, proposed § 615.5143(d) would reserve FCA's authority to require an institution to divest of any investment at any time for safety and soundness purposes. In using this authority, the FCA would consider the expected loss on the transaction (or transactions) and the impact on the institution's financial condition and performance. Because the proposed rule would not require divestiture of any investment that was eligible when purchased, FCA must reserve the authority to require divestiture of investments when necessary.

[29] As discussed elsewhere in this preamble, section 939A of the Dodd-Frank Act requires us to remove credit ratings from our eligibility criteria and to substitute other appropriate standards of creditworthiness. We are currently asking questions about how best to develop appropriate creditworthiness standards to include in our eligibility criteria in § 615.5140. Once we have revised our eligibility criteria, a credit-rating downgrade would no longer cause an investment to fail to satisfy the criteria, but an inability to meet the new creditworthiness standards would cause an investment to fail to satisfy the criteria.

[30] In this context, ''purchase'' would include an acquisition such as a swap of one ineligible security for another. It would not include an acquisition through a merger or consolidation of institutions. Investments that do not meet our eligibility criteria that are acquired through a merger or consolidation would be subject to the requirements of § 615.5143(b).

J. Section 615.5174—Farmer Mac Securities

We propose changes to § 615.5174(d), which governs stress testing of Farmer Mac securities, which Farm Credit banks, associations, and service corporations are permitted to purchase and hold for the purposes of managing credit and interest rate risk and furthering their mission to finance agriculture. Existing § 615.5174(d) requires institutions to perform stress tests on Farmer Mac securities in accordance with the requirements of § 615.5141. It also requires institutions to divest Farmer Mac securities that fail a stress test, as required by § 615.5143.

Institutions often participate existing mortgage loans to Farmer Mac in exchange for mortgage-backed securities guaranteed by Farmer Mac. These securities are, in essence, loans that have had the credit risk transferred to Farmer Mac. The loans were not subject to the stress-testing requirements applicable to investments, and it does not seem reasonable to impose those stress-testing requirements on the securities with which the loans were exchanged. Accordingly, we propose to remove the requirement that a System institution must subject Farmer Mac securities backed by loans that the institution originated to the stress testing applicable to investments.[31] If a System institution purchases a Farmer Mac security from another System institution or from outside the System, however, the security would remain subject to the stress testing applicable to investments.[32]

In addition, because other investments would no longer have to be divested if they fail a stress test, we propose to remove this requirement for Farmer Mac securities as well.

We also propose to add a definition of the term ''you'' in a new § 615.5174(e), to clarify that the regulation applies to Farm Credit banks, associations, and service corporations.

Finally, throughout § 615.5174 we propose conforming changes to references to regulations we are proposing to revise, to ensure the references continue to refer to the appropriate regulatory provisions.

[31] Institutions remain subject to the stress-testing expectations we set forth in our Informational Memorandum dated March 4, 2010. These expectations apply to all sources of risk to an institution's balance sheet, including but not limited to loans and investments.

[32] As discussed above, we propose to move the investment stress-testing requirements from § 615.5141 to § 615.5133(f).

IV. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the FCA hereby certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Each of the banks in the System, considered together with its affiliated associations, has assets and annual income in excess of the amounts that would qualify them as small entities. Therefore, System institutions are not ''small entities'' as defined in the Regulatory Flexibility Act.

List of Subjects in 12 CFR Part 615

Accounting, Agriculture, Banks, banking, Government securities, Investments, Rural areas.

For the reasons stated in the preamble, part 615 of chapter VI, title 12 of the Code of Federal Regulations is proposed to be amended as follows:

PART 615—FUNDING AND FISCAL AFFAIRS, LOAN POLICIES AND OPERATIONS, AND FUNDING OPERATIONS

1. The authority citation for part 615 is revised to read as follows:

Authority: Secs. 1.5, 1.7, 1.10, 1.11, 1.12, 2.2, 2.3, 2.4, 2.5, 2.12, 3.1, 3.7, 3.11, 3.25, 4.3, 4.3A, 4.9, 4.14B, 4.25, 5.9, 5.17, 6.20, 6.26, 8.0, 8.3, 8.4, 8.6, 8.7, 8.8, 8.10, 8.12 of the Farm Credit Act (12 U.S.C. 2013, 2015, 2018, 2019, 2020, 2073, 2074, 2075, 2076, 2093, 2122, 2128, 2132, 2146, 2154, 2154a, 2160, 2202b, 2211, 2243, 2252, 2278b, 2278b–6, 2279aa, 2279aa–3, 2279aa–4, 2279aa–6, 2279aa–7, 2279aa–8, 2279aa–10, 2279aa–12); sec. 301(a) of Pub. L. 100–233, 101 Stat. 1568, 1608; sec. 939A of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat 1326, 1887 (15 U.S.C. 78o–7 note) (July 21, 2010).

Subpart E—Investment Management

2. Section 615.5131 is amended by:

a. Removing designations for paragraphs (a) through (l); and

b. Adding alphabetically two new definitions to read as follows:

§ 615.5131 Definitions.

* * * * *

Government agency means the United States Government or an agency, instrumentality, or corporation of the United States Government whose obligations *are* fully and explicitly insured or guaranteed as to the timely repayment of principal and interest by the full faith and credit of the United States Government.

Government-sponsored agency means an agency, instrumentality, or corporation chartered or established to serve public purposes specified by the United States Congress but whose obligations *are not* explicitly insured or guaranteed by the full faith and credit of the United States Government, including but not limited to any Government-sponsored enterprise.

* * * * *

3. Section 615.5132 is amended by adding a new sentence at the end to read as follows:

§ 615.5132 Investment purposes.

* * * Eligible investments listed under § 615.5140 that are pledged by a Farm Credit bank to meet margin requirements for derivative transactions may be excluded when calculating the amount of eligible investments held by the Farm Credit bank pursuant to this section.

4. Revise §§ 615.5133 to read as follows:

§ 615.5133 Investment management.

(a) *Responsibilities of board of directors.* Your board of directors must adopt written policies for managing your investment activities. Your board must also ensure that management complies with these policies and that appropriate internal controls are in place to prevent loss. At least annually, the board, or a designated committee of the board, must review and affirmatively validate the sufficiency of these investment policies. Any changes to the policies must be adopted by the board.

(b) *Investment policies—general requirements.* Your board's written investment policies must address the purposes and objectives of investments; risk tolerance; delegations of authority; internal controls; due diligence to determine eligibility, suitability, and the value of investments; and reporting requirements. Furthermore, your investment policies must address the means for reporting, and approvals needed for, exceptions to established policies. Investment policies must be sufficiently detailed, consistent with, and appropriate for the amounts, types, and risk characteristics of your investments. You must document in your records or board minutes any analyses used in formulating your policies or amendments to the policies.

(c) *Investment policies—risk tolerance.* Your investment policies must establish risk and concentration limits for the various types, classes, and sectors of eligible investments and for the entire investment portfolio. These policies must ensure that you maintain appropriate and prudent diversification of your investment portfolio. Risk limits must be based on your institutional

objectives, capital position, and risk tolerance. Your policies must identify the types and quantity of investments that you will hold to achieve your objectives and control credit, market, liquidity, and operational risks. Each association or service corporation that holds significant investments and each bank must establish risk limits in its investment policies for the following four types of risk.

(1) *Credit risk.* Investment policies must establish:

(i) *Credit quality standards, limits on counterparty risk, and risk diversification standards that limit concentrations as follows.* Concentration limits must be based on a single or related counterparty(ies). Concentration limits must also be based on a geographical area, industries or sectors, asset classes, or obligations with similar characteristics.

(ii) *Criteria for selecting brokers, dealers, and investment bankers (collectively, securities firms).* You must buy and sell eligible investments with more than one securities firm. As part of your review of your investment policies required under paragraph (a) of this section, your board of directors, or a designated committee of the board, must review the criteria for selecting securities firms. Any changes to the criteria must be approved by the board. Also, as part of your review required under paragraph (a) of this section, the board, or a designated committee of the board, must review your existing relationships with securities firms and determine whether to continue your relationships with them. Any changes to the existing relationships with securities firms must be approved by the board.

(iii) *Collateral margin requirements on repurchase agreements.* You must regularly mark the collateral to market and ensure appropriate controls are maintained over collateral held.

(2) *Market risk.* Investment policies must set market risk limits for specific types of investments and for the investment portfolio. Your board of directors must establish market risk limits in accordance with these regulations (including, but not limited to, § 615.5135 and paragraph (f)(2) of this section) and our other policies and guidance.

(3) *Liquidity risk.* Investment policies must describe the liquidity characteristics of eligible investments that you will hold to meet your liquidity needs and institutional objectives.

(4) *Operational risk.* Investment policies must address operational risks, including delegations of authority and internal controls in accordance with paragraphs (d) and (e) of this section.

(d) *Delegation of authority.* All delegations of authority to specified personnel or committees must state the extent of management's authority and responsibilities for investments.

(e) *Internal controls.* You must:

(1) Establish appropriate internal controls to detect and prevent loss, fraud, embezzlement, conflicts of interest, and unauthorized investments.

(2) Establish and maintain a separation of duties and supervision between personnel who execute investment transactions and personnel who post accounting entries, reconcile trade confirmations, report compliance with investment policy, and approve, revalue, and oversee investments.

(3) Maintain management information systems that are appropriate for the level and complexity of your investment activities.

(4) Implement an effective internal audit program to review, at least annually, your investment controls, processes, and compliance with FCA regulations and other regulatory guidance. Your internal audit program must specifically include a review of your process for ensuring all investments, at the time of purchase, are eligible and suitable for purchase under your board's investment policies.

(f) *Due diligence to determine eligibility, suitability, and value of investments.*

(1) *Eligibility and suitability for purchase.* Before you purchase an investment, you must conduct sufficient due diligence to determine whether it is eligible under § 615.5140 and suitable for purchase under your board's investment policies. You must verify the value of the investment (unless it is a new issue) with a source that is independent of the broker, dealer, counterparty or other intermediary to the transaction. Your investment policies must fully address the extent of pre-purchase analysis that management must perform for various classes of investments. You must document your assessment of eligibility and suitability, including the information used in your assessment. You may use all sources available to you, including third party sources, to assess the investment. Your assessment of each investment at the time of purchase must at a minimum include an evaluation of credit risk, liquidity risk, market risk, and interest rate risk, and an assessment of the cash flows and the underlying collateral of the investment.

(2) *Pre-purchase and quarterly stress testing.*

(i) Prior to purchasing an investment, you must stress test it, in accordance with paragraph (f)(2)(iii) of this section, as defined in your board policy. Your board must approve the purchase of any investment that exceeds the stress-test parameters defined in your board policy.

(ii) On a quarter-end basis, you must stress test your entire investment portfolio, including a stress test of each individual investment, in accordance with paragraph (f)(2)(iii) of this section, as defined in your board policy. The policy defining the stress tests must specify what actions you will take if your portfolio exceeds the quarter-end, stress-test parameters defined in the board policy, and, at a minimum must include the development of a plan to bring your portfolio back into compliance with those parameters.

(iii) Your pre-purchase and quarter-end stress tests must be defined in a board approved policy and must include defined parameters for the types of securities you purchase. The stress tests must be comprehensive and appropriate for the risk profile of your institution. At a minimum, the stress tests must be able to measure the price sensitivity of investments over different interest rate/yield curve scenarios. The methodology that you use to analyze investment securities must be appropriate for the complexity, structure, and cash flows of the investments in your portfolio. The stress tests must enable you to determine at the time of purchase and each subsequent quarter that your investment securities, either individually or on a portfolio-wide basis, do not expose your capital, earnings, or liquidity to excessive risks. Your stress tests must enable you to evaluate the overall risk in the investment portfolio compared to your defined board policy limits. You must rely to the maximum extent practicable on verifiable information to support all your assumptions, including prepayment and interest rate volatility assumptions, when you apply your stress tests. You must document the basis for all assumptions that you use to evaluate the security and its underlying collateral. You must also document all subsequent changes in your assumptions.

(3) *Ongoing value determination.* At least monthly, you must determine the fair market value of each investment in your portfolio and the fair market value of your whole investment portfolio. In doing so you must also evaluate the credit quality and price sensitivity to the change in market interest rates of each investment in your portfolio and your whole investment portfolio.

(4) *Presale value verification.* Before you sell an investment, you must verify its value with a source that is

independent of the broker, dealer, counterparty, or other intermediary to the transaction.

(g) *Reports to the board of directors.*

(1) *Quarterly.* At least quarterly, your management must report on the following to your board of directors or a designated board committee:

(i) Plans and strategies for achieving the board's objectives for the investment portfolio;

(ii) Whether the investment portfolio effectively achieves the board's objectives;

(iii) The current composition, quality, and liquidity profile of the investment portfolio;

(iv) The performance of each class of investments and the entire investment portfolio, including all gains and losses that you incurred during the quarter on individual investments that you sold before maturity and why they were liquidated;

(v) Potential risk exposure to changes in market interest rates as identified through quarterly stress testing and any other factors that may affect the value of your investment holdings;

(vi) How investments affect your capital, earnings, and overall financial condition;

(vii) Any deviations from the board's policies (must be specifically identified); and

(viii) The results of your quarterly stress test.

(2) *Special.* You must provide immediate notification to your board of directors or to a designated board committee if your portfolio exceeds the quarterly stress test parameters defined in the board policy required by paragraph (f)(2)(ii) of this section.

5. Revise §§ 615.5135, 615.5136 and 615.5140 to read as follows:

§ 615.5135 Management of interest rate risk.

(a) The board of directors of each Farm Credit Bank, bank for cooperatives, and agricultural credit bank must develop and implement an interest rate risk management program as set forth in subpart G of this part.

(b) The board of directors of each Farm Credit Bank, bank for cooperatives, and agricultural credit bank must adopt an interest rate risk management section of an asset/liability management policy that establishes interest rate risk exposure limits as well as the criteria to determine compliance with these limits. At a minimum, the interest rate risk management section must establish policies and procedures for the bank to:

(1) Address the purpose and objectives of interest rate risk management;

(2) Identify and analyze the causes of risks within its existing balance sheet structure;

(3) Measure the potential impact of these risks on projected earnings and market values by conducting interest rate shock tests and simulations of multiple economic scenarios at least on a quarterly basis and by considering the impact of investments on interest rate risk based on the results of the stress testing required under § 615.5133(f)(2);

(4) Describe, explore, and implement actions needed to obtain its desired risk management objectives;

(5) Document the objectives that the bank is attempting to achieve by purchasing eligible investments that are authorized by § 615.5140 of this subpart;

(6) Evaluate and document, at least quarterly, whether these investments have actually met the objectives stated under paragraph (b)(5) of this section;

(7) Identify exception parameters and approvals needed for any exceptions to the requirements of the board's policies;

(8) Describe delegations of authority;

(9) Describe reporting requirements, including exceptions to limits contained in the board's policies;

(10) Consider the nature and purpose of derivative contracts and establish counterparty risk thresholds and limits for derivatives used to manage interest rate risk.

(c) At least quarterly, management of each Farm Credit Bank, bank for cooperatives, or agricultural credit bank must report to its board of directors, or a designated committee of the board, describing the nature and level of interest rate risk exposure. Any deviations from the board's policy on interest rate risk must be specifically identified in the report and approved by the board.

§ 615.5136 Emergencies impeding normal access of Farm Credit banks to capital markets.

An emergency shall be deemed to exist whenever a financial, economic, agricultural or national defense crisis could impede the normal access of Farm Credit banks to the capital markets. Whenever the Farm Credit Administration determines, after consultation with the Federal Farm Credit Banks Funding Corporation to the extent practicable, that such an emergency exists, the Farm Credit Administration Board may, in its sole discretion, adopt a resolution that:

(a) Modifies the amount, qualities, and types of eligible investments that Farm Credit Banks, banks for cooperatives and agricultural credit banks are authorized to hold pursuant to § 615.5132 of this subpart;

(b) Modifies or waives the liquidity reserve requirement in § 615.5134 of this subpart; and/or

(c) Authorizes other actions as deemed appropriate.

§ 615.5140 Eligible investments.

(a) You may purchase only the investments that satisfy the eligibility criteria in this section. An investment that does not satisfy the eligibility criteria at the time of purchase is not eligible for purchase and is subject to the requirements of § 615.5143(a) if purchased. An investment that satisfies the eligibility criteria at the time of purchase but subsequently fails to satisfy the eligibility criteria is subject to the requirements of § 615.5143(b).

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Investment Eligibility Criteria Table

Asset Class	Final Maturity Limit	NRSRO Credit Rating	Other Requirements	Investment Portfolio Limit
(1) Obligations of the United States Obligations (except mortgage securities) fully insured or guaranteed by a Government agency	None	NA	None	None
(2) Obligations of Government-sponsored agencies Government-sponsored agency securities (except mortgage securities) Other obligations (except mortgage securities) fully insured or fully guaranteed by Government-sponsored agencies	None	NA	Senior debt securities only	None
(3) Municipal Securities				
• General obligations	10 years	One of the highest two	None	15 percent
• Revenue bonds	5 years	Highest	At the time of purchase, you must document that the issue is actively traded in an established secondary market	15 percent
(4) International and Multilateral Development Bank Obligations	10 years	None	The United States must be a voting shareholder	15 percent
(5) Money Market Instruments				
• Federal funds	1 day or continuously callable up to 100 days	One of the two highest short-term	None	None
• Negotiable certificates of deposit	1 year		None	None
• Bankers acceptances	None		Issued by a depository institution	None
• Commercial paper	270 days	Highest short-term		None

• Non-callable Term Federal funds and Eurodollar time deposits	100 days		None	20 percent
• Master notes	270 days			20 percent
• Repurchase agreements collateralized by eligible investments or marketable securities rated in the highest credit rating category by an NRSRO	100 days	NA		None
(6) Mortgage Securities				
• Fully insured or guaranteed by a Government agency	None	NA		None
• Fannie Mae or Freddie Mac mortgage securities	None	NA		50 percent
• Securities that are not fully insured or fully guaranteed by a Government agency, Fannie Mae, or Freddie Mac and that comply with 15 U.S.C. 77d(5) or 15 U.S.C. 78c(a)(41)	None	Highest	Senior-most position only	10 percent
(7) Asset-Backed Securities secured by: Credit card receivables Automobile loans Home equity loans Wholesale automobile dealer loans Student loans Equipment loans Manufactured housing loans	None	Highest	5-year WAL for fixed rate or floating rate ABS at their contractual interest rate caps 7-year WAL for floating rate ABS that remain below their contractual interest rate cap	15 percent in total and no more than 5 percent of any single collateral type

(8) Corporate Debt Securities	5 years	One of the two highest	Senior debt securities only Cannot be convertible to equity securities	20 percent in total, and no more than 10 percent in any one of the 10 industry sectors as defined by the Global Industry Classification Standard (GICS)
(9) Diversified Investment Funds Shares of an investment company registered under section 8 of the Investment Company Act of 1940	NA	NA	Open-end funds only The portfolio of the investment company must consist solely of eligible investments authorized by §§ 615.5140 and 615.5174. The investment company's risk and return objectives and use of derivatives must be consistent with FCA guidance and your investment policies.	50 percent in total. No more than 10 percent in any single fund; otherwise counts towards limit for each type of investment.

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(b) *Denomination.* All investments must be denominated in United States dollars.

(c) *Rating of foreign countries.* Whenever the obligor or issuer of an eligible investment is located outside the United States, the host country must maintain the highest sovereign rating for political and economic stability by an NRSRO.

(d) *Obligor limits.*

(1) *General.* You may not invest more than 15 percent of your total capital in eligible investments issued by any single institution, issuer, or obligor. This obligor limit does not apply to obligations, including mortgage securities, that are issued or guaranteed as to interest and principal by Government agencies or Government-sponsored agencies.

(2) *Obligor limits for your holdings in an investment company.* You must count securities that you hold through an investment company towards the obligor limit of this section unless the investment company's holdings of the security of any one issuer do not exceed five (5) percent of the investment company's total portfolio.

(e) *Other investments approved by the FCA.* You may purchase and hold other investments that we approve. Your request for our approval must explain the risk characteristics of the investment and your purpose and objectives for making the investment.

§ 615.5141 [Removed]

6. Section 615.5141 is removed.

7. Section 615.5142 is amended by:

a. Adding the designation (a) to the existing paragraph; and

b. Adding a new paragraph (b) to read as follows:

§ 615.5142 Association investments.

(a) * * *

(b) Before an association purchases an eligible investment for the purpose of managing surplus short-term funds, it must ensure that the investment's repricing and maturity characteristics match the characteristics of the surplus short-term funds to be invested.

8. Section 615.5143 is revised to read as follows:

§ 615.5143 Management of ineligible and unsuitable investments.

(a) *Investments ineligible when purchased.* Investments that do not satisfy the eligibility criteria set forth in § 615.5140 at the time of purchase are ineligible. You may not purchase ineligible investments. If you determine that you have purchased an ineligible investment, you must notify us promptly in writing after such determination. You must divest of the investment no later than 60 calendar days after you determine that the investment is ineligible unless we approve, in writing, a plan that authorizes you to divest the investment over a longer period of time. Until you divest of the investment:

(1) It must not be used to fund the liquidity reserve necessary to meet the liquidity reserve requirement in § 615.5134;

(2) It must be included in the § 615.5132 investment portfolio limit; and

(3) It must not be included as collateral under § 615.5050 or net collateral under § 615.5301(c).

(b) *Investments that no longer satisfy eligibility criteria or are unsuitable.* If an investment (that satisfied the eligibility criteria set forth in § 615.5140 when purchased) no longer satisfies the eligibility criteria, or if an investment is not suitable because it does not fit the risk tolerance established in your board policy pursuant to § 615.5133(c), you may continue to hold it, subject to the following requirements:

(1) You must notify FCA promptly in writing upon your determination that the investment no longer satisfies the eligibility criteria contained in § 615.5140 or is not suitable;

(2) You must not use the investment to fund the liquidity reserve necessary to meet the liquidity reserve requirement in § 615.5134;

(3) You must include the investment in the § 615.5132 investment portfolio limit;

(4) You must include the investment as collateral under § 615.5050 and net collateral under § 615.5301(c) at the lower of cost or market value; and

(5) You must develop a plan to reduce the investment's risk to you.

(c) *Board reporting requirements.* You must report to your board at least quarterly on the following:

(1) The status and performance of each investment described in paragraphs (a) and (b) of this section.

(2) The impact that any investments described in paragraphs (a) and (b) of this section may have on your capital, earnings, liquidity, and collateral position; and

(3) The terms and status of any required divestiture plan or risk reduction plan.

(d) *Reservation of authority.* FCA retains the authority to require you to divest of any investment at any time for safety and soundness reasons. The timeframe set by FCA will consider the expected loss on the transaction (or transactions) and the impact on your financial condition and performance.

Subpart F—Property, Transfers of Capital, and Other Investments

9. Section 615.5174 is amended by:

a. Removing the reference ''§ 615.5131(f)'' and adding in its place, the reference ''§ 615.5131'' in paragraph (a); and

b. Revising paragraph (d); and

c. Adding a new paragraph (e) to read as follows:

§ 615.5174 Farmer Mac securities.

* * * * *

(d) *Stress Test.* You must perform stress tests, in accordance with § 615.5133(f)(2), on mortgage securities, issued or guaranteed by Farmer Mac, that are backed by loans that you did not originate.

(e) *You.* Means a Farm Credit bank, association, or service corporation.

Dated: August 12, 2011.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2011–20965 Filed 8–17–11; 8:45 am]

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FEDERAL TRADE COMMISSION

16 CFR Part 424

Retail Food Store Advertising and Marketing Practices Rule

AGENCY: Federal Trade Commission (''FTC'' or ''Commission'').

ACTION: Advance notice of proposed rulemaking; request for public comment.

SUMMARY: As part of the Commission's systematic review of all current FTC rules and guides, the Commission requests public comment on the overall costs, benefits, necessity, and regulatory and economic impact of the FTC's rule for ''Retail Food Store Advertising and Marketing Practices'' (''Unavailability Rule'' or ''Rule'').

DATES: Comments must be received on or before October 19, 2011.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''16 CFR Part 424—Retail Food Store Advertising Rule, Project No. P104203'' on your comment, and file your comment online at *https://ftcpublic.commentworks.com/ftc/unavailabilityruleanpr,* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex N), 600 Pennsylvania Avenue, NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Jock Chung, (202) 326–2984, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Background

The Unavailability Rule states that it is an unfair or deceptive act or practice for ''retail food stores'' to advertise ''food, grocery products or other merchandise'' at a stated price if those stores do not have the advertised products in stock and readily available to consumers during the effective period of the advertisement. The original Rule, promulgated in 1971,[1] permitted food retailers to defend against a charge of failure to have items available by maintaining records showing that the advertised items were timely ordered and delivered in quantities sufficient to meet reasonably anticipated demand.[2]

In 1989, after a comment period and public hearings, the Commission concluded that the costs of complying with the original Rule exceeded the benefits to consumers and amended the Rule.[3] The Rule now provides that even if stores do not have the advertised products in stock and readily available during the effective period of their advertisement, they comply with the Rule if ''the advertisement clearly and adequately discloses that supplies of the advertised products are limited or the advertised products are available only at some outlets.''[4] In addition, the amendment provides that it would not be a rule violation if: (1) The store ordered the advertised products in adequate time for delivery in quantities

[1] *Federal Trade Commission: Retail Food Store Advertising and Marketing Practices: Statement of Basis and Purpose: The Rule,* 36 FR 8777 (May 13, 1971). The Rule became effective on July 12, 1971.

[2] *Id.* at 8781.

[3] *Federal Trade Commission: Amendment to Trade Regulation Rule Concerning Retail Food Store Advertising and Marketing Practices,* 54 FR 35456 (Aug. 28, 1989).

[4] *Id.* at 35467.

sufficient to meet reasonably anticipated demand; (2) the store offers a ''raincheck'' for the advertised products; (3) the store offers a comparable product at the advertised price or at a comparable price reduction; or (4) the store offers other compensation at least equal to the advertised value.[5] The Commission stated that the amended Rule ''will not significantly reduce consumer protection because injury caused by such instances of unexpected unavailability * * * will be substantially mitigated by the amended Rule's requirement that consumers be offered rainchecks or comparable substitute items.''[6]

II. Regulatory Review Program

The Commission reviews its rules and guides periodically. These reviews seek information about the costs and benefits of the rules and guides as well as their regulatory and economic impact. These reviews assist the Commission in identifying rules and guides that warrant modification or rescission. Therefore, the Commission now solicits comments on, among other things, the economic impact of, and the continuing need for, the Unavailability Rule; the benefits of the Rule to consumers purchasing products at retail food stores; and the burdens the Rule places on firms subject to its requirements.

III. Request for Comments

The Commission solicits comments on the following specific questions related to the Unavailability Rule:

(1) Is there a continuing need for the Rule? Why or why not?

(2) What benefits has the Rule provided to consumers, or what significant costs has the Rule imposed on consumers? Provide any evidence that supports your position.

(3) What modifications, if any, should the Commission make to the Rule to increase its benefits or reduce its costs to consumers?

(a) Provide any evidence that supports your proposed modifications.

(b) How would these modifications affect the costs and benefits of the Rule for consumers?

(c) How would these modifications affect the costs and benefits of the Rule for businesses, particularly small businesses?

(4) What impact has the Rule had on the flow of truthful information to consumers and on the flow of deceptive information to consumers? Provide any evidence that supports your position.

(5) What benefits, if any, has the Rule provided to businesses, or what significant costs, including costs of compliance, has the Rule imposed on businesses, particularly small businesses? Provide any evidence that supports your position.

(6) What modifications, if any, should be made to the Rule to increase its benefits or reduce its costs to businesses, particularly small businesses?

(a) Provide any evidence that supports your proposed modifications.

(b) How would these modifications affect the costs and benefits of the Rule for consumers?

(c) How would these modifications affect the costs and benefits of the Rule for businesses, particularly small businesses?

(7) Provide any evidence concerning the degree of industry compliance with the Rule. Does this evidence indicate that the Rule should be modified? If so, why, and how? If not, why not?

(8) Provide any evidence concerning whether any of the Rule's provisions are no longer necessary. Explain why these provisions are unnecessary.

(9) What potentially unfair or deceptive practices, not covered by the Rule, concerning price advertising of products by retail food stores are occurring in the marketplace?

(a) Provide any evidence, such as empirical data, consumer perception studies, or consumer complaints, that demonstrates the extent of such practices.

(b) Provide any evidence that demonstrates whether such practices cause consumer injury.

(c) With reference to such practices, should the Rule be modified? If so, why, and how? If not, why not?

(10) Should the Commission broaden the Rule to include stores not currently covered, such as drugstores, department stores, electronics retailers, etc.? Provide any evidence that supports your position.

(11) What modifications, if any, should be made to the Rule to account for current or impending changes in technology or economic conditions?

(a) Provide any evidence that supports your position.

(b) How would these modifications affect the costs and benefits of the Rule for consumers and businesses, particularly small businesses?

(12) Does the Rule overlap or conflict with other federal, state, or local laws or regulations? If so, how?

(a) Provide any evidence that supports your position.

(b) With reference to the asserted conflicts, should the Rule be modified? If so, why, and how? If not, why not?

(c) Provide any evidence concerning whether the Rule has assisted in promoting national consistency with respect to the advertising by retail food stores of products for sale at a stated price.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 19, 2011. Write ''16 CFR Part 424—Retail Food Store Advertising Rule, Project No. P104203'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment doesn't include any sensitive personal information, such as anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment doesn't include any sensitive health information, like medical records or other individually identifiable health information. In addition, don't include any ''[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential,'' as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, don't include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR

[5] *Id.* at 35467–35468.

[6] *Id.* at 35457. Although the majority of the Commission voted to amend the Rule, Commissioner Calvani dissented, stating that ''existing market forces adequately police unavailability, and * * * therefore, no Federal Trade Commission rule is necessary, amended or otherwise.'' *Id.* at 35468. Conversely, Commissioner Strenio dissented, stating that there was ''insufficient evidence * * * to conclude that these changes will result in net consumer benefits;'' thus, he could not support these amendments. *Id.*

4.9(c).[7] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/unavailabilityruleanpr,* by following the instructions on the Web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''16 CFR Part 424—Retail Food Store Advertising Rule, Project No. P104203'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex N), 600 Pennsylvania Avenue, NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 19, 2011. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

List of Subjects in 16 CFR Part 424

Advertising, Foods, Trade practices.

Authority: 15 U.S.C. 41–58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2011–21020 Filed 8–17–11; 8:45 am]

BILLING CODE 6750–01–P

[7] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 51

[REG–112805–10]

RIN 1545–BJ39

Branded Prescription Drug Fee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to the branded prescription drug fee imposed by the Affordable Care Act (ACA). The regulations affect persons engaged in the business of manufacturing or importing certain branded prescription drugs. The text of the temporary regulations also serves as the text of the proposed regulations.

DATES: Written and electronic comments and requests for a public hearing must be received by November 16, 2011.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–112805–10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–112805–10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–112805–10).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Celia Gabrysh at (202) 622–3130; concerning submissions of comments and requests for a hearing *Richard.A.Hurst@irscounsel.treas.gov*, (202) 622–7180 (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) and assigned control number 1545–2209.

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, *Attn:* IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by October 17, 2011. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs of operation, maintenance, and purchase of service to provide information.

The collection of information in this proposed regulation is in § 51.7. This information is necessary to evaluate whether an error report regarding a preliminary fee calculation is valid and justifies an adjustment to the preliminary fee calculation. The likely respondents are manufacturers and importers of branded prescription drugs.

Estimated total annual reporting and/or recordkeeping burden: 1800 hours.

Estimated annual burden per respondent/recordkeeper: 40 hours.

Estimated number of respondents and/or recordkeepers: 45.

Estimated frequency of responses: Annually.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** add a new part, part 51, to subchapter D, Miscellaneous

Excise Taxes. Part 51 provides guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs by section 9008 of the ACA. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the new part.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory flexibility assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that these regulations primarily affect large corporations. Thus, Treasury Department and the IRS do not expect a substantial number of small entities to be effected. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. Comments are requested on all aspects of the proposed regulations. In addition, the IRS and the Treasury Department specifically request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register.**

Drafting Information

The principal author of these regulations is Celia Gabrysh, Office of Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 51

Drugs, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, and under the authority of 26 U.S.C. 7805 (sec. 9008, Pub. L. 111–347 (124 Stat. 119)), 26 CFR part 51 is proposed to be added to read as follows:

PART 51—BRANDED PRESCRIPTION DRUGS

[The text of proposed §§ 51.1 through 51.11 is the same as the text of §§ 51.1T through 51.11T published elsewhere in this issue of the **Federal Register**.]

[The text of proposed § 51.6302–1 is the same as the text of paragraphs (a) and (b) of § 51.6302–1T published elsewhere in this issue of the **Federal Register**.]

Sarah Hall Ingram,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2011–21012 Filed 8–15–11; 11:15 am]

BILLING CODE 4830–01–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3020

[Docket No. RM2011–8; Order No. 666]

Administrative Practice and Procedure, Postal Service

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: A Federal statute directs the Commission to implement a modern classification system. This proposal responds to that directive by presenting a comprehensive Mail Classification Schedule. Issuance of this document will allow the Commission to consider comments and, if appropriate, to make revisions prior to adoption of a final schedule.

DATES: *Comments are due:* September 6, 2011.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx*. Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY HISTORY: *Regulatory History:*

72 FR 29284, May 25, 2007;
72 FR 33261, June 15, 2007;
72 FR 50744, September 4, 2007.

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I. Introduction

The Postal Regulatory Commission (Commission) establishes a rulemaking docket pursuant to its responsibilities under the Postal Accountability and Enhancement Act (PAEA), Public Law 109–435, 120 Stat. 3198, December 20, 2006, to consider modifications to the Commission's rules governing the Mail Classification Schedule (MCS). Modifications are proposed to add material describing some Postal Service products and make conforming changes. The Commission provides this notice and opportunity for comment on whether the Commission should incorporate the proposed modifications by final rule into the Commission's rules at 39 CFR 3020, Subpart A—Mail Classification Schedule.

For products currently being offered by the Postal Service, this rulemaking does not add products to, remove products from, or transfer products between the existing market dominant or competitive product lists. However, this rulemaking does reorganize how products appear within each individual list. This reorganization is most apparent within the competitive product list where, at the suggestion of the Postal Service, the vestiges of ''class'' groupings have been replaced with functional product groupings.

Additionally, the currently published product lists require updating to remove

products no longer offered (certain negotiated service agreements) and otherwise to correct for inaccuracies as a better understanding of how the Postal Service's product structure has developed under the PAEA. This task is incorporated into the rulemaking.

The Commission has consulted with the Postal Service as the proposed MCS was developed and has found the Postal Service's input invaluable in concisely and accurately describing all product offerings.

II. Background

On August 15, 2007, the Commission initiated the process of developing an MCS with a request to the Postal Service to develop language describing individual products.[1] The Postal Service was requested to draw from existing material provided in the Domestic Mail Classification Schedule (DMCS) and the International Mail Manual to develop a model MCS at a comparable level of detail as provided in the DMCS. The Postal Service complied with this request and provided a MCS proposal on September 24, 2007.[2]

An initial MCS was published on October 29, 2007.[3] This publication met the requirements of publishing market dominant and competitive product lists necessary for operation of the regulatory system. However, the initial MCS did not include descriptions of individual products.

The publication of the initial product lists, which for the first time included international products and a division of products into market dominant and competitive categories, generated a need for additional descriptive material to more accurately describe the then-current state of the product lists. The Commission again asked the Postal Service to provide additional proposals for MCS language. Order No. 26 at 4002–4. The additional material focused on treatment of negotiated service agreements, certain international products, and the final categorization of products as either market dominant or competitive. The Postal Service complied with this request and provided additional proposals on November 20, 2007.[4]

In the interim, the Commission developed a ''draft'' MCS which included material describing each product. As various market dominant product price adjustments, competitive product price adjustments, and classification changes have been reviewed and approved by the Commission, the Commission has kept this draft version of the MCS up to date. Price and classification changes have been incorporated into the proposed MCS as of December 31, 2010. The Commission intends to incorporate any subsequently approved rate or classification changes that occur prior to issuing the final rule in this docket into the final rule in this docket. This proceeding shall consider formal incorporation of all draft material describing each market dominant and competitive product into the official MCS, and conforming language to the Commission's rules governing the MCS.

III. Accessibility of the Mail Classification Schedule

The Commission intends to make two versions of the MCS available. The first version will be posted to the Commission's Web site in a format that will allow interested persons the ability to search and copy sections of the MCS for use in Commission proceedings. The Postal Service, and others, may find this version most convenient for communicating proposals to the Commission. The second version will appear in the Code of Federal Regulations (CFR). The organization and appearance of the MCS in the CFR will be different to meet CFR publication requirements. However, there should be no difference in substantive material between the Web site and the CFR versions.[5]

The electronic documentation appearing on the Commission's Web site with this order will contain both versions of the MCS. The Commission would find it helpful if comments addressing the contents of the MCS refer to the version of the MCS that will appear on the Commission's Web site.

IV. Mail Classification Schedule Structure

The revised MCS, as proposed, consists of preface material followed by four substantive sections. The preface material includes a Revision History, which is intended to comply with the 39 U.S.C. 3642(d)(2) requirement to ''indicate how and when'' product lists are modified, Trademark Notices, and a Table of Contents. The four substantive sections that follow are titled Part A—Market Dominant Products, Part B—Competitive Products, Part C—Glossary of Terms and Conditions, and Part D—Country Price Lists for International Mail.

Part A—Market Dominant Products, is divided into two major sections: the Market Dominant Product List, and the Market Dominant Product Descriptions. Both sections retain the ''class'' structure for categorizing products developed under the Postal Reorganization Act with the classes including: First-Class Mail, Standard Mail (Commercial and Nonprofit), Periodicals, Package Services, and Special Services.[6] Three new separate categories are added to this part to contain market dominant Negotiated Service Agreements, market dominant Nonpostal Services, and market dominant Market Tests. International products, which did not appear in the former DMCS, now are included within the appropriate associated class.

Each class subsection in Part A follows a similar structure. The individual class subsections first provide a description of class-wide characteristics and a list of all products in the class. This is followed by information about each product in the class. The individual product descriptions generally include the following topics in the following order: (1) Product description (where necessary); (2) size and weight limitations; (3) minimum volume requirements; (4) price categories; (5) optional features; and (6) prices. The Special Services subsection requires less detail and generally includes the following topics in the following order: (1) Product description; and (2) prices.

Part B—Competitive Products also is divided into two major sections: the Competitive Product List, and the Competitive Product Descriptions. As originally published in Order No. 43, the competitive product list retained a class-like structure for organizing competitive products. In informal discussions, the Postal Service appropriately pointed out that a class-like structure has lost much of its meaning for competitive products under the PAEA. The Postal Service proposed that the products in the competitive product list be reorganized into three subsections: Domestic Products, International Products, and Negotiated Service Agreements. The proposed organization better aligns competitive

[1] Docket No. RM2007–1. Order Proposing Regulations to Establish a System of Ratemaking, August 15, 2007, at paras. 4008–9 (Order No. 26).

[2] Docket No. RM2007–1. United States Postal Service Submission of Initial Mail Classification Schedule in response to Order No. 26, September 24, 2007.

[3] Docket No. RM2007–1. Order Establishing Ratemaking Regulations for Market Dominant and Competitive Products, October 29, 2007 (Order No. 45); *see also* 72 FR 63662 (November 9, 2007).

[4] Docket No. RM2007–1. United States Postal Service Submission of Additional Mail Classification Schedule Information in Response to Order No. 43, November 20, 2007.

[5] If any substantive discrepancies inadvertently appear, the CFR version will govern, until such time as both versions again can be made consistent.

[6] Special Services is treated as a class for MCS purposes.

products with the separate domestic and international business functions of the Postal Service. It also allows all products that are not of general applicability to be grouped within a Negotiated Service Agreement section. This concept is reflected in the proposed MCS. Note that the Negotiated Service Agreement subsection is further subdivided into Domestic, Outbound International, and Inbound International. Two additional separate subsections are added to this part, one for competitive Special Services, and one for competitive Nonpostal Services.

Part B has a similar structure to Part A, except that class separations are not made in competitive products. Thus, there is no need for class descriptions. Each subsection contains a list of all products appearing within that heading. Descriptions applicable to several related products are provided where appropriate. This is followed by information about each product in the subsection. The product descriptions generally include the following topics in the following order: (1) Product description (where necessary); (2) size and weight limitations; (3) minimum volume requirements; (4) price categories; (5) optional features; and (6) prices. The competitive Special Services subsection requires less detail and generally includes the following topics in the following order: (1) Product description; and (2) prices. Note that many of the Negotiated Service Agreement products merely reference the product name, associated dockets, PRC order numbers, and termination dates due to the confidential nature of these agreements.

Part C—Glossary of Terms and Conditions is self explanatory. Part D—Country Price Lists for International Mail contains the country codes used to identify individual countries in the various international product price lists appearing in Parts A and B.

V. Rule Modifications

The Commission's rules concerning the MCS currently are codified at 39 CFR 3020, Subpart A—Mail Classification Schedule. The existing MCS itself is codified at Appendix A to Subpart A—Mail Classification Schedule of 39 CFR 3020.

This rulemaking proposes changes to the rules governing the MCS and replaces the existing Appendix A with four more administratively manageable appendices. The intent of the rule changes are to incorporate the market dominant product list and the competitive product list into the Commission's rules so that the lists are prominently available for examination, and to incorporate the majority of the material describing individual products into four appendices.

Rule 3020.2 General (old rule 3020.10) is revised to describe the proposed new format of the MCS.

Rule 3020.11 Initial Mail Classification Schedule is being deleted. It only was applicable to the initial MCS that is now being replaced.

Rule 3020.3 Publication of the Mail Classification Schedule (old rule 3020.12), paragraph (a), is revised to indicate that the MCS is being incorporated into the rules themselves, *i.e.,* the MCS no longer will be contained solely in Appendix A. Paragraph (b) is modified to indicate that the Commission only will be making the most recent version of the MCS available to the public. With almost weekly revisions to the MCS, it would be administratively burdensome, and confusing to the public, to make multiple, mainly outdated, versions readily available. In any event, all changes will be published in the **Federal Register** for interested persons to reference if the need arises to reconstruct earlier versions.

Rule 3020.4 Notice of change (old rule 3020.14) is revised to indicate that any changes to the material describing products will cause notice to be published in the **Federal Register.**

Rule 3020.5 Contents of the Mail Classification Schedule (old rule 3020.13) will contain the MCS. The same information contained within the MCS version proposed to appear on the Commission's Web site will be divided among paragraphs (b) through (h) of this rule.

Paragraph (b) will provide a revision history as required by 39 U.S.C. 3642(d)(2).

Paragraph (c) will provide trademark notices.

Paragraph (d) will provide a table of contents by section numbers. The section numbers will correspond to the section numbers appearing in the Appendices.

Paragraph (e) will provide information concerning market dominant products. This paragraph is divided into (e)(1), which contains the list of market dominant products, and (e)(2), which specifies the market dominant product descriptive information that is to be provided and references Appendix A where that information is provided.

Paragraph (f) will provide information concerning competitive products. This paragraph is divided into (f)(1), which contains the list of competitive products, and (f)(2), which specifies the competitive product descriptive information that is to be provided and references Appendix B where that information is provided.

Paragraph (g) references Appendix C, which provides a glossary of terms of conditions.

Paragraph (h) references Appendix D, which provides the country price lists for international mail.

The four appendices will contain the majority of the descriptive material. Appendix A will contain the description of market dominant products. This corresponds to Part A, Section 1001, Market Dominant Product Descriptions provided in the proposed Web version of the MCS. Appendix B will contain the description of competitive products. This corresponds to Part B, Section 2001, Competitive Product Descriptions provided in the proposed Web version of the MCS. Appendix C will contain a glossary of terms and conditions. This corresponds to Part C, Section 3000, Glossary of Terms and Conditions provided in the proposed Web version of the MCS. Appendix D, Section 4000, will contain the country price lists for international mail. This corresponds to Part D, Country Price Lists for International Mail provided in the proposed Web version of the MCS.

VI. Public Representative

Pursuant to 39 U.S.C. 505, Kenneth E. Richardson is appointed to serve as officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

VII. Public Comments

Comments concerning the proposed modifications to the MCS by interested persons are due September 6, 2011.[7] Interested persons previously filing comments in response to this Notice appearing on the Commission's Web site with an earlier due date may file supplemental comments, if necessary. All comments previously filed in this docket shall be considered and need not be re-filed.

VIII. Directions for Federal Register Publication and Access to Unpublished Material

An abbreviated version of this notice shall be published in the **Federal Register**. This version shall include the material appearing up to the signature of this notice. This material includes among other items ''a description of the subjects and issues involved'' with the

[7] All references to August 5, 2011 in Order No. 666 issued February 7, 2011 will be replaced with September 6, 2011.

proposed rule as required by 5 U.S.C. 553(b)(3).

The abbreviated version shall also include pages 1 through 13 of the material titled ''Mail Classification Schedule'' appearing after the signature in Order No. 666 issued on February 7, 2011. This material describes the textual changes proposed to existing 39 CFR part 3020, subpart A.

As previously stated in paragraph III of this notice, all material, including the proposed four new appendices, appears on the Commission's Web site. For interested persons without access to the Internet, a copy of all material is available for inspection at the Postal Regulatory Commission, 901 New York Avenue, NW., Suite 200, Washington, DC 20268–0001. Reasonable alternative access also may be arranged by contacting the Commission's docket section at 202–789–6846.

It is ordered:

1. Docket No. RM2011–8 is established for the purpose of receiving comments on the Commission's proposal.

2. The Commission proposes to amend its rules of practice and procedure. The proposed amendments involve amending 39 CFR part 3020 Subpart A—Mail Classification Schedule.

3. Kenneth E. Richardson is designated as an officer of the Commission representing the interests of the general public in this docket.

4. Interested persons may submit comments by September 6, 2011.

5. The Secretary shall arrange for publication of this notice in the **Federal Register** as directed in the body of this notice.

List of Subjects in 39 CFR Part 3020

Administrative practice and procedure, Postal Service.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2011–21015 Filed 8–17–11; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2011–0610; FRL–9452–9]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Adoption of Drum and Pail Coating Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Maryland (Maryland). This SIP revision includes amendments to the Code of Maryland (COMAR) 26.11.19.13, Volatile Organic Compounds from Specific Processes, Drum and Pail Coating. Maryland's SIP revision meets the requirement to adopt Reasonably Available Control Technology (RACT) for sources covered by EPA's Control Techniques Guidelines (CTG) for Miscellaneous Metal and Plastic Parts Coatings and will help Maryland attain and maintain the National Ambient Air Quality Standard (NAAQS) for ozone. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 19, 2011.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2011–0610 by one of the following methods:

A. *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *E-mail: fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2011–0610, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2011–0610. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://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 e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail 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.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Irene Shandruk, (215) 814–2166, or by e-mail at *shandruk.irene@epa.gov.*

SUPPLEMENTARY INFORMATION: On June 22, 2011, the Maryland Department of the Environment (MDE) submitted to EPA a SIP revision concerning the adoption of the drum and pail coating standards found in the Miscellaneous Metal and Plastic Parts Coatings CTG.

I. Background

Section 172(c)(1) of the CAA provides that SIPs for nonattainment areas must include reasonably available control measures (RACM), including RACT for sources of emissions. Section 182(b)(2)(A) provides that for certain nonattainment areas, states must revise their SIPs to include RACT for sources of VOC emissions covered by a CTG document issued after November 15, 1990 and prior to the area's date of attainment.

CTGs are intended to provide state and local air pollution control

authorities information that should assist them in determining RACT for VOCs from various sources, including drum and pail coatings. In developing these CTGs, EPA, among other things, evaluated the sources of VOC emissions from this industry and the available control approaches for addressing these emissions, including the costs of such approaches. Based on available information and data, EPA provided recommendations for RACT for VOCs from drum and pail coatings.

In June 1978, EPA published a CTG for controlling VOC emissions from surface coating of miscellaneous metal and plastic products (EPA–450/2–78–015), which includes drum and pail coatings. This CTG discusses the nature of VOC emissions from this industry, available control technologies for addressing such emissions, the costs of available control options, and other items. EPA promulgated national standards of performance for new stationary sources New Source Performance Standards for miscellaneous metal and plastic products industry and EPA also published a national emission standard for hazardous air pollutants (NESHAP) for this industry.

In 2008, after conducting a review of currently existing state and local VOC emission reduction approaches for this industry, reviewing the 1978 CTG and the NESHAP for this industry, and taking into account the information that has become available since then, EPA developed a new CTG for miscellaneous metal and plastic parts, entitled *Control Techniques Guidelines for Miscellaneous Metal and Plastic Parts Coatings* (Publication No. EPA 453/R–08–003).

The miscellaneous metal product and plastic parts surface coatings categories under section 183(e) of the CAA includes the coatings that are applied to the surfaces of a varied range of metal and plastic parts and products. Such parts or products are constructed either entirely or partially from metal or plastic. The VOC emissions from miscellaneous metal product and plastic parts surface coating processes result from the evaporation of the volatile components of the coatings and cleaning materials used in these operations.

II. Summary of SIP Revision

On June 22, 2011, MDE submitted to EPA a SIP revision (#11–04) concerning the adoption of the emission limits for drum and pail coatings, part of the EPA miscellaneous metal and plastic parts coatings CTG. EPA develops CTGs as guidance on control requirements for source categories. States can follow the CTGs or adopt more restrictive standards. Maryland has adopted EPA's CTG standards for drum and pail coating processes. These regulations are in COMAR 26.11.19, Volatile Organic Compounds from Specific Processes. Specifically, this revision amends the existing regulation in Section 26.11.19.13 to include emission limits for drum and pail coatings (Table 1). A detailed summary of EPA's review of and rationale for proposing to approve this SIP revision may be found in the Technical Support Document (TSD) for this action which is available on line at *http://www.regulations.gov,* Docket number EPA–R03–OAR–2011–0610.

TABLE 1—DRUM AND PAIL COATING STANDARDS

Coating types	Pounds VOC/ gallon coating (minus water)	Kilogram VOC/ liter coating (minus water)
New, Exterior	2.8	0.34
New, Interior	3.5	0.42
Reconditioned, Exterior	3.5	0.42
Reconditioned, Interior	4.2	0.50

III. Proposed Action

EPA is proposing to approve Maryland's SIP revision for adoption of the CTG standards for drum and pail coatings. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

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

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

In addition, this proposed rule concerning Maryland's adoption of CTG standards for drum and pail coatings does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: August 1, 2011.

W.C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2011–21098 Filed 8–17–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1983–0002; FRL–9452–2]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Barceloneta Landfill Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule; notice of intent.

SUMMARY: The Environmental Protection Agency (EPA) Region II is issuing a Notice of Intent to Delete the Barceloneta Landfill Superfund Site (Site) located in Florida Afuera, Puerto Rico from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the Commonwealth of Puerto Rico, through the Puerto Rico Environmental Quality Board, have determined that all appropriate response actions under CERCLA, other than operation, maintenance, and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments must be received by September 19, 2011.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–1983–0002, by one of the following methods:

- *http://www.regulations.gov*. Follow on-line instructions for submitting comments.
- *E-mail:* Luis E. Santos, Remedial Project Manager, *santos.luis@epa.gov.*
- *Fax:* 787–289–7104.
- *Mail:* Luis E. Santos, Remedial Project Manager, U.S. Environmental Protection Agency, Region II, Caribbean Protection Division, Centro Europa Building, Suite 417, Ponce de León Ave., Stop 22, San Juan, Puerto Rico 00907–4127.
- *Hand delivery:* U.S. Environmental Protection Agency, Region II, Caribbean Protection Division, Centro Europa Building, Suite 417, Ponce de León Ave., Stop 22, San Juan, Puerto Rico 00907–4127. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID no. EPA–HQ–SFUND–1983–0002. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://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 e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail 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.

Docket: All documents in the docket are listed in the *http://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 statue. Certain other material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at:

U.S. Environmental Protection Agency, Region II, Superfund Records Center, 290 Broadway, 18th Floor, New York, NY 10007–1866, *Phone:* 212–637–4308, *Hours:* Monday to Friday from 9 a.m. to 5 p.m.

Or

U.S. Environmental Protection Agency, Region II, Caribbean Environmental Protection Division Centro Europa Building, Suite 417, 1492 Ponce de León Ave., Stop 22, San Juan, Puerto Rico 00907–4127, *Phone:* (787) 977–5802, Hours: 8:30 a.m. to 4:30 p.m.—Monday through Friday (excluding holidays) Contact: Luis E. Santos

FOR FURTHER INFORMATION CONTACT: Luis E. Santos, Remedial Project Manager, U.S. Environmental Protection Agency, Region II, telephone at (787) 977–5824; fax at 787–289–7104; or e-mail at *santos.luis@epa.gov.*

SUPPLEMENTARY INFORMATION:

In the ''Rules and Regulations'' Section of today's **Federal Register**, we are publishing a direct final Notice of Deletion of Barceloneta Landfill Superfund Site without prior Notice of Intent to Delete because we view this as a noncontroversial revision and anticipate no adverse comment. We have explained our reasons for this deletion in the preamble to the direct final Notice of Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this deletion action, we will not take further action on this Notice of Intent to Delete. If we receive adverse comment(s), we will withdraw the direct final Notice of Deletion, and it will not take effect. We will, as appropriate, address all public comments in a subsequent final Notice of Deletion based on this Notice of Intent to Delete. We will not institute a second comment period on this Notice of Intent to Delete. Any parties interested in commenting must do so at this time.

For additional information, see the direct final Notice of Deletion which is located in the Rules section of this **Federal Register**.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

Dated: August 8, 2011.

Judith Enck,

Regional Administrator, Region 2.

[FR Doc. 2011–21122 Filed 8–17–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 28

[Docket No. USCG–2010–0625]

RIN 1625–AB50

Waiver of Citizenship Requirements for Crewmembers on Commercial Fishing Vessels

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to add to its regulations a description of the procedures for requesting and processing waivers of citizenship requirements on commercial fishing vessels. The Coast Guard aims to improve its efforts to inform the commercial fishing industry of this opportunity by publishing the application procedure policy into the Code of Federal Regulations (CFR).

DATES: Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before November 16, 2011 or reach the Docket Management Facility by that date. Comments sent to the Office of Management and Budget (OMB) on the collection of information must reach OMB on or before November 16, 2011.

ADDRESSES: You may submit comments identified by docket number USCG–2010–0625 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.

Collection of Information Comments: If you have comments on the collection of information discussed in section V.D of this NPRM, you must also send comments to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget. To ensure that your comments to OIRA are received on time, the preferred methods are by e-mail to *oira_submission@omb.eop.gov* (include the docket number and ''Attention: Desk Officer for Coast Guard, DHS'' in the subject line of the e-mail) or fax at 202–395–6566. An alternate, though slower, method is by U.S. mail to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, ATTN: Desk Officer, U.S. Coast Guard.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Mr. David Belliveau, Office of Vessel Activities (CG–5433), Coast Guard; telephone 202–372–1247, e-mail *David.J.Belliveau@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Ms. Renee V. Wright, 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–2010–0625), 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 e-mail 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* and type ''USCG–2010–0625'' in the ''Enter Keyword or ID'' box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments.

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,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Enter Keyword or ID'' box, insert ''USCG–2010–0625'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. 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., 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 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 a public meeting 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.
COMDTINST Commandant Instruction.
DHS Department of Homeland Security.
DOL Department of Labor.
FR **Federal Register.**
INA Immigration and Nationality Act, as amended (8 U.S.C. 1101 *et seq.*).
§ Section symbol.
U.S.C. United States Code.

III. Background

Under title 46 United States Code (U.S.C.) 8103(i)(1), each unlicensed seaman on a fishing, fish processing, or fish tender vessel that is engaged in the fisheries in the navigable waters of the United States or the exclusive economic zone must be—

1. A citizen of the United States;
2. An alien lawfully admitted to the United States for permanent residence; or
3. Any other alien allowed to be employed under the Immigration and Nationality Act (8 U.S.C. 1101 *et seq.*) (INA).

Furthermore, 46 U.S.C. 8103(i)(2) states that no more than 25 percent of the unlicensed seamen on these vessels may be non-permanent resident aliens authorized for employment in the United States under the Immigration and Nationality Act (INA), category 3 above.

Relief from these citizenship and permanent resident status requirements is provided in 46 U.S.C. 8103(b)(3)(C). If the Secretary of Homeland Security determines, after an investigation, that qualified seamen who are citizens of the United States are not available, the Secretary may waive these citizenship requirements.

Congress did not specify a procedure for requesting the waiver allowed under section 8103(b)(3). To fill the need for a procedure, the Coast Guard published a policy letter in June 2001 titled ''Procedures for Waiver of Requirements for Citizenship Aboard Commercial Fishing Vessels'' (2001 policy letter). This policy letter is available at *http://homeport.uscg.mil/mycg/portal/ep/programView.do?channelId=-17679&programId=12861.* This policy letter explains the steps involved in the request for a waiver process. The Coast Guard intended the letter to be the means of informing the fishing industry of the waiver opportunity and the application procedure.

In past years, the Coast Guard received between 125 and 200 waiver requests annually. In 2008, that volume slowed appreciably.[1] Through experience gained during the ten years since the publication of the policy letter and feedback received from the Commercial Fishing Industry Vessel Safety Advisory Committee, the Coast Guard believes that not all fishing vessel owners, operators, and employers are aware they can request a waiver from citizenship requirements. As a result, these vessels often either sail short-handed, creating potential safety issues, or choose to exceed the 25 percent limit for non-permanent resident aliens authorized for employment in the United States under the INA without an approved waiver. This proposed rule mirrors the requirements that exist in the 2001 policy letter with the exception of the mandatory dockside examination.

Despite the benefits of the waiver option for owners, operators, and employers, the Coast Guard is concerned that the continued practice of granting requests for waivers under this program gives rise to potential safety and emergency preparedness problems on fishing vessels for U.S. citizen and alien crewmembers. It is incumbent on owners, operators, and employers to ensure the vessel is in full compliance with all safety, survival equipment, and systems requirements.

Therefore, in this proposed rule, the Coast Guard proposes to make satisfactory completion of a dockside safety examination under the Coast Guard's Commercial Fishing Industry Vessel Safety program a condition for receiving a waiver from the citizenship requirements. (For more information on this program, see *http://www.fishsafe.info.*) Section 604 of the Coast Guard Authorization Act of 2010 (Pub. L. 111–281) mandates dockside examinations for commercial fishing vessels operating beyond 3 nautical miles from shore. For vessels operating inside of 3 nautical miles from shore, examinations would remain voluntary. Under these proposed rules, any commercial fishing vessel requesting a waiver would be required to show satisfactory completion of a dockside safety examination, regardless of its area of operation.

IV. Discussion of Proposed Rule

Through this rulemaking, the Coast Guard would amend 46 CFR part 28, Requirements for Commercial Fishing Industry Vessels, by adding a new subpart to specifically address the citizenship waiver program. This subpart would formally incorporate the 2001 policy letter into the CFR and would also require that any vessel citizenship waiver request and approval be conditioned on the successful completion of a required dockside exam.

In the proposed new subpart, the Coast Guard would explain that owners, operators, and employers must send to the Coast Guard a written citizenship waiver request, which would include the number of alien seamen to be employed who are not lawfully admitted for permanent residence but are otherwise authorized for employment in the United States under the INA, along with certification that the vessel(s) would comply with all other applicable citizenship requirements regarding the Master or other officers in charge of deck or engineering watches on a documented vessel. The owner, operator, or employer would also be required to provide a U.S. Citizenship and Immigration Services (USCIS) or other DHS-issued authorization for employment in the U.S. under the INA for each alien seaman it intends to employ who is not lawfully admitted for permanent residence, as well as information, as discussed below, demonstrating that there are no qualified U.S. seamen available for the position.

If, within 30 days of receipt of a request for a waiver, the Coast Guard does not make a determination, or informs the employer that the Coast Guard needs more time for review, the waiver request would be provisionally approved for 90 days from the end of the original 30 days. If the Coast Guard grants a waiver, the term of the approval would be for the same period as specified by the USCIS or other DHS-issued authorization for employment in the U.S. under the INA.

Additionally, to help ensure the safe condition of the vessel, the Coast Guard would require the employer to submit documentation of a satisfactory dockside safety examination conducted by the Coast Guard.

The written request for a waiver must contain the following:

1. *Vessel owner, operator, or employer's contact information.* This information is required to cross-

[1] In 2008, the Coast Guard received a total of six waiver requests.

reference with the Marine Information for Safety and Law Enforcement database to verify vessel ownership; to facilitate contact with the owner, operator, or employer if any questions arise after reviewing the request for a waiver package; and to mail a waiver letter back to the owner, operator, or employer in an expeditious manner.

2. *List of fishing vessels and information on those vessels that the owner, operator, or employer wishes to exempt.* The owner, operator, or employer would be asked to provide, for each vessel that he/she wants a waiver, the following: the fishing vessel's name, official number, length (in feet), gross tonnage, and the types of fisheries the vessel will fish. This information would be used to verify the documentation of the vessel, to check the vessel's safety history, and to ensure that the vessel belongs to the person who is making the request for citizenship waiver.

3. *A list of persons working on the vessel(s).* The list would include: The total number of crewmembers; the number of seamen who are neither U.S. citizens nor lawful permanent residents; the name, nationality, birth place, position to be held, and basis for employment authorization in the U.S. under the INA of each seaman who is neither a U.S. citizen nor a lawful permanent resident; and the number of alien seamen who are neither U.S. citizens nor lawful permanent residents for whom the waiver is being requested. This requested information would allow the Coast Guard to ascertain what percentage of a vessel's crew would be non-permanent resident aliens to ensure that non-U.S. citizens would only be used as seamen and not Watch Officers or Masters, and to ensure that the persons named on a waiver request would be non-permanent resident aliens who are authorized for employment in the United States under the INA.

4. *Identification of the time period over which the 25 percent limit would be exceeded:* This information would include the start date (MM/DD/YYYY) and expiration date (MM/DD/YYYY) of the requested waiver. This information would be required to ensure the owner, operator, or employer is asking for an exemption that falls within the period of the named individuals' authorization for employment in the U.S. under the INA.

5. *Demonstration that the vessel(s) is/are in full compliance with all applicable safety and other regulatory requirements set forth in 46 CFR part 28.* In order to document compliance, the owner, operator, or employer would be required to submit documentation that shows that: a dockside safety examination was conducted; the examination was successfully passed; the vessel(s) received a safety examination decal (and include the serial number of the decal; the decal is displayed on the vessel; and that the decal will not expire during the entire time period of the requested waiver. Since commercial fishing vessels operating within 3 nautical miles from shore are generally not required to be examined, compliance with 46 CFR part 28 requirements would usually be determined by a random boarding or by the vessel owner, operator, or employer requesting a dockside safety examination. Thus absent these rules, it is conceivable that a vessel could go to sea and fish for months, or even years, without being checked for its compliance with regulations. Through these examinations, we intend to identify and correct safety issues, eliminate preventable hazards, and minimize any problems that might exist prior to the Coast Guard approving a request for a waiver. Satisfactory completion of a dockside safety examination for all commercial fishing vessels requesting a waiver under this proposed rule would ensure all applicable vessels provide all emergency equipment and instruction for all crewmembers and otherwise comply with applicable laws and regulations.

6. *Owner, operator, or employer's statement certifying that the vessel(s) would operate in compliance with all other applicable citizenship requirements regarding the Master or other Officers in Charge of deck or engineering watches on U.S. documented vessels.*

7. *Documentation demonstrating satisfactory evidence of authorization for employment as a seaman with the owner, operator, or employer under the INA for aliens who are not lawful permanent residents but are otherwise authorized for employment in the United States under the INA; and that qualified seamen who are United States citizens are not available.*

The H–2B visa has proven to be the primary avenue for demonstrating compliance with these statutory requirements. The 2001 policy letter thus required a temporary labor certification from the Department of Labor (DOL) for the position in question in addition to DHS authorization for the alien's employment with the owner, operator, or employer as an H–2B nonimmigrant. Together, the documents from DHS and DOL demonstrate that these prerequisites are met. In this proposed rulemaking, we plan on removing the requirement in the 2001 policy letter that an alien authorized for employment with the owner, operator, or employer as a seaman pursuant to admission as H–2B nonimmigrant provide evidence of a DOL temporary labor certification; the owner, operator, or employer need only provide evidence of the alien's authorization from DHS to work with the employer as a crewman in H–2B nonimmigrant status. The requirement to provide evidence of the DOL temporary labor certification is being removed because USCIS approval of an H–2B nonimmigrant visa petition is premised on DOL certification that there are no qualified and available U.S. workers (a term which includes U.S. citizens) to perform the respective temporary services or labor as a seaman. See 8 CFR 214.2(h)(6)(iii)(A); 20 CFR 655.4 (defining ''United States Worker'' for H–2B purposes).

Additionally, we seek comment on alternative documentation that may be submitted for our review and evaluation if an alien is not authorized for employment with the owner, operator, or employer as an H–2B nonimmigrant. H–2B nonimmigrant status is but one means by which a non-permanent resident alien might be authorized for employment in the U.S. under the INA. If an alien who is neither a lawful permanent resident nor an H–2B nonimmigrant is authorized for employment, the owner, operator, or employer must nevertheless establish that qualified seamen who are citizens of the United States are not available in order to qualify for a waiver. In this instance, the burden is upon the requestor of the waiver to provide satisfactory evidence (1) Of authorization for employment with the owner, operator, or employer as a seaman under the INA, as required by 46 U.S.C. 8103(i)(1)(C), and (2) that qualified U.S. citizen seamen are not available as required by 46 U.S.C. 8103(b)(3)(C). We seek comments on the type of documents that could possibly be submitted to establish compliance with the statutory requirements when an alien's authorization for employment in the U.S. with the owner, operator, or employer is not derived from his or her classification as an H–2B nonimmigrant.

VI. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below, we summarize our analyses based on 13 of these statutes or executive orders.

A. Executive Order 12866 and Executive Order 13563

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, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

The following table summarizes the costs and benefits of this rule. We estimated annual and 10-year costs of the rule. And, based on data availability, we identified qualitative benefits of the proposed rule.

TABLE 1—SUMMARY OF COSTS AND BENEFITS

Category	Estimate
Costs	
Annual Cost to Apply for Waiver	$42,365.
Cost of Dockside Examination*	$9,160.
Ten Year Monetized Costs ..... (rounded values, 7% discount rate)	$330,812.
Benefits	
Qualitative Benefits	This proposed rule would provide industry with greater visibility to the waiver application procedures. The inclusion of the dockside examination would ensure that all vessels granted waivers are in compliance with existing safety regulations.

* The cost to apply for a waiver is an annual cost. The cost of the dockside exam occurs every two years.

This proposed rule would create a regulatory burden for those owners and operators of commercial fishing vessels electing to request a waiver. From 2005 to 2009, there was an average of 91 requests for waivers sent to the Coast Guard per year. Note that applications for waivers have declined from a high of 203 in 2005 to 20 in 2009. The number of applications for waivers will vary from year to year based on many factors, such as national and regional economic conditions and management programs for specific fisheries. We use a 5-year average to reflect the range of conditions that may occur over the 10-year period of analysis. In addition, during the period of 2005 to 2009, Coast Guard issued an average of 108 violations of 46 U.S.C. 8103, which would include violations related to the citizenship requirements for the crew of fishing vessels and the citizenship requirements for the Master and Officer in charge of deck or engineering watches. During 2009, 75 of these violations were issued. Based on the continuing level of violations of citizenship requirements for fishing vessels, the average over 5 years of requests for waivers, rather than the low number of recent requests, is more indicative of the future use of waivers once their use is established in the regulations.

We estimate that it takes an owner or operator approximately 9.25 hours [2] to compile and submit the appropriate documentation to the Coast Guard per the 2001 policy letter. The Bureau of Labor Statistics provides a wage of $34.01 for captains, mates, and pilots of water vessels.[3] We apply a load factor of 1.48 to this wage to account for benefits, which makes the hourly wage for a captain, mate, or pilot approximately $50.33.[4] At a cost of $50.33 per hour to the civilian sector, the cost is $465.55 per request for a waiver ($50.33 per hour × 9.25 hours). The total annual burden would be approximately 842 labor hours (9.25 hours per request × 91 requests per year) for a cost to industry of $42,377 ($50.33 × 842 hours) to submit the request for a waiver. This cost is only borne if a vessel owner, operator, or employer chooses to seek relief of the citizenship requirement. The proposed rule would require that all vessels requesting a waiver undergo a dockside examination.

As noted, the Coast Guard Authorization Act of 2010 added a requirement for mandatory dockside safety examinations once every 2 years for vessels that operate beyond 3 nautical miles from the shoreline. Some of the vessels requesting citizenship waivers may be required to undergo the dockside examinations due to the Authorization Act. Since this proposal would make the dockside safety examination a requirement for obtaining a waiver, the total cost of these examinations is attributable to this proposed rule.

According to Coast Guard Fishing Vessel Safety Division subject matter experts, the dockside safety examination takes, on average, 2 hours to complete, which would represent an opportunity cost to the vessel owner, operator, or employer equal to the time lost multiplied by the wage for a captain, mate or pilot. This opportunity cost would equal approximately $9,160 (2 hours × $50.33 × 91 examinations).

The dockside examination would serve as a check to ensure that the vessel is in full compliance with all applicable safety and other regulatory requirements set forth in 46 CFR part 28. Vessels may have to take corrective actions as a result of the dockside examinations. As the examinations focus on compliance with existing regulations, the costs of any corrective actions would not be attributable to this rulemaking, but instead is attributable to compliance with existing regulations.

The total annual cost to industry associated with this proposal would be approximately $51,537. This includes the $42,365 cost for applying for a waiver per the 2001 policy letter and the $9,160 opportunity cost associated with the addition of the dockside examination to the current request for a waiver process.

Reviewing a waiver application currently takes a Coast Guard employee approximately 3 hours, on average. We assume a wage rate equal to that of a GS–13 for the reviewer. Based on Commandant Instruction (COMDTINST) 7310.1L, Coast Guard Reimbursable Standard Rates, (available at *http://uscg.mil/directives/ci/7000-7999/CI_7310_1L.PDF*), the hourly wage for the reviewer would be $67 per hour. The total annual projected cost to the Coast Guard to review applications would be $18,291 (3 hours × $67 × 91 requests). The dockside examination portion of this proposal would also create additional government costs to perform the examinations. Civilian

[2] Time estimates provided by Coast Guard Fishing Vessel Safety Division subject matter experts.

[3] *http://www.bls.gov/oes/2009/may/oes535021.htm*. This wage information is from May 2009 and is the most recent figure from BLS.

[4] The load factor is determined by dividing BLS total compensation by BLS wages.

examiners are usually GS–11 or GS–12 positions while Coast Guard uniformed examiners are usually E–5 or E–6 grades, which, according to COMDTINST 7310.1L, would lead to an average wage for examiners of $49.[5] According to Coast Guard subject matter experts, a dockside examination, including travel time and administrative time, would take an examiner 4 hours to complete. The total cost to the government from this requirement would be $17,836 (4 hours per examination × $49 × 91 examinations). As with the costs to industry, government costs would only be incurred if owners or operators opt to apply for a waiver.

By incorporating the current policy into regulation, the Coast Guard would promote greater awareness of the policy, and provide commercial fishermen with one location for all rules governing their operations. Greater visibility of the application procedures may help reduce the number of crew requirement violations. Also, the inclusion of the dockside examination would ensure that all vessels granted waivers are in compliance with existing safety regulations that apply to commercial fishing vessels.

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.

Based on 2007 data, we identified 79,058 entities owning fishing vessels. Of these, a small number (13) were owned by government entities or non-profits, all of which exceed the threshold for being classified as a small entity. The remaining owners are classified as businesses. Based on available revenue data, approximately 99.8 percent (78,901) of the commercial fishing businesses fall below the Small Business Administration threshold for a small business based on their primary North American Industry Classification System designation.

Based on historical data, we expect an average of 91 requests for a waiver per year. If we assume that all of these requests are from small commercial fishing businesses, we can assess the potential impacts of this proposal on the industry. Coast Guard records show that the majority of vessels requesting waivers in the period from 2006–2009 are between 50 and 70 feet in length. By comparing the $566 cost per vessel of the proposal to the revenues for commercial fishing vessels in the 50–70 ft. size range, we estimate that only 3 percent of all commercial fishing vessels would have a revenue impact greater than 3 percent from this proposal. Table 2 shows the percent of vessels by revenue impact.

TABLE 2—REVENUE IMPACTS OF PROPOSED RULE

Revenue impact	Percent of vessels
0% < Impact <= 1%	62
1% < Impact <= 3%	35
3% < Impact <= 5%	1
5% < Impact <= 10%	2
Above 10%	0

The primary purpose of this proposed rule is to codify existing policy into regulation, although, there would be one new cost element introduced. We estimate 91 of approximately 80,000 commercial fishing vessels apply for a waiver annually, which is not a substantial number. Furthermore, because the waiver process is voluntary, in that vessel owners, operators, or employers would only apply for a waiver if the benefits of doing so outweigh the costs, we can assume that if the approximate $566 per vessel cost of this rulemaking is prohibitive, vessel owners would choose to not pursue a waiver. Therefore, 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. 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 it qualifies and how and to what degree this rule would economically affect it.

C. 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 so that they can better evaluate its effects on them and participate in the rulemaking. 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 with the Coast Guard personnel listed under **FOR FURTHER INFORMATION CONTACT** section of this proposed rule. 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.

D. Collection of Information

This proposed rule would call for a revision to an existing collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). This revision is explained below under ESTIMATE OF TOTAL ANNUAL BURDEN. As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other, similar actions. The title and description of the information collections, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

Title: Commercial Fishing Industry Vessel Safety Regulations.

OMB Control Number: 1625–0061.

Summary of the Collection of Information: This information collection is intended to improve safety on board vessels in the commercial fishing industry. The requirements apply to those vessels and to seamen on them.

Need for Information: The Coast Guard needs to collect this information for all vessels requesting a waiver for relief of the citizenship requirements on a commercial fishing vessel.

Proposed Use of Information: The Coast Guard would use this information solely to determine whether or not a vessel should be granted relief of the citizenship requirements on a commercial fishing vessel.

Description of the Respondents: The respondents are vessel owners, operators, and employers of U.S. commercial fishing vessels who opt to seek relief of the citizenship requirements on a commercial fishing vessel.

Number of Respondents: The existing OMB-approved number of respondents, as adjusted in May 2008, is 5,103. The proposed rule would not change that total.

Frequency of Response: 91 respondents, based on a five-year average.

[5] COMDTINST 7310.1L lists reimbursable rates for government workers.

Burden of Response: Those vessels that voluntarily choose to request a waiver bear the burden of this collection. We estimate that a request for a waiver would take about 9.25 hours per response.

Estimate of Total Annual Burden: The existing OMB-approved total annual burden, as adjusted in May 2008, is 5,917 hours. The annual increase from the proposed rule would be approximately 842 hours to the public, assuming 91 waiver requests are submitted per year.

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we will submit a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of the collection of information.

We ask for public comment on the proposed collection of information to help us determine how useful the information is; whether it can help us perform our functions better; whether it is readily available elsewhere; how accurate our estimate of the burden of collection is; how valid our methods for determining the burden are; how we can improve the quality, usefulness, and clarity of the information; and how we can minimize the burden of collection.

If you submit comments on the collection of information, submit them both to OMB and to the Docket Management Facility where indicated under **ADDRESSES**, by the date under **DATES**.

You need not respond to a collection of information unless it displays a currently valid control number from OMB. Before the Coast Guard could enforce the collection of information requirements in this proposed rule, OMB would need to approve the Coast Guard's request to collect this information.

E. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them.

We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism because states may not regulate citizenship requirements onboard fishing, fish processing, or fish tender vessels engaged in the fisheries in the navigable waters of the United States or the exclusive economic zone.

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

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 might 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.

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 that 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 rule involves the qualifying of maritime personnel and the manning of vessels and falls under § 2.B.2, figure 2–1, paragraphs (c) and (d) of the Instruction. 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 46 CFR Part 28

Alaska, Fire prevention, Fishing vessels, Marine safety, Occupational safety and health, Reporting and recordkeeping requirements, Seamen.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 46 CFR Part 28 as follows:

PART 28—REQUIREMENTS FOR COMMERCIAL FISHING INDUSTRY VESSELS

1. The authority citation for part 28 is revised to read as follows:

Authority: 46 U.S.C. 4502, 4505, 4506, 8103; Department of Homeland Security Delegation No. 0170.1.

Subpart H—[Reserved]

2. Amend part 28 by reserving subpart H.

3. Amend part 28 by adding new subpart I to read as follows:

Subpart I—Citizenship Waiver Procedures

Sec.
28.1100 General
28.1105 Request for a waiver
28.1110 Waiver approval
28.1115 Waiver request and approval records

Subpart I—Citizenship Waiver Procedures

§ 28.1100 General.

As set forth in 46 U.S.C. 8103, a citizenship requirement, other than a requirement that applies to the master of a documented vessel, on commercial fishing vessels may be waived for unlicensed seamen when qualified seamen who are citizens of the United States are not available. Under the provisions of this subpart, the Coast Guard approves or denies requests for a waiver of the citizenship requirement from owners, operators, or employers seeking to exceed the 25 percent limit applicable to unlicensed seamen aboard fishing industry vessels who are non-permanent resident aliens authorized for employment in the United States under the Immigration and Nationality Act (INA) (8 U.S.C. 1101 *et. seq.*).

§ 28.1105 Request for a waiver.

(a) Vessel owners, operators, or employers who desire a waiver of citizenship requirements from the Coast Guard must submit a written request to the Commandant (CG–5433), United States Coast Guard, 2100 Second St., SW., Stop 7581, Washington, DC 20593–7581.

(b) The written request required under paragraph (a) of this section must contain—

(1) The vessel owner, operator, or employer's contact information—

(i) The vessel owner, operator, or employer's full name (last, first, middle initial);

(ii) Address;

(iii) Work phone number;

(iv) Fax number (if applicable); and

(v) E-mail address (if applicable);

(2) Information on fishing vessel(s) for which the owner, operator, or employer requests a citizenship waiver. For each listed vessel, the owner, operator, or employer must include—

(i) Fishing vessel name;

(ii) Fishing vessel official number;

(iii) Fishing vessel length (in feet);

(iv) Fishing vessel gross tonnage; and

(v) Type(s) of fishery(ies) in which the vessel is engaged;

(3) Information on persons who will work on the vessel(s). For each listed vessel, the owner, operator, or employer must include—

(i) The total number of unlicensed crew normally employed;

(ii) The name, nationality, birth place, position to be held, and basis for employment authorization in the United States of each alien who is not lawfully admitted for permanent residence but is otherwise authorized for employment in the United States under the INA; and

(iii) The number of alien seamen who are not lawfully admitted for permanent residence but are otherwise authorized for employment in the United States under the INA for which the waiver is requested; and

(4) The time period over which the 25 percent limit will be exceeded—

(i) Start date (MM/DD/YYYY); and

(ii) Expiration date (MM/DD/YYYY).

(c) The vessel owner, operator, or employer submitting a request for a waiver under paragraph (a) of this section is required to demonstrate that the vessel(s) is/are in full compliance with all applicable safety and other regulatory requirements set forth in 46 CFR part 28. To that end, the owner, operator, or employer must submit documentation that shows—

(1) A dockside safety examination was conducted;

(2) The examination was successfully passed and a safety decal was issued and affixed to the vessel;

(3) The serial number of the decal issued; and

(4) The period of validity of the safety decal issued.

(d) The owner, operator, or employer submitting a request for a waiver under paragraph (a) of this section must include a statement certifying that the vessel(s) will operate in compliance with all other applicable citizenship requirements regarding the Master or other Officers in Charge of deck or engineering watches on U.S. documented vessels.

(e) The owner, operator, or employer submitting a request for a waiver under paragraph (a) of this section must provide evidence that aliens who are not lawfully admitted for permanent residence are authorized for employment with the owner, operator, or employer under the INA and evidence that qualified seamen who are U.S. citizens are not available for employment. The following documentation is satisfactory evidence both of authorization for employment with the owner, operator, or employer under the INA and that qualified seamen who are U.S. citizens are not available:

Documentation for H–2B nonimmigrants.

(1) U.S. Citizenship and Immigration Services (USCIS) Form I–797, ''Notice of Action: Approval Notice'' classifying the alien as an H–2B nonimmigrant for purposes of employment with the owner, operator, or employer submitting a request for a waiver under paragraph (a) of this section; and

(2) USCIS Form I–94 indicating that the alien has been lawfully admitted to the United States (or has been lawfully granted a change of nonimmigrant status or extension of nonimmigrant stay in H–2B classification) for the dates covered by the proposed employment.

(f) Upon receipt of a request submitted under paragraph (a) of this section and required information submitted in accordance with paragraphs (b)–(e) of this section, the Coast Guard (CG–5433) will evaluate the information and may investigate further, as necessary, to determine the validity of the information provided.

§ 28.1110 Waiver approval.

(a)(1) If, within 30 days of receipt of a properly submitted request for a waiver, the Coast Guard does not make a determination whether to approve the request or does not advise the owner, operator, or employer that additional time is needed for consideration, the request will be considered provisionally approved for 90 days from the end of that 30-day period.

(2) If the Coast Guard does not make a determination whether to approve a properly submitted request for a waiver in writing within 30 days of receipt, the owner, operator, or employer must have a copy of the request and supporting documentation available onboard the vessel as proof of submission of a request for waiver of the citizenship requirement for unlicensed seamen for that vessel.

(b)(1) If the Coast Guard determines, based on the waiver request, supporting documentation, and any other relevant information, that no qualified U.S. citizen seamen are available, the Coast Guard (CG–5433) will grant the waiver to exceed the 25 percent limit for employment of non-permanent resident alien seaman for the period of employment authorized for each alien under the INA. The Coast Guard will issue a letter of approval to the owner, operator, or employer for the applicable vessel(s).

(2) The owner, operator or employer must have a copy of the waiver approval letter available onboard the vessel as proof of waiver of the citizenship requirement for unlicensed seamen for that vessel.

§ 28.1115 Waiver request and approval records.

The Coast Guard will maintain a record of citizenship waiver requests and approvals. Approvals will be documented for the applicable vessel(s) in the Coast Guard's vessel information database.

Dated: August 9, 2011.

James A. Watson,

Rear Admiral, U.S. Coast Guard, Director of Prevention Policy.

[FR Doc. 2011–21024 Filed 8–17–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 172, 173, 174, 179, and 180

[Docket No. PHMSA–2010–0018 (HM–216B)]

RIN 2137–AE55

Hazardous Materials: Incorporating Rail Special Permits Into the Hazardous Materials Regulations

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Pipeline and Hazardous Materials Safety Administration is proposing to amend the Hazardous Materials Regulations to incorporate provisions contained in certain widely used or longstanding special permits that have general applicability and established safety records. Special permits allow a company or individual to package or ship a hazardous material in a manner that varies from the regulations provided that an equivalent level of safety is maintained. The revisions in this proposed rule are intended to provide wider access to the regulatory flexibility offered in special permits and eliminate the need for numerous renewal requests, thus reducing paperwork burdens and facilitating commerce while maintaining an appropriate level of safety. This rulemaking also proposes to respond to two petitions for rulemaking, P–1497 concerning the use of electronic shipping papers, and P–1567 concerning the removal of the Association of American Railroad's (AAR's) AAR–600 portable tank program for previously adopted standards that meet or exceed the AAR–600 requirements.

DATES: Written comments should be submitted on or before October 17, 2011.

ADDRESSES: You may submit comments identified by the docket number (PHMSA–2010–0018 (HM–216B)) by any of the following methods:

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

Fax: 1–202–493–2251.

Mail: Docket Operations, U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, Routing Symbol M–30, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Hand Delivery: To Docket Operations, Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and docket number for this notice at the beginning of the comment. All comments received will be posted without change to the Federal Docket Management System (FDMS), including any personal information.

Docket: For access to the dockets to read background documents or comments received, go to *http://www.regulations.gov* or DOT's Docket Operations Office (*see* **ADDRESSES**).

Privacy Act: Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, *etc.*). 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).

FOR FURTHER INFORMATION CONTACT: Eileen Edmonson or Steven Andrews, Standards and Rulemaking Division, Office of Hazardous Materials Safety, (202) 366–8553, Pipeline and Hazardous Materials Safety Administration (PHMSA), or Karl Alexy, Office of Safety Assurance and Compliance, (202) 493–6247, Federal Railroad Administration (FRA), 1200 New Jersey Avenue, SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. Background
II. Overview of Proposed Amendments
III. Regulatory Analyses and Notices

I. Background

Special Permits

The Pipeline and Hazardous Materials Safety Administration (PHMSA) is proposing to amend the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) to incorporate certain requirements based on existing special permits for transportation by railroad issued by PHMSA under 49 CFR part 107, subpart B (§§ 107.101 to 107.127). A special permit sets forth alternative requirements (variances) to the requirements in the HMR by means that achieve a safety level that at a minimum corresponds to the safety level required under the regulations and is consistent with the public interest. Congress expressly authorized DOT to issue these variances in the Hazardous Materials Transportation Act of 1975.

The HMR generally are performance-oriented regulations that provide the regulated community a certain amount of flexibility in meeting safety requirements. Even so, not every transportation situation can be anticipated and built into the regulations. Innovation is a strength of our economy, and the hazardous materials community is particularly strong at developing new materials and technologies as well as innovative ways of transporting materials. Special permits enable the hazardous materials industry to quickly, effectively, and safely integrate new products and technologies into the production and transportation streams. Thus, special permits provide a mechanism for testing new technologies, promoting increased transportation efficiency and productivity, and ensuring global competitiveness.

A special permit must achieve at least an equivalent level of safety to that specified in the HMR. Implementation of new technologies and operational techniques can enhance safety because the authorized operations or activities may achieve a greater level of safety than currently required under the regulations. Special permits also reduce the volume and complexity of the HMR by addressing unique or infrequent transportation situations that would be difficult to accommodate in regulations intended for use by a wide range of shippers and carriers.

PHMSA conducts ongoing reviews of special permits to identify widely used and longstanding special permits having general applicability with established safety records for adoption into regulations for broader applicability. To

obtain a special permit, interested parties must prepare and submit a detailed application that PHMSA reviews extensively. If granted and its use is needed after the expiration date assigned, the person authorized to use the special permit must submit an application to continue their use of it and undergo an extensive PHMSA renewal process. Converting these special permits into regulations reduces paperwork burdens and facilitates commerce while maintaining an acceptable level of safety. Additionally, adoption of special permits as rules of general applicability provides wider access to the benefits and regulatory flexibility of the provisions granted in the special permits. Factors that influence whether a specific special permit is a candidate for regulatory action include: the safety record for hazardous materials transported, or the transport operations conducted, under a special permit; the potential for broad application of a special permit; suitability of provisions in the special permit for incorporation into the HMR; rulemaking activity in related areas; and agency priorities. Special permits involving packaging used by a large number of persons—such as those issued to many persons with party status or issued to a manufacturer as a ''manufacture, mark, and sell''—are potentially among the most suitable types of special permits for adoption into the HMR. Such special permits have broad applicability; moreover, many of them have been in effect for a number of years and have demonstrated safety records.

Further, although we make every effort to stay as true as possible to the conditions prescribed in each special permit when converting it to proposed regulatory text, PHMSA recognizes that sometimes, due to existing regulations or historical interpretations, provisions in a special permit may require revision to convert them into regulations of general applicability. In addition, when converting special permits we often have to modify the language to describe documents and procedures that are authorized under the special permit but not specifically described in it or to modify the language to comply with requirements for proposed regulatory text prescribed by this agency, the Department of Transportation, and the **Federal Register**.

This notice of proposed rulemaking (NPRM) proposes to incorporate seven (7) special permits that authorize tank car transportation operations not specifically permitted under the HMR. These special permits were initially issued to members of industry associations or similar organizations. They are DOT–SP:

1. 7616
2. 9388
3. 11184
4. 12095
5. 12905
6. 14333
7. 14622

These special permits have well-established safety records and, thus, are candidates for incorporation into the HMR. A few of the special permits in this NPRM have expired for various reasons, such as from delays that occur during the renewal process, or as a result of modifications to the HMR, packagings, processes, or other technologies that eliminate the need for the special permit. PHMSA has included them in this NPRM because both PHMSA and the Federal Railroad Administration (FRA) have determined these special permits also have well-established safety records and would benefit the regulated industry if incorporated into the HMR. Incorporating these special permits into the HMR would eliminate the need for over 250 current grantees to reapply for the renewal of these special permits every four years and for PHMSA to process the renewal applications.

Incorporation of these special permits into the HMR also eliminates a significant paperwork burden for the recipient. Unless otherwise excepted by this agency, a copy of each special permit must be: maintained at each facility where a packaging is manufactured under a special permit, maintained at each facility where a package is offered or re-offered for transportation under a special permit, carried on board each cargo vessel or aircraft, and, in some cases, carried on board each transport vehicle when used to transport a hazardous material under a special permit.

Petitions for Rulemaking

Two proposals PHMSA is addressing in this proposed rulemaking were also presented to PHMSA in petitions for rulemaking. A more detailed description of each is provided below.

Petition No. P–1497

The petition from the International Vessel Operators Hazardous Materials Association, Inc. (IVOHMA) (P–1497), dated March 15, 2007, is similar to relief authorized under DOT–SP 7616 in that it requests PHMSA allow shipping paper information required under 49 CFR Part 172, Subpart C (shipping papers) to be transmitted electronically by computer through use of electronic data interchange (EDI). The IVOHMA states ''differences in hazard communication or the interpretation of their application are a principle[sic] source of disharmony in intermodal and/or international transportation of [hazardous materials].'' The IVOHMA also states ''electronic data interchange has become a recognized method of efficient and accurate communication currently being used successfully throughout the industrialized world'' that permits ''immediate access to hazard communication by all those involved in the transportation infrastructure as well as by emergency responders equipped'' with this technology. Further, the IVOHMA states in its petition that the proposals it submitted were vetted with its staff and members and determined to be opportunities for regulatory amendment to promote efficiencies in the modal interchange of these containers in both domestic and international transportation.

PHMSA and the FRA met with the IVOHMA, on January 17, 2007, to discuss several issues concerning the HMR and containerized hazardous materials cargo that the association and its members believe may be presenting operational difficulties, impediments, and obstacles to efficient and safe intermodal transportation. These issues included inconsistencies between the shipping paper requirements for each mode for documents that can be construed as meeting the HMR shipping paper requirements, ''such as work orders, dock receipts or train consists,'' and determining which shipping document is considered legally in control of the shipment. The IVOHMA also identified two problems associated with the train consist. The first problem is §§ 174.24 and 174.26 do not require that the agency or person be identified that corresponds to the emergency response information telephone number on the document. The HMR requires this information on a shipping paper document under § 172.604(b). The IVOHMA states ''valuable time is often lost'' while emergency responders using these telephone numbers or inspectors checking their validity track down the correct individual and/or organization associated with a specific telephone number. The IVOHMA also states a similar problem occurs when international telephone numbers are offered as the emergency response telephone number that provides access from the United States to the emergency responder, and includes delays that occur obtaining a telephonic connection while using the international access codes. The second problem is the

emergency response telephone number needs to be accessible by all the persons associated with the transport of the shipment, such as those carriers trying to obtain information to respond to a shipboard emergency.

To address these concerns, the IVOHMA submitted proposed regulatory language that would define the term ''interlining carrier'' in § 171.8, establish requirements for ''interlining carrier documents'' in a new § 172.206, and make several additional related revisions concerning shipping papers and emergency response information in §§ 172.204(d), 172.604(a), and 174.26(b). Although the petition the IVOHMA submitted primarily concerned the transportation of containerized hazardous materials between railcars and vessels, the regulatory language the IVOHMA proposed would apply to interlining carriers in all modes. This rulemaking applies to rail transportation only. Therefore, PHMSA determined proposing regulations that apply to carriers in all modes would exceed the scope of this rulemaking. PHMSA considered revising the IVOHMA's proposals to limit them to rail transport only with the possibility of considering their application to other modes of transport in a future rulemaking. However, FRA determined the IVOHMA's proposals are not needed because the language in existing § 174.24(a) applies to the transfer of all interlining documents. This section requires that each person accept a hazardous material for rail transportation or transport a hazardous material by rail only if that person has received a shipping paper for that material. If the material is excepted from the shipping paper requirements under the HMR, this section does not apply. PHMSA requests public comment not only on the proposals in this rulemaking, but on IVOHMA's suggestions not included in this rulemaking and on the possible effects EDI may have on distributing hazardous materials shipping paper information if its use is permitted in all modes of transport. Based on the comments received, PHMSA may consider the use of EDI in other modes of transport in a future rulemaking.

Petition No. P–1567

PHMSA adopted standards for portable tanks in container-on-flat-car (COFC) or trailer-on-flat-car (TOFC) service under § 174.63 and other sections of the HMR that meet or exceed the AAR–600 requirements. The petition from the Gold Tank Inspection Service, Inc. (P–1567), requests that PHMSA discontinue the AAR–600 program and amend § 174.63(c) to remove the requirement that portable tanks in COFC or TOFC service comply with the standard ''AAR–600'' of the Association of American Railroad's (AAR's) Specification for Tank Cars, entitled ''Specifications for the Acceptability of Tank Containers,'' because: (1) The current HMR regulations exceed the AAR 600 requirements; (2) after January 1, 2003, all the specifications for original portable tank construction listed in the AAR 600 standard are not allowed to be built except DOT Specification 60 and International standard 1496–3 portable tanks, which are already covered under §§ 178.255 and 178.274, respectively, of the HMR; and (3) after January 1, 2010, the AAR 600 standard will no longer be needed since, in accordance with § 171.14, all portable tanks will have to meet or exceed the AAR 600 requirements and AAR 600 does not cover portable tank requirements. In a May 20, 2009 letter of clarification PHMSA issued to Robert E. Fronczak, Assistant Vice President, Environment and Hazardous Materials, Association of American Railroads, under Reference No. 09–0125, PHMSA states ''most of the portable tanks listed in the AAR–600 standard are prohibited from new construction, although they may remain in service provided they continue to meet the applicable standard,'' and that ''we intend to propose a revision to § 174.63(c) as soon as practicable.'' The changes Mr. Fronczak described have effectively made the HMR's reference to the AAR–600 standard outdated. Therefore, PHMSA proposes to revise § 173.63(c) to remove its reference to the AAR 600 standard and to require that portable tanks transported in COFC or TOFC service must conform to all HMR requirements applicable to portable tanks in this type of service.

II. Overview of Proposed Amendments

In this NPRM, PHMSA is proposing to incorporate into the HMR provisions that: (a) Establish an alternative tank car qualification program; (b) permit the electronic transmission of shipping paper information; (c) permit straight threads in the clean out and/or inspection port openings of a DOT Specification 110A500W multi-unit tank car tank; (d) permit alternative start-to-discharge pressure requirements for certain DOT Specification 105J500W tank cars containing chlorine; (e) permit alternative pressure relief requirements for pressure relief devices for DOT Specification 105J300W tank cars containing certain flammable liquids; (f) permit certain DOT and AAR specification tank cars with stainless steel identification plates to have their specification and other required information stamped on the identification plate instead of the tank car head provided certain requirements are met; (g) permit liquefied anhydrous ammonia gas to be measured by a metering device when loaded into a tank car as an alternative to measuring the cars by weight; (h) revise § 179.13(b) to require that rail tank cars with a gross weight that exceeds 263,000 but not 286,000 pounds containing poisonous-by-inhalation (PIH) materials must be approved for use by the Federal Railroad Administration's (FRA's) Associate Administrator for Railroad Safety; and (i) eliminate use of the AAR 600 program concerning the FRA's approval of bulk packagings in COFC and TOFC service that is incorporated into § 174.63(c)(2). PHMSA invites comment on the potential costs and safety benefits associated with the proposals in this NPRM, including any information that may be used in a cost-benefit safety analysis. Each proposal is discussed in greater detail in the following preamble sections.

A. Alternative Tank Car Qualification Program

The FRA established the Alternative Tank Car Qualification Program, also known as TCQ–1, in 1998 in collaboration with the railroad industry and PHMSA under Special Permit DOT–SP 12095. The TCQ–1 program serves as a minimally acceptable framework for owners to qualify their DOT specification and non-specification tank cars and components using requirements in place of those prescribed in 49 CFR Part 180. The TCQ–1 program permits owners to develop tank car inspection requirements specific to their construction and use, provided the FRA has determined the new methods are as safe or safer than those prescribed in the HMR. FRA determined the new program is successful and its use has dramatically increased since its inception. In fact, FRA and PHMSA have determined the industry's use of the TCQ–1 program is so complete that it essentially is the only tank car inspection standard used today. Currently, 559 parties are operating under TCQ–1. PHMSA and FRA are not aware of any incidents that have occurred as a result of the issuance of special permits for the tank car qualification program.

PHMSA and FRA believe incorporating Special Permit DOT–SP 12095 into the HMR will provide an equivalent level of safety for the qualification of both specification and

non-specification rail tank cars, and will reduce the administrative burden of reapplying for this special permit. Therefore, in this NPRM, PHMSA and FRA are proposing to incorporate Special Permit DOT–SP 12095 into the HMR. This proposal pertains to: marking and stamping; adding new definitions pertaining to tank cars; adding qualifications for tank car inspections and tests; revising the requirements for tank car repairs, alterations, conversions, and modifications; clarifying recordkeeping requirements; and listing hazardous and other materials corrosive to tanks or service equipment. The following table summarizes the proposed changes:

Number	Section No.	Proposed change to 49 CFR part 180	Proposed change from DOT–SP 12095
1	*180.501*	Applicability	Existing paragraph (b) is now paragraph (c), and new paragraph (b) and (d) are added to clarify, respectively, the minimally acceptable framework each owner's tank car qualification program must have, and specifies that documents must be made available upon request to FRA or an authorized representative of the U.S. Department of Transportation.
2	*180.503* (Definitions)	Bottom shell	Not added. This definition already exists in § 171.8.
		Corrosive to the tank or service equipment.	No change.
		Defects	Added to eliminate industry confusion.
		Design level of reliability and safety.	Minor edits.
		Interior heating system	No change.
		Lining/Coating owner	No change.
		Maintenance	Minor edits.
		Modification	Added to aid industry compliance.
		Objectively reasonable and articulable belief.	Added to explain the use of this term in § 180.509(b)(4).
		Qualification	First sentence states what the term means instead of how to achieve it. Second sentence (essentially unchanged) states how to achieve qualification and emphasizes that "qualification" requires a representation that the process has been completed successfully.
		Railworthy, Railworthiness	Explains the term. When FRA requires a recall of a tank car or series of tank cars it issues a "Railworthiness Directive."
		Reactive to the tank or service equipment.	Adds reactivity language based on § 173.24(b)(2) and (3).
		Reinforced tank shell butt weld	No change.
		Reinforcing plate	No change.
		Reliability	No change.
		Representation	Reworded.
		Safety system	No change.
		Service equipment	Minor edits.
		Service equipment owner	Added to clarify the party responsible and to accommodate a growing trend in the industry that the owner of the car may or may not own the service equipment.
		Tank car owner	This is a codification of previous FRA interpretations and statements.
		Top shell	Not added. This definition already exists in § 171.8.
3	*180.507*	Paragraph (b)(2)	"Marked" replaces "stamped" to allow for flexibility with regulatory compliance.
		Paragraph (b)(5)	This TCQ–1 paragraph is omitted but language is used from existing § 180.507(b)(5).
4	*180.509*	Paragraph (a)(4)	Added last sentence to ameliorate a concern from tank car owners that modifications have been made to their cars without their knowledge; minor edits.
		Paragraph (b)(4)	Replaced "probable cause" with the wording "objectively reasonable and articulable belief" because the former is a term of art in criminal law and is also used in FRA drug and alcohol regulations. The intent of § 180.509(b)(4) is to create a standard less strict than that of an emergency order, but rigorous enough to compel a tank car owner to reinspect and repair, if necessary, tank cars considered potential hazards irrespective of their periodic test and inspection requirements.
		Paragraph (c)(1)	Minor edits.
		Paragraph (d)	Minor edits.
		Paragraph (d)(2)	Added last sentence for clarity.
		Paragraph (d)(3)	Added "Corrosion" as specific element for inspection.
		Paragraph (d)(5)	To insure inclusiveness, added "all closures" as substitute for specific item names.
		Paragraph (d)(6)	Dropped "operability" test of excess flow valves because it is not a practical test and a successful result might damage the excess valve seat and preclude seating in a future event.
		Paragraph (e)(1)	Replace "high-stressed structural elements" with the simpler words "structural elements."

Number	Section No.	Proposed change to 49 CFR part 180	Proposed change from DOT–SP 12095
		Paragraph (f)(1)	Added the responsibility of the tank car owner for clarity.
		Paragraph (f)(4)	Added a general prohibition against operating overly thin tank cars; this responsibility is changed from putting it solely on tank car owners who often have no control over the day to day movements of their tank cars.
		Paragraph (g)	Minor edits; removes the language that implies only a ''qualified individual'' could find a thin tank car and invoke the restrictions in this paragraph.
		Paragraph (h)	No change.
		Paragraph (i)	Minor edits.
		Paragraph (j)	Minor edits; Replaced the wording ''after reassembly of a tank car'' from Part 180, Subpart F, and ''installed on the tank car'' with ''installed, replaced, or reinstalled on the tank car.''
		Paragraph (l)	Minor edits.
		Paragraph (m)	After 12/2010 the requirements of paragraph (m) should have been fulfilled. There may be late tank cars or tank cars with extended alternate inspection intervals; therefore, this provision will be retained for an additional 5–10 years.
5	*180.511*		Added minor edits; included those in Part 180, Subpart F, to capture requirements for qualifying service equipment.
6	*180.513*	Paragraph (a)	Reworded to encompass the entire AAR Tank Car Manual rather than certain appendices.
		Paragraph (b)	Added for clarification and as a reminder that tank car or component owners are responsible for verifying compliance with the owner's maintenance instructions.
		Paragraph (c)	Is the same language as existing paragraph (b) from DOT–SP 12095. The last sentence was added for clarification.
7	*180.515*	Paragraph (a)	Added last sentence to clarify the primacy of dates marked in Appendix C of the AAR Tank Car Manual.
8	*180.517*		Revised to clarify that marking or retaining the specification on the tank, either after initial construction in paragraph (a) or subsequent qualification in paragraph (b), is the ''representation'' of ''qualification'' defined in § 180.503.

Additional provisions from Special Permit DOT–SP 12095 as proposed will be in §§ 179.201–10, 179.220–25, and 180.501, and 180.503, 180.507, 180.509, 180.511, 180.513, 180.515, 180.517, and Appendix D of part 180.

B. Telephone and Electronic Data Interchange Shipping Papers

Special Permit DOT–SP 7616 permits the transmission of shipping paper information by telephone and electronic data interchange (EDI). Special Permit DOT–SP 7616 is currently used by 626 parties. Prior to this special permit, shippers entered information on shipping papers by hand, typewriter, or with the use of a computer and then transmitted these documents by hand, railroad agent, facsimile, or postal system to a train crew or rail yard. These methods were very time consuming. This shipping information would then be entered into the receiver's tracking system, a process that resulted in a large number of key entry errors for hazardous materials shipments.

Starting in the 1960s, many companies began using in-house computer systems and networks to assist with preparing and tracking shipping information, but technological limitations often prevented or restricted one company's system from communicating with another's. Rail companies and shippers attempting to address these issues and find solutions formed the Transportation Data Coordination Committee (TDCC) in 1968, and started publishing standards on EDI in 1975. In the mid-1970's, the U.S. Department of Transportation (USDOT) issued Exemption DOT–E 7616 to permit railroad companies to ''certify'' their shipping papers for hazardous materials by permitting the shipper to leave a ''voice'' message stating that a hazardous materials shipment loaded on a railcar was being offered for transportation. Eventually, the exemption was revised to allow an ''electronic'' shipping document to be faxed and later transmitted electronically from computer to computer. Today, EDI standards are used worldwide for most industries that rely on electronic data transfer of information, such as banks, medical institutions, and shipping companies outside of railroad-related businesses.

In consultation with USDOT, the TDCC evolved, and the EDI standards were published as guidelines on electronic data standards for the transportation industry. These guidelines established format codes and protocols for communicating and verifying the accuracy of electronic information, including hazardous materials information on a shipping paper, for hazardous materials shippers and carriers. Currently, the Accredited Standards ''X12'' Committee (ACS) of the American National Standards Institute (ANSI) creates standards specifically for EDI. Industry organizations take these standards and modify them to fit the types of electronic transmissions and/or transactions needed by each industry. This is what is done in the railway industry. As a result, there is no one specific standard that includes all the electronic transmissions permitted as EDI.

Special Permit DOT–SP 7616 allows a carrier to accept shipping paper information via telephone (*i.e.*, voice communications) for hazardous material shipments that have been transported by railroad, and authorizes several variations in the certification requirement when this information is transmitted telephonically or through EDI. The Federal Aviation Administration and Federal Motor Carrier Safety Administration have informed PHMSA and FRA that some

inconsistencies exist when these standards are applied between the different transportation modes. Therefore, in this NPRM, PHMSA and FRA are proposing to incorporate into the HMR the provisions for EDI prescribed in Special Permit DOT–SP 7616 and requested in Petition No. P–1497 for any hazardous materials shipment transported by rail only. This will exclude, for example, the use of voice communications as an authorized method for carriers to accept hazardous materials shipping paper information for transporting these shipments by aircraft or motor vehicle. Further, PHMSA and FRA are proposing to allow a signature in the signature block of an EDI form to represent completion of the shipper's certification prescribed under § 172.204. Users of EDI may wish to consult the ANSI's ACS X12 Committee for guidance on EDI transmissions and transactions for electronic shipping documents, along with any other guidance developed on this subject by the Department's agencies, such as the FRA.

PHMSA and FRA are not aware of any incidents that have occurred as a result of the issuance of Special Permit DOT–SP 7616. PHMSA and FRA have also determined the overall effect of the special permit has improved the timely and accurate receipt of hazardous materials information, thereby improving safety. As mentioned earlier in this preamble, the IVOHMA also requested through a petition for rulemaking (P–1497) that PHMSA revise the HMR to include the transmission of shipping documents through EDI. PHMSA and FRA acknowledge that hazardous materials shipping document information is routinely transmitted by computer but no provision in the HMR specifically addresses this. PHMSA and FRA also note that the use of EDI to transmit this information does not eliminate the requirement for the printed copy of a shipping paper to accompany a hazardous materials shipment. PHMSA and FRA specifically request comments on the costs and safety benefits associated with these proposals, as well as the possible effects and/or modifications needed to permit EDI to transmit successfully the shipping paper information for hazardous materials in all transportation modes.

The provisions for Special Permit DOT–SP 7616 and Petition No. P–1497 are proposed in §§ 172.201, 172.202, 172.204, and 172.604. The changes that IVOHMA proposed for § 174.24 are also located in § 172.202; therefore, they are not needed in § 174.24 and we are not proposing to revise that section.

C. Straight Threads on Multi-Unit Tank Cars

Special Permit DOT–SP 14333 authorizes the manufacture, marking, sale and use of a non-DOT specification tank car conforming to all the regulations applicable to the DOT Specification 110A500W multi-unit tank car tank, except that the tank must be equipped with straight threads in the clean-out/inspection port openings instead of the National Gas Taper Threads. Four parties currently use this special permit.

This special permit also permits retrofitting. Section 179.300–13(b) requires that taper threads must be used on the valve opening. In the safety equivalency evaluation for Special Permit DOT–SP 14333, PHMSA and FRA determined that straight threads on the clean-out/inspection port opening would provide an equivalent level of safety. Tapered threads are designed to provide a seal when torqued. The seal is a result of the compression of the male and female threads. Because they compress, there is an inevitable degree of deformation. This deformation decreases the likelihood that a proper seal can be obtained upon subsequent applications. Straight threads are used on connections where a gasket is compressed to create a seal. Therefore, a seal can be obtained by repeated application as long as the gasket has not degraded. The clean-out/inspection port openings are used repeatedly and introduce an opportunity for leaks. The straight threads on these openings help to minimize leaking. Special Permit DOT–SP 14333 limits the use of the straight threads opening to certain high-hazard Division 2.3 (poisonous gas), Division 6.1 (poisonous), and Class 8 (corrosive) hazardous materials, as well as those materials authorized to be transported in DOT Specification 110A500W multi-unit tank car tanks. However, PHMSA and FRA believe straight threads in inspection ports can be used for all hazardous materials authorized to be transported in DOT Specification 110A multi-unit tank car tanks and are proposing this action in this NPRM.

PHMSA and FRA are not aware of any incidents that have occurred as a result of the issuance of this special permit, and believe these provisions, if adopted, will provide an adequate level of safety. Therefore, PHMSA and FRA are proposing to incorporate Special Permit DOT–SP 14333 into the HMR and further allowing straight threads in inspection ports to be used for all hazardous materials authorized to be transported in DOT Specification 110A multi-unit tank car tanks. The provisions for this special permit are proposed in § 179.300–13(b) for DOT Specification 110A multi-unit tank cars only.

D. Alternative Start-to-Discharge Pressure Requirements for Tank Cars Containing Chlorine

Special Permit DOT–SP 14622 authorizes the transportation of certain DOT Specification 105J500W tank cars containing chlorine that have start-to-discharge settings that do not meet the regulatory requirements for pressure relief devices. Three parties currently use this special permit.

In its original application for this special permit, Occidental Chemical Corporation (OxyChem) requested relief from § 179.15(b) to allow tank cars in chlorine service to be equipped with combination pressure relief valves (PRV) with a set pressure of 360 pounds per square inch (psi) rather than the required set pressure of 356 psi. OxyChem justified its request based on its history of operating tank cars safely in a manner similar to what it was requesting. OxyChem also based its request on the HMR's regulatory history prior to the final rule issued under Docket No. HM–216, effective on October 1, 1996 (61 FR 28666; 61 FR 38642; 61 FR 50252), which permitted DOT Specification 105J500W tank cars used to transport chlorine to be equipped with a PRV with a set pressure of 356 psi.

The FRA conducted an evaluation of the level of safety provided by the terms and allowances of Special Permit DOT–SP 14622. As part of this evaluation, FRA staff contacted the Chlorine Institute, which represents all of the companies that are a party to this special permit. The Chlorine Institute reported it has not received a report of any incident related to the conditions allowed under Special Permit DOT–SP 14622. In addition, the Chlorine Institute found the PRV setting does not affect the standard start-to-discharge pressure that is the basis for the flow rating pressure. The flow rating pressure, in turn, is used to calculate the required PRV flow capacity. Therefore, the FRA finds the valve is sized appropriately for the required design conditions.

The FRA has one safety concern related to Special Permit DOT–SP 14622. If the relief discs or pins burst or break within their tolerances, there is the potential that the valve will be exposed to the lading and its vapor for an extended period of time. A rupture disc or breaking pin is used in conjunction with a reclosing PRV to

provide a barrier between the valve and its components from the lading and the vapor of the lading, as exposure to these can lead to corrosion and ultimately the malfunctioning of the valve. Furthermore, the FRA believes it is important that combination PRVs are equipped with ''tell-tale devices'' located outboard (outside) of the rupture disc (or breaking pin) and inboard (inside) of the valve. When the disc or breaking pin is intact, the valve indicates no pressure. If the disc or pin has been compromised, the valve will show an elevated pressure. An operator inspecting the condition of the tell-tale device can determine if the rupture disc or breaking pin has been compromised.

A rupture disc has a rated pressure burst-pressure tolerance of +/− 5 percent. A breaking pin has a rated pressure burst-pressure tolerance of +/− 10 percent (see ASME Section VIII, UG–126 Pressure Relief Valves). An evaluation of the special permit relative to both the rupture disc and breaking pin is provided in the following paragraph.

Special Permit DOT–SP 14622 allows for the PRV to have a set pressure of 360 psi. The special permit allows the burst pressure of the relief device to be 96 percent of the start-to-discharge pressure rather than the required maximum of 95 percent. As stated earlier, the set pressure in SP–14622 is within the rated pressure burst tolerance of the rupture disc and rated pressure burst tolerance of the breaking pin described earlier in this paragraph. However, it is possible that a rupture disc could burst at the limit of its negative tolerance at 356 psi. In this case, the valve with a set pressure of 360 psi would be undetected and exposed to the lading or the vapor of the lading. While this sequence is possible, the negative effects to the valve are very limited. This can be demonstrated by reviewing the thermodynamic properties of chlorine and the time needed to increase the vapor pressure of the chlorine to the set pressure of the PRV. Based on the vapor pressure-temperature relationship of chlorine, the temperature of chlorine at a vapor pressure of 356 psi is approximately 165 °F and its temperature at 360 psi is approximately 170 °F. It is evident that as the temperature of chlorine increases, the vapor pressure of the chlorine also increases at a slightly faster rate.

A pool fire represents the only scenario in which the temperature of chlorine in a tank could reach 165 °F. In this scenario, the heat input is so great that the specific heat and heat of vaporization requirements would be met quickly and raise the temperature and the respective vapor pressure of the chlorine in the tank car to a level that would actuate the PRV, causing the PRV to function and vent the pressure in the tank. Under these hazardous conditions, corrosion of the PRV body and components are very minor considerations.

Regarding the breaking pin, as stated earlier, the rated pressure tolerance is +/− 10 percent. Both the start-to-discharge pressure requested in Special Permit DOT–SP 14622 and required in the HMR are within the design tolerance of the breaking pin. As a result, neither poses a greater risk to the safe operation of the relief valve and tank car.

Based on this analysis, PHMSA and FRA believe operation of a tank car under the terms of Special Permit DOT–SP 14622 provides a level of safety that is equivalent to that of a similar tank car operated under the HMR. Therefore, we propose to adopt this requirement into the HMR. The provisions for this special permit are proposed in § 173.314(k)(2).

E. Alternative Pressure Relief Requirements for Pressure Relief Devices for Tank Cars Containing Certain Flammable Liquid Materials

Special Permit DOT–SP 11184 authorized the transportation in commerce of certain Class 3 materials in DOT Specification 105J300W tank cars with a pressure relief device rated at 25 percent of tank test pressure. The commodities authorized under this special permit were typically shipped in general purpose (GP) tank cars (*e.g.*, DOT Specification 111A100W). In 1996, PHMSA, then known as the Research and Special Programs Administration, added § 179.15 to the HMR in a final rule it issued on June 5, 1996, under Docket No. HM–216 (61 FR 28666). In paragraph (b)(2)(i) of that section, the agency added the requirement that reclosing pressure relief devices in tank cars, other than DOT Class 106, 107, 110, and 113 tank cars, may not have a start-to-discharge pressure setting lower than 5.17 Bar (75 psig) or higher than 33 percent of the minimum tank burst pressure, a range that included the 25 percent of tank test pressure relief device rating required in paragraph 2.a of DOT–SP 11184. As a result, DOT–SP 11184 was no longer needed and PHMSA let it expire. When it was active, 21 parties used this special permit.

PHMSA and FRA are discussing DOT–SP 11184 in this NPRM to clarify that the rulemaking action issued under Docket No. HM–216 eliminated the need for this special permit, and to emphasize that this revision improved safety in two ways. First, it lowered the start-to-discharge pressure for the PRV, which allowed the car to vent at lower pressures when in an overheated condition—such as a pool fire. Commodities listed in this special permit when exposed to extreme heat and pressure will undergo rapid polymerization that could result in an energetic and catastrophic failure of the tank car. Second, the DOT Specification 105J300W tank car's thicker shell and head will result in the tank car having a significantly greater survivability than its GP tank car counterparts. PHMSA and FRA have determined these revisions to the HMR are performing satisfactorily; therefore, we are expiring this special permit. PHMSA and FRA are not aware of any incidents that have occurred as a result of the issuance of Special Permit DOT–SP 11184.

F. Transportation in Commerce of Certain Tank Cars With Identification Plates in Lieu of Stamping the Tank Car Heads

Special Permit DOT–SP 12905 permits certain DOT and AAR specification tank cars with stainless steel identification plates to have their specification and other required information stamped on the identification plate instead of the tank car heads if certain requirements are met. The AAR requires all cars built after December 31, 2003, to be equipped with identification plates as specified in Appendix C, paragraph 4.0. Additionally, for several years manufacturers have built portable tanks and cargo tanks with a data plate containing all pertinent information related to the construction of the tank. Incorporating Special Permit DOT–SP 12905 into the HMR will bring the railcar data identification in line with the AAR standards and the portable tank and cargo tank industries. Also, FRA acknowledges that stamping this information into the tank car wall may introduce a defect into its steel. Although minimal, stamping results in a stress concentration in the area of the stamp. Use of a data plate would eliminate this defect. Currently, 22 parties use this special permit.

PHMSA and FRA are not aware of any incidents that have occurred as a result of the issuance of Special Permit DOT–SP 12905. PHMSA and FRA believe that incorporating this special permit into the HMR will provide an equivalent level of safety for the qualification of both specification and non-specification rail tank cars. AAR tank cars are required to have an identification plate after December 31, 2011. Therefore, PHMSA and FRA are proposing to amend the HMR to require tank cars to

have a stamped identification plate one year after the publication date of the final rule issued as a result of this proposed rulemaking. We propose to adopt this requirement into new section § 179.24 and existing sections §§ 179.100–20, 179.200–24, 179.201–10, and 179.220–25 of the HMR.

G. Measuring Liquefied Gases Loaded into a Tank Car With Metering Devices as an Alternative to Measuring These Cars by Weight

Special Permit DOT–SP 9388 authorizes the transportation in commerce of DOT specification tank cars that have ''UN 1005, Ammonia, anhydrous, 2.2 (non-flammable gas)'' liquefied gas measured by a metering device when loaded into the tank. Although anhydrous ammonia is defined as meeting both a Division 2.3 (poisonous gas) and Class 8 (corrosive) hazard class under the United Nations Recommendations on the Transport of Dangerous Goods, International Civil Aviation Organization Technical Instructions on the Transport of Dangerous Goods by Air, and International Maritime Dangerous Goods Code, the HMR permits anhydrous ammonia to be defined as meeting the Division 2.2 hazard class in domestic transportation only. For increased safety, DOT–SP 9388 requires that each of these tank cars must be loaded and unloaded using procedures that specify at a minimum: Employee safety equipment; proper signage; set brakes and installed wheel blocks; an examination of the tank and/or jacket, its undercarriage assembly, hoses, connections, valves, and accessories inside the loading dome for damage; recording of defects; certification of inspection and completion of loading and/or unloading procedures, as well as other recordkeeping requirements. PHMSA and FRA propose to incorporate these requirements in new § 173.314(e)(2)(i). Also, DOT–SP 9388 requires that one out of every 10 tanks cars must have the metered gauge verified with the tank car gauge in accordance with certain procedures to determine the current capacity of the car. PHMSA and FRA propose to incorporate these procedures in new § 173.314(e)(2)(ii). Although Special Permit DOT–SP 9388 is currently expired, 28 parties previously used it. Since the original issuance of DOT–SP 9388, flow meter technology is much more accurate and reliable.

PHMSA and FRA are not aware of any incidents that have occurred as a result of the issuance of this special permit. PHMSA and FRA believe that incorporating this special permit into the HMR will provide an equivalent level of safety for the qualification of both specification and non-specification rail tank cars. Therefore, we propose to adopt this requirement, with the additions noted above, into § 173.314(e) of the HMR.

H. Approval for Gross Weight on Rail Tank Cars

Special Permits DOT–SP 11241, 11654, 11803, 12423, 12561, 12613, 12768, 12858, 12903, 13856, 13936, 14004, 14038, 14442, 14505, 14520, 14570, and 14619, allowed rail tank cars with a gross weight on rail that exceeded 263,000 pounds but not exceeding 286,000 pounds to be used to transport certain hazardous materials provided the tank car is approved by the FRA's Associate Administrator for Railroad Safety. PHMSA adopted these special permits, along with several others, in a final rule issued under Docket No. PHMSA–2009–0289 (HM–233A; 75 FR 27205, 5/14/2010) because they were widely used and had established safety records. However, the final rule erroneously omitted from § 179.13(b) a provision to require FRA approval for those gross-weight-on-rail tank cars authorized to contain materials that are poisonous-by-inhalation. PHMSA is proposing to correct this omission in this rulemaking by revising § 179.13(b) to add the FRA approval statement.

I. Reference to the Association of American Railroads AAR 600 Program

The AAR Tank Car Committee and the AAR Hazardous Materials Committee have recommended the discontinuance of the AAR 600 program as incorporated in § 174.63(c)(2). Currently, this program requires that a bulk packaging, including a portable tank, transported in COFC or TOFC service must conform to the conditions specified in § 174.63 of the HMR. These regulations require approval by FRA's Associate Administrator for Railroad Safety, unless, among other things, the tank conforms to requirements in AAR 600 of the AAR Specifications for Tank Cars, ''Specifications for Acceptability of Tank Containers.'' In accordance with AAR 600, approval and registration of compliant portable tanks is required based on a determination that the tank meets all applicable standards and payment of a registration fee.

Since incorporation of the AAR 600 standard into the HMR, PHMSA has adopted standards for portable tanks that meet or exceed the AAR 600 requirements. The AAR committees believe that the current HMR portable tank regulations have now exceeded the AAR 600 requirements and that all of the specifications for original construction listed in the AAR 600 Standard were not allowed to be built after January 1, 2003, except for the DOT Specification 60 and other United Nations (UN) portable tanks that are authorized in the HMR. As stated earlier in this rulemaking, PHMSA agreed with the AAR proposal in a letter dated May 20, 2009 and stated we would propose a revision to § 174.63(c). As also discussed earlier in this preamble, PHMSA received a petition (P–1567) dated July 9, 2010, from Gold Tank Inspection Services, Inc., requesting the removal of the reference to the AAR 600 program in § 174.63 because the HMR now includes standards for portable tanks that meet or exceed AAR 600 requirements. Accordingly, in this NPRM, PHMSA is proposing to require that portable tanks transported in COFC or TOFC service must conform to all HMR requirements applicable to portable tanks. Consistent with this proposed revision, PHMSA is proposing to remove the reference in § 171.7(a)(3) to § 173.63 under the listing ''AAR Manual of Standards and Recommended Practices, Section C–Part III, Specifications for Tank Cars, Specification M–1002, (AAR Specifications for Tank Cars), December 2000.''

III. Rulemaking Analyses and Notices

A. Statutory/Legal Authority for This Rulemaking

This NPRM is published under the authority of 49 U.S.C. 5103(b) which authorizes the Secretary to prescribe regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce. 49 U.S.C. 5117(a) authorizes the Secretary of Transportation to issue a special permit from a regulation prescribed in sections 5103(b), 5104, 5110, or 5112 of the Federal Hazardous Materials Transportation Law to a person transporting, or causing to be transported, hazardous material in a way that achieves a safety level at least equal to the safety level required under the law, or consistent with the public interest, if a required safety level does not exist. If adopted as proposed, the final rule would amend the regulations incorporating provisions from certain widely used and longstanding special permits that have established a history of safety and which may, therefore, be converted into the regulations for general use.

B. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

This proposed rule is not considered a significant regulatory action under section 3(f) and was not reviewed by the Office of Management and Budget (OMB). The proposed rule is not considered a significant rule under the Regulatory Policies and Procedures order issued by the Department of Transportation [44 FR 11034].

Executive Orders 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') require agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' In this notice, PHMSA proposes to amend the HMR by incorporating alternatives this agency has permitted under widely used and longstanding special permits with established safety records that we have determined meet the safety criteria for inclusion in the HMR. Incorporation of these special permits into regulations of general applicability will provide shippers and carriers with additional flexibility to comply with established safety requirements, thereby reducing transportation costs and increasing productivity. In addition, the proposals in this NPRM will reduce the paperwork burden on industry and this agency caused by continued renewals of special permits. The provisions of this proposed rule will promote the continued safe transportation of hazardous materials while reducing transportation costs for the industry and administrative costs for the agency. Therefore, the requirements of Executive Orders 12866 and 13563, and the DOT policies and procedures concerning these orders have been satisfied.

C. Executive Order 13132

This proposed rule was analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This proposed rule would preempt state, local and Indian Tribe requirements but does not propose any regulation that has substantial direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of governments. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply. Federal hazardous material transportation law, 49 U.S.C. 5101, *et seq.,* contains an express preemption provision (49 U.S.C. 5125(b)) preempting state, local and Indian Tribe requirements on certain covered subjects. Covered subjects are:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or

(5) The designing, manufacturing, fabricating, marking, maintaining, reconditioning, repairing, or testing of a package, container or packaging component that is represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This proposed rule addresses covered subject items (2), (3), and (5) and would preempt any State, local, or Indian Tribe requirements not meeting the ''substantively the same'' standard. Federal hazardous materials transportation law provides at 49 U.S.C. 5125(b)(2) that if PHMSA issues a regulation concerning any of the covered subjects, PHMSA must determine and publish in the **Federal Register** the effective date of Federal preemption. The effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance. PHMSA proposes the effective date of Federal preemption be 90 days from publication of a final rule in this matter in the **Federal Register**.

D. Executive Order 13175

This proposed rule was analyzed in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''). Because this proposed rule does not have Tribal implications and does not impose substantial direct compliance costs on Indian Tribal governments, the funding and consultation requirements of Executive Order 13175 do not apply.

E. Regulatory Flexibility Act, Executive Order 13272, and DOT Procedures and Policies

The Regulatory Flexibility Act (5 U.S.C. 601–611) requires each agency to analyze regulations and assess their impact on small businesses and other small entities to determine whether the rule is expected to have a significant impact on a substantial number of small entities. The NPRM proposes to amend the HMR to incorporate provisions contained in seven widely used or longstanding railroad special permits that have an established safety record. Although many of the applicants may be small businesses or other small entities, PHMSA believes that the revisions in this proposed rule are intended to provide wider access to the regulatory flexibility offered in special permits and eliminate the need for numerous renewal requests, thus reducing paperwork burdens and facilitating commerce while maintaining an appropriate level of safety. Therefore, PHMSA certifies that the provisions of this NPRM would not have a significant economic impact on a substantial number of small entities.

This proposed rule has been developed in accordance with Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'') and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts of draft rules on small entities are properly considered.

F. Paperwork Reduction Act

PHMSA has approved information collections under OMB Control Number 2137–0051, ''Rulemaking, Special Permits, and Preemption Requirements,'' OMB Control Number 2137–0557, ''Approvals for Hazardous Materials,'' and OMB Control Number 2137–0559, ''(Rail Carriers and Tank Car Requirements) Requirements for Rail Tank Cars—Transportation of Hazardous Materials by Rail. This NPRM may result in a decrease in the annual burden and costs under OMB Control Number 2137–0051 and an increase in the annual burden and costs under OMB Control Number 2137–0557 and OMB Control Number 2137–0559 due to proposed changes to incorporate provisions contained in certain widely used or longstanding special permits that have an established safety record.

Under the Paperwork Reduction Act of 1995, no person is required to respond to an information collection unless it has been approved by OMB and displays a valid OMB control number. Section 1320.8(d), title 5, Code of Federal Regulations requires that PHMSA provide interested members of the public and affected agencies an opportunity to comment on information and recordkeeping requests.

This notice identifies a revised information collection request that PHMSA will submit to OMB for approval based on the requirements in

this proposed rule. PHMSA has developed burden estimates to reflect changes in this proposed rule. PHMSA estimates that the information collection and recordkeeping burden as proposed in this rule is as follows:

OMB Control No. 2137–0051:	
Decrease in Annual Number of Respondents	255
Decrease in Annual Responses:	255
Decrease in Annual Burden Hours	255
Decrease in Annual Burden Costs	$9,500

OMB Control No. 2137–0557:	
Increase in Annual Number of Respondents	200
Increase in Annual Responses:	200
Increase in Annual Burden Hours	50
Increase in Annual Burden Costs	$1,100

OMB Control No. 2137–0559:	
Increase in Annual Number of Respondents	350
Increase in Annual Responses	350
Increase in Annual Burden Hours	350
Increase in Annual Burden Costs	$10,500

PHMSA specifically requests comments on these information collections and recordkeeping burdens associated with developing, implementing, and maintaining these requirements for approval under this proposed rule.

Requests for a copy of this information collection should be directed to Deborah Boothe or Steven Andrews, Standards and Rulemaking Division, (PHH–10), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001, Telephone (202) 366–8553.

Address written comments to the Dockets Unit as identified in the **ADDRESSES** section of this rulemaking. We must receive comments regarding information collection burdens prior to the close of the comment period identified in the DATES section of this rulemaking. In addition, you may submit comments specifically related to the information collection burden to the PHMSA Desk Officer, Office of Management and Budget, at fax number 202–395–6974.

G. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document may be used to cross-reference this action with the Unified Agenda.

H. Unfunded Mandates Reform Act of 1995

This proposed rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of $141.3 million or more to either state, local or Tribal governments, in the aggregate, or to the private sector, and is the least burdensome alternative that achieves the objective of the rule.

I. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321–4347), and implementing regulations by the Council on Environmental Quality (40 CFR part 1500) require Federal agencies to consider the consequences of Federal actions and prepare a detailed statement on actions that significantly affect the quality of the human environment.

The hazardous materials regulatory system is a risk management system that is prevention oriented and focused on identifying a hazard and reducing the probability and quantity of a hazardous materials release. This rulemaking is concerned with the transportation of hazardous materials by rail, but is prepared with the understanding that these materials are often transported by aircraft, vessel, and highway before or after they are transported by rail. The need for hazardous materials to support essential services means transportation of highly hazardous materials is unavoidable. However, these shipments frequently move through densely populated or environmentally sensitive areas where the consequences of an incident could be loss of life, serious injury, or significant environmental damage. The ecosystems that also could be affected by a hazardous materials release during transportation include atmospheric, aquatic, terrestrial, and vegetal resources (for example, wildlife habitats). The adverse environmental impacts associated with releases of most hazardous materials are short-term impacts that can be greatly reduced or eliminated through prompt clean-up of the incident scene. In this NPRM, we are requesting comments on the potential environmental impacts of the proposals.

In all modes of transport, the potential for environmental damage or contamination exists when packages of hazardous materials are involved in transportation incidents. Most of the special permits considered in this rulemaking involve bulk packages of hazardous materials in DOT specification and non-specification tank cars. While the volume of hazardous material present in these packagings has the potential to be released into the environment during a transportation incident, these packagings are constructed to withstand greater forces during impact and are also equipped with safety relief devices and valves specifically designed to maintain the containment ability of the tank car.

The purpose and need of this rulemaking is to incorporate widely used special permits or those with an established safety record into the HMR for universal use. More information about benefits of the proposed action can be found in the preamble (*i.e.,* ''Overview of Proposed Amendments) to this rulemaking. The alternatives considered in the analysis include (1) the proposed action, that is, incorporation of the proposed special permits as amendments to the HMR; (2) incorporation of some subset of the proposed special permits (*i.e.,* only some of the proposed special permits) as amendments to the HMR; and (3) the ''no action'' alternative, meaning that none of the proposed special permits would be incorporated into the HMR. PHMSA believes that the each of these alternatives would result in equal environmental risk and/or impact because special permits are intended to offer equivalent safety and environmental protection as the HMR.

In considering the potential environmental impacts of the proposed action, PHMSA does not anticipate that the incorporation of the listed special permits will result in any significant impact on the human environment because the process through which special permits are issued requires the applicant to demonstrate that the alternative transportation method or packaging proposed provides an equivalent level of safety as that provided in the HMR. However, PHMSA welcomes and will consider and address comments about foreseeable environmental impacts or risk associated with the incorporation of any proposed special permit. The agencies and persons consulted in the development of this regulatory proposal include the International Vessel Operators Hazardous Materials Association, Inc.; Gold Tank Inspection Services, Inc.; Surface Deployment and Distribution Command (SDDC); Conrail; Agrium N.A.Wholesale Transportation Compliance; Koch Nitrogen Company; Columbiana Boiler Company; and subject matter expert staff in FRA and PHMSA.

Given that this rulemaking proposes to amend the HMR to incorporate provisions contained in certain widely used or longstanding railroad special permits that have an established safety record, these proposed change in regulation would increase safety and environmental protections. There are no significant environmental impacts associated with this proposed rule.

J. Privacy Act

Anyone is able to 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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, pages 19477–78), or at *http://www.regulations.gov.*

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Reporting and recordkeeping requirements.

49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

49 CFR Part 174

Hazardous materials transportation, Radioactive materials, Rail carriers, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 179

Hazardous materials transportation, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 180

Hazardous materials transportation, Motor carriers, Motor vehicle safety, Packaging and containers, Railroad safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, we propose to amend 49 CFR Chapter I as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.45 and 1.53; Pub. L. 101–410 section 4 (28 U.S.C. 2461 note); Pub. L. 104–134 section 31001.

§ 171.7 [Amended]

2. In the ''Table of material incorporated by reference,'' at § 171.7(a)(3), for the entry ''AAR Manual of Standards and Recommended Practices, Section C–Part III, Specifications for Tank Cars, Specification M–1002, (AAR Specifications for Tank Cars), December 2000, the reference to § 174.63 is removed.

3. In § 171.8, the definition ''Train consist'' is added in alphabetical order to read as follows:

§ 171.8 Definitions and abbreviations.

* * * * *

Train consist means a written record of the contents and location of each rail car in a train.

* * * * *

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, TRAINING REQUIREMENTS, AND SECURITY PLANS

4. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.53.

5. In § 172.201, revise paragraph (a)(2) and add paragraph (a)(5) to read as follows:

§ 172.201 Preparation and retention of shipping papers.

(a) * * *

(2) The required shipping description on a shipping paper and all copies of the shipping paper used for transportation purposes must be legible and printed (manually or mechanically) in English.

* * * * *

(5) *Electronic shipping papers.* For transportation by rail, a rail carrier may accept shipping paper information either telephonically (*i.e.,* voice communications and facsimiles) or electronically (EDI) from an offeror of a hazardous materials shipment in accordance with the provisions in paragraphs (a)(5)(i) through (v) of this section. For the purposes of this section *electronic data interchange* (EDI) means the computer-to-computer exchange of business data in standard formats. In EDI, information is organized according to a specific format (electronic transmission protocol) agreed upon by the sender and receiver of this information, and transmitted through a computer transaction that requires no human intervention or retyping at either end of the transmission.

(i) When the information applicable to the consignment is provided under this requirement the information must be available to the shipper and carrier at all times during transport, and the carrier must have and maintain a printed copy of this information until delivery of the hazardous materials on the shipping paper is complete. When a paper document is produced, the data must be presented as required by this subpart.

(ii) The offeror must forward the shipping paper (record) for a loaded movement to the carrier prior to shipment unless the carrier prepares the shipping paper on behalf of the offeror. The offeror is only relieved of the duty to forward the shipping paper once the offeror has received a copy of the shipping paper from the carrier;

(iii) A carrier that generates a residue shipping paper using information from the previous loaded movement of a hazardous materials packaging must ensure the description of the hazardous material that accompanies the shipment complies with the offeror's request;

(iv) *Verification.* The carrier and the offeror must have a procedure by which the offeror can verify accuracy of the transmitted hazard communication information that will accompany the shipment; and

(v) *Retention.* The shipping document that is generated must be retained in conformance with § 172.201(e).

* * * * *

6. In § 172.202, paragraph (b) is amended by adding a third sentence to read as follows:

§ 172.202 Description of hazardous material on shipping papers.

* * * * *

(b) * * * Shipping descriptions for hazardous materials offered or intended for transportation by rail that contain all the information required in this subpart and that are formatted and ordered in accordance with recognized electronic data interchange standards and, to the extent possible, in the order and manner required by this subpart are deemed to comply with this paragraph.

* * * * *

7. In § 172.204 paragraph (a) introductory text, a sentence is added to the end and paragraphs (a)(3) and (d)(3) are added to read as follows:

§ 172.204 Shipper's certification.

(a) * * * For transportation by rail only, the certification may be received verbally or with abbreviated written language in conformance with paragraphs (a)(3)(i) and (ii) of this section.

* * * * *

(3) *Rail only certifications.* For transportation by rail, the shipping paper certification may also be accomplished by one of the following methods:

(i) *Verbal certification.* When received telephonically, by the carrier reading the complete shipping description that will accompany the shipment to the offeror and receiving verbal acknowledgment that the description is as required. This verbal acknowledgement must be recorded, either on the shipping document or in a separate record, *e.g.,* the train consist, in accordance with § 174.24, and must include the date and name of the person who provided this information; or

(ii) *Written abbreviated certification.* When transmitted electronically, by including the following abbreviated certification, in lieu of the full certification: ''* * *, on behalf of shipper [or ''offeror''] avers [or ''declares''] certification specified in § 172.204(a).'' The name of the principal partner, officer, or employee of the offeror or his agent must be substituted for the asterisks;

* * * * *

(d) * * *

(3) For transportation by rail, when transmitted by telephone or electronically, the signature may be in one of the following forms: the name of the principal person, partner, officer, or employee of the offeror or his agent in a computer field defined for that purpose.

8. In § 172.604, paragraphs (a) introductory text and (a)(3)(ii) are revised to read as follows:

§ 172.604 Emergency Response Telephone Number.

(a) A person who offers a hazardous material for transportation must provide an emergency response telephone number, including the area code, for use in an emergency involving the hazardous material. For telephone numbers outside the United States, the international access code or the ''+'' (plus) sign, country code, and city code, as appropriate, that are needed to complete the call must be included. The telephone number must be—

* * * * *

(3) * * *

(ii) Entered once on the shipping paper in the manner prescribed in paragraph (b) of this section in a prominent, readily identifiable, and clearly visible manner that allows the information to be easily and quickly found, such as by highlighting, use of a larger font or a font that is a different color from other text and information, or otherwise setting the information apart to provide for quick and easy recognition. This provision may be used only if the telephone number applies to each hazardous material entered on the shipping paper, and if it is indicated that the telephone number is for emergency response information (for example: ''EMERGENCY CONTACT: * * *'').

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

9. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.45, 1.53.

10. In § 173.314, paragraph (e) is redesignated as (e)(1) and its first sentence is revised, paragraph (k) is redesignated as (k)(1), and paragraphs (e)(2) and (k)(2) are added to read as follows:

§ 173.314 Compressed gases in tank cars and multi-unit tank cars.

* * * * *

(e) *Verification of content.* (1) The amount of liquefied gas loaded into each tank may be determined either by measurement or calculation of the weight, except that DOT specification tank car tanks authorized for the transportation of ammonia solution and anhydrous ammonia may have the amount of liquefied gas loaded into the tank car measured by a metering device in conformance with paragraph (e)(2) of this section. * * *

(2) *Metering device.* (i) *Loading procedures.* Tank cars loaded with a metering device in conformance with this section are not required to be weighed, but must have their outage measured with a magnetic gauging device to determine that the tank car is properly loaded in compliance with this subchapter. Each tank car using a metering device must be loaded using the following procedures. A copy of these procedures must be available at each location where such loading takes place. Certification in writing of the inspection and completion of these loading and/or unloading procedures must be maintained for each tank car loaded with a metering device and maintained in accordance with the recordkeeping requirements in paragraph (e)(2)(iii) of this section, and all necessary records must be completed. At a minimum, these procedures will specify:

(A) The minimum safety equipment that must be worn by each employee performing a loading and unloading task under this paragraph (e)(2). The equipment must be designed to protect employees from the dangers associated with exposure to and contact with the hazardous material and must also comply with the laws of the Department of Labor's Occupational Safety and Health Administration, and the state and local laws of the jurisdiction where the task is being performed.

(B) That prior to loading a rail tank car all truck brakes must be set and chock blocks installed on one set of truck's wheels, and the rail tank car must be properly spotted and signed, and the tank visually inspected for any sign of damage in the—

(1) Hoses, connections, and valves;

(2) Truck and rail car under carriage assemblies;

(3) Tank and/or jacket; and

(4) Accessories inside of loading dome.

(C) Any defects found must be recorded, and the tank must not be loaded until the repairs to eliminate each defect are completed.

(D) The tank car must be allowed to sit undisturbed for at least 10 minutes after loading to allow material within the tank to settle. After this has occurred a final check for leaks must be conducted prior to closing the dome cover and properly inserting the dome pin.

(ii) *Verification.* One out of every 10 tank cars loaded by the use of the metering device must be gauged utilizing the fixed gauging equipment on the tank car to verify by calculation the amount of ammonia solution or anhydrous ammonia contained in the tank car.

(iii) *Recordkeeping.* The following information must be maintained and be made available to any representative of the DOT upon request for each tank car loaded with the use of a metering device:

(A) Date loaded,

(B) Date shipped,

(C) Tank car reporting marks,

(D) DOT Specification,

(E) Tank car stenciled shell capacity (gallons),

(F) Tank car stenciled tare weight (pounds),

(G) Outage or innage table number,

(H) Water capacity of tank car (pounds),

(I) Maximum permitted filling density (see § 173.314, Table note 1),

(J) Specific gravity of NH_3 (@105 °F = 0.5796 and @115 °F = 0.5706),

(K) Tank car outage (inches/gallons),

(L) Gallons of liquid ammonia in tank car,

(M) Quantity of vapor ammonia in tank car, and

(N) Total calculated ammonia (liquid & vapor) in tank car (pounds).

* * * * *

(k) * * *

(2) DOT105J500W tank cars may be used as authorized packagings, as prescribed in this subchapter for transporting ''Chlorine, 2.3 (8), UN 1017, Poison Inhalation Hazard, Zone B, RQ,'' if the tank cars meet all DOT specification requirements and the tank cars are equipped with combination safety relief valves with a start-to-discharge pressure of 360 psi, rather than the 356 psi. The start-to-discharge pressure setting must be marked on the pressure relief device in conformance with the AAR Specification for Tank Cars (IBR, see § 171.7 of this subchapter).

* * * * *

PART 174—CARRIAGE BY RAIL

11. The authority citation for part 174 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.53.

§ 174.63 [Amended]

12. In § 174.63(c)(2) is removed and reserved.

PART 179—SPECIFICATIONS FOR TANK CARS

13. The authority citation for part 179 is revised to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.53.

14. In § 179.13, paragraph (b) is revised to read as follows:

§ 179.13 Tank car capacity and gross weight limitation.

* * * * *

(b) Tank cars containing poisonous-by-inhalation material meeting the applicable authorized tank car specifications listed in § 173.244(a)(2) or (3), or § 173.314(c) or (d) may have a gross weight on rail of up to 286,000 pounds upon approval by the Associate Administrator for Railroad Safety, FRA. Tank cars exceeding 263,000 pounds and up to 286,000 pounds gross weight on rail must meet the requirements of AAR Standard S–286, Free/Unrestricted Interchange for 286,000 lb Gross Rail Load Cars (IBR, see § 171.7 of this subchapter). Any increase in weight above 263,000 pounds may not be used to increase the quantity of the contents of the tank car.

15. In Subpart B, add § 179.24 to read as follows:

§ 179.24 Stamping.

(a)(1) After December 31, 2011, to certify compliance with Federal requirements, the tank manufacturer must install two identical permanent identification plates, one located on both inboard surfaces of the ''A'' (*i.e.,* opposite) end of the tank car. One identification plate must be installed on the right side (AR) of the tank car, and the other must be installed on the back end left side (BL) body bolster webs so that each plate is readily accessible for inspection. The plates must be at least 3/32-inch thick and manufactured from corrosion resistant metal. When the tank jacket (flashing) covers the body bolster web and identification plates, additional identical plates must be installed on the AR and BL corners of the tank in a visible location. Tank cars built before December 31, 2011, may have the plate instead of or in addition to the stamping.

(2) Each plate must be stamped, embossed, or otherwise marked by an equally durable method in letters 3/16-inch high with the following information (parenthetical abbreviations may be used, and the AAR form reference is to the AAR Specifications for Tank Cars, December 2000 edition (IBR, see § 171.7 of this subchapter)):

(i) *Tank Manufacturer (Tank MFG):* Full name of the car builder as shown on the certificate of construction (AAR form 4–2).

(ii) *Tank Manufacturer's Serial Number (SERIAL NO):* For the specific car.

(iii) *AAR Number (AAR NO):* The AAR number from line 3 of AAR Form 4–2.

(iv) *Tank Specification (SPECIFICATION):* The specification to which the tank was built from line 7 of AAR form 4–2.

(v) *Tank Shell Material/Head Material (SHELL MATL/HEAD MATL):* ASTM or AAR specification of the material used in the construction of the tank shell and heads from lines 15 and 16 of AAR Form 4–2. For Class DOT–113W, DOT–115W, AAR–204W, and AAR–206W, the materials used in the construction of the outer tank shell and heads must be listed. Only list the alloy (*e.g.,* 5154) for aluminum tanks and the type (*e.g.,* 304L or 316L) for stainless steel tanks.

(vi) *Insulation Material (INSULATION MATL):* Generic names of the first and second layer of any thermal protection/insulation material applied.

(vii) *Insulation Thickness (INSULATION THICKNESS):* In inches.

(viii) *Underframe/Stub Sill Type (UF/SS DESIGN):* The design from Line 32 of AAR Form 4–2.

(ix) *Date of Manufacture (DATE OF MFR):* The month and year of tank manufacture. If the underframe has a different built date than the tank, then show both dates.

(3) When a modification to the tank changes any of the information shown in paragraph (a)(2) of this section, the car owner or the tank car facility making the modification must install an additional variable identification plate on the tank in accordance with paragraph (a)(1) of this section showing the following information:

(i) *AAR Number (AAR NO):* The AAR number from line 3 of AAR Form 4–2 for the alteration or conversion.

(ii) All items of paragraph (a)(2) of this section that were modified, followed by the month and year of modification.

(b) [Reserved]

16. In § 179.100–20, paragraph (b) is added to read as follows:

§ 179.100–20 Stamping.

* * * * *

(b) Authorized DOT tank cars with stainless steel identification plates must have their DOT Specification and other required information stamped plainly and permanently on their identification plate in conformance with the applicable requirements prescribed in § 179.24(a).

17. In § 179.200–24, paragraph (c) is added to read as follows:

§ 179.200–24 Stamping.

* * * * *

(c) Authorized DOT non-pressure tank car tanks with stainless steel identification plates may have their DOT Specification and other required information stamped plainly and permanently on their identification plate instead of into the metal of the tank in conformance with the applicable requirements prescribed in § 179.24(a).

18. In § 179.201–10, paragraph (b) is added to read as follows:

§ 179.201–10 Water capacity marking.

* * * * *

(b) After December 31, 2011, authorized DOT non-pressure tank cars that comply with this section and are equipped with stainless steel identification plates may have the water capacity of the tank in pounds prescribed in the first sentence of paragraph (a) of this section stamped plainly and permanently on their identification plate instead of into the

metal of the tank, or immediately below the stamped marks specified in § 179.200–24(a) in conformance with the applicable marking requirements prescribed in § 179.24(a).

19. In § 179.220–25, the existing text is redesignated as paragraph (a) and paragraph (b) is added to read as follows:

§ 179.220–25 Stamping.

* * * * *

(b) Authorized Class DOT–115 non-pressure tank car tanks with stainless steel identification plates may have their DOT Specification and other required information stamped plainly and permanently on their identification plate instead of into the metal of the tank in conformance with the applicable requirements prescribed in § 179.24(a).

20. In § 179.300–13, paragraph (b) is revised to read as follows:

§ 179.300–13 Venting, loading and unloading valves.

* * * * *

(b) Threads for openings must be National Gas Taper Threads (NGT) tapped to gauge, clean cut, even and without checks. Threads for the clean-out/inspection ports of DOT Specification 110A multi-unit tank car tanks may be straight threads instead of taper threads. The straight threads must meet the requirements of § 178.61(h)(3)(i) and (iii). Taper threads must comply with § 178.61(h)(3)(i) and (ii). Hex plugs may be secured to threaded boss ports using stainless steel safety wire of adequate strength and design for its intended use.

PART 180—CONTINUING QUALIFICATION AND MAINTENANCE OF PACKAGINGS

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

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.53.

22. Revise § 180.501 to read as follows:

§ 180.501 Applicability.

(a) This subpart prescribes requirements, in addition to those contained in parts 107, 171, 172, 173, 174, and 179 of this subchapter, applicable to any person who manufactures, fabricates, marks, maintains, repairs, inspects, or services tank cars to ensure continuing qualification.

(b) This subpart also establishes the minimum acceptable framework for an owner's qualification program for tank cars and components. Owners should follow this subpart in developing their written procedures (work instructions), as required under § 179.7(d), for use by tank car facility employees. The owner's qualification program for each tank car, or a fleet of tank cars, must identify where to inspect, how to inspect, and the acceptance criteria. Tank car facilities must incorporate the owner's qualification program in their quality assurance program, as required under § 179.7(a)(2), (b)(3), and (b)(5).

(c) Any person who performs a function prescribed in this part must perform that function in accordance with this part.

(d) Where, in this subpart, a person is required to make documents available to FRA upon request, such request means that credentialed FRA personnel or an authorized representative of the Department may view the documents and make copies of them. The document owner's may seek confidential treatment of the documents presented. See § 105.30.

23. Revise § 180.503 to read as follows:

§ 180.503 Definitions.

The following definitions and those contained in §§ 171.8 and 179.2 of this subchapter apply:

Corrosive to the tank or service equipment means a material identified in Appendix D of this part or a material when in contact with the inner shell of the tank or service equipment may have a severe corrosion rate on steel or aluminum based on criteria in § 173.137(c)(2).

Defects mean abrasions; corrosion; cracks; dents; flaws in welds; distortions; erosion; missing, damaged, leaking or loose components and fasteners; and other conditions or imperfections that may make a tank car unsafe for transportation and/or require it to be removed from service.

Design level of reliability and safety means the level of reliability and safety built into the tank car and therefore inherent in its specification, design, and manufacture.

Interior heater system means a piping system located within the tank shell that uses a fluid medium to heat the lading for the purposes of unloading.

Lining/Coating owner means the person responsible for bearing the costs of maintaining the lining/coating.

Maintenance means inspection, upkeep, or preservation, including ordinary repairs necessary and proper.

Modification means any change to a tank car that affects the certificate of construction prescribed in § 179.5, including an alteration prescribed in § 179.6, or conversion.

Objectively reasonable and articulable belief means a belief based on particularized and identifiable facts that provide an objective basis to believe or suspect that a tank car or a class or design of tank cars may be in an unsafe operating condition.

Qualification, as relevant to a tank car, means the car conforms to the specification to which it was built or modified, to the requirements of this subpart, to the requirements of the AAR Tank Car Manual (IBR, see § 171.7 of this subchapter) and to the owner's acceptance criteria. Qualification is accomplished by careful and critical examination using inspections and tests based on a written program that verifies conformance, followed by a written representation of that conformance. A tank car that passes the appropriate tests for its specification, has a signed test report, is marked to denote this passage, and is considered qualified for hazardous materials transportation under this subchapter.

Qualification of	Tests and Inspections	§ 180.509(*)
Tank	Visual Inspection	d
	Structural Integrity Inspection	e
	Thickness Test: Note 1	f
	Safety System Inspection	h
	Leakage Pressure Test	j
Service Equipment	Service Equipment	k
Lining/Coating	Linings and Coatings	i

Note 1: Paragraph (f)(2) in *§ 180.509 of this part* may require thickness tests at an interval different from the other items for qualification of the tank.

Railworthy, Railworthiness for a tank car, means that the tank, service equipment, safety systems, and all other components are capable of performing their intended function until their next qualification.

Reactive to the tank or service equipment means a material that, in contact with the inner shell of the tank, or with the service equipment, may react to produce heat, gases, and/or pressure which could substantially reduce the effectiveness of the packaging or the safety of its use.

Reinforced tank shell butt weld means the portion of a butt weld covered by a reinforcing plate.

Reinforcing plate means an attachment welded directly to the tank supporting major structural components for the purpose of preventing damage to the tank through fatigue, overstressing, denting, puncturing, or tearing.

Reliability means the quantified ability of an item or structure to operate without failure for the specified period of its design life or until its next qualification.

Representation means attesting through documenting, in writing or by marking on the tank (or jacket), that a tank car is qualified and railworthy.

Safety system means one or more of the following: thermal protection systems, insulation systems, tank head puncture resistance systems, coupler vertical restraint systems, and systems used to protect discontinuities (*e.g.,* skid protection and protective housings) as required under the HMR.

Service equipment means equipment used for loading and unloading (including an interior heating system), sampling, venting, vacuum relief, pressure relief, and measuring the amount of lading or the lading temperature.

Service equipment owner means the party responsible for bearing the cost of the maintenance of the service equipment.

Tank car owner means the person to whom a rail car's reporting marks are assigned, as listed in the Universal Machine Language Equipment Register (UMLER).

24. In § 180.507, the first sentence in paragraph (b)(2) is revised to read as follows:

§ 180.507 Qualification of tank cars.

* * * * *

(b) * * *

(2) For each tank car conforming to and used under a special permit (exemption) issued before October 1, 1984, which authorized the transportation of a cryogenic liquid in a tank car, the owner or operator must remove the exemption number stenciled on the tank car and mark the tank car with the appropriate Class DOT–113 specification followed by the applicable Special Permit (DOT SP) number. * * *

* * * * *

25. Amend § 180.509 as follows:

a. Revise paragraphs (a), (b)(1), (2), and (4), (c) introductory text heading, and (c)(3);

b. Add paragraphs (d)(1)(i) and (ii);

c. Revise paragraphs (d)(2) through (6);

d. Add paragraph (d)(7);

e. Revise paragraphs (e) and (f);

f. Redesignate paragraph (g)(1) as (g) and revise it;

g. Revise paragraphs (h) through (l); and

h. Add paragraph (m).

The revisions and additions read as follows:

§ 180.509 Requirements for qualification of specification tank cars.

(a) *General.* Each tank car owner must ensure that a tank car facility:

(1) Inspects and tests each item according to the requirements specified in this section;

(2) Evaluates each item according to the acceptable results of inspections and tests specified in § 180.511;

(3) Marks each tank car as specified in § 180.515 for each item that successfully passes an inspection and test, and

(4) Prepares the documentation as required by § 180.517 for each item qualified under this section. A copy of the documentation required by § 180.517 must be sent to the builder or owner as appropriate and according to the builder's or owner's instructions.

(b) *Conditions requiring inspection and test of tank cars.* Without regard to the qualification compliance date requirements of any paragraph of this section, an owner of a tank car or a lining or coating must have an appropriate inspection and test according to the type of defect and the type of maintenance or repair performed if:

(1) The tank car shows evidence of abrasion, corrosion, cracks, dents, distortions, defects in welds, or any other condition that may make the tank car unsafe for transportation,

(2) The tank car was in an accident and shows evidence of damage to an extent that may adversely affect its capability to retain its contents or to otherwise remain railworthy.

* * * * *

(4) The Associate Administrator for Railroad Safety, FRA, requires it based on the existence of an objectively reasonable and articulable belief that a tank car or a class or design of tank cars may be in an unsafe operating condition.

(c) *Frequency of qualification.* * * *

(3) Fusion welded tank cars must be inspected and tested to be qualified and maintained in accordance with the following table. All qualification requirements need not be done at the same time or at the same facility.

Frequency of qualification inspection and tests.

Section 180.509(*)	Description	Maximum interval
d	Visual inspection	10 years.
e	Structural integrity inspection	10 years.
f	Thickness test	See § 180.509(f).
h	Safety Systems	10 years.
i	Lining or coating (for materials corrosive or reactive to the tank) (See definitions at § 180.503)	See § 180.509(i).
j	Leakage pressure test	After reassembly.
k	Service equipment (including pressure relief device)	See § 180.509(k).

(d) * * *

(1) * * *

(i) Except in areas where tank structure, insulation, head protection, thermal protection, internal linings or coatings preclude it, an internal and external inspection of the tank shell and heads for abrasion, corrosion, cracks, dents, distortions, flaws in welds, or any other condition that may make the tank car unsafe for transportation; and

(ii) For DOT 115 class tank cars, an internal inspection of the inner container and external inspection of the outer shell and heads for defects in welds, or any other condition that may

make the tank car unsafe for transportation;

(2) When a lining, coating, head protection, insulation, or thermal protection is removed in part or in whole, the exposed surface, *i.e.,* internal and external, of the tank must be visually inspected for defects in welds, or any other condition that may make the tank car unsafe for transportation. This inspection must precede any application or reapplication of a lining or coating.

(3) An inspection of the service equipment, including gaskets, for indications of corrosion and other conditions that may make the tank car unsafe for transportation;

(4) An inspection for missing or loose bolts, nuts, or elements that may make the tank car unsafe for transportation;

(5) An inspection of all closures on the tank car for conditions that may make the tank car unsafe for transportation, including an inspection of the protective housings for proper condition;

(6) An inspection of excess flow valves with threaded seats for tightness; and

(7) An inspection of the required markings on the tank car for legibility.

(e) *Structural integrity inspections and tests.* (1) Each tank car owner must ensure the structural elements on the tank car qualify with the applicable requirements of this subchapter. At a minimum, the structural integrity inspection and test must include:

(i) All transverse fillet welds greater than 0.64 cm (0.25 inch) within 121.92 cm (4 feet) of the bottom longitudinal centerline except body bolster pad attachment welds;

(ii) The termination of longitudinal fillet welds greater than 0.64 cm (0.25 inch) within 121.92 cm (4 feet) of the bottom longitudinal centerline; and

(iii) The tank shell butt welds within 60.96 cm (2 feet) of the bottom longitudinal centerline, unless the tank car owner can determine by analysis (*e.g.,* finite element analysis, damage-tolerance analysis, or service reliability assessment) that the structure will not develop defects that reduce the design level of safety and reliability or fail within its operational life or prior to the next required inspection. The owner must maintain all documentation used to make such determination at its principal place of business and make the data available to FRA or an authorized representative of the Department upon request.

(2) For DOT 115 class tanks, paragraphs (e)(1)(i—iii) of this section apply only to the outer shell fillet welds and to the non-reinforced exposed outer shell butt welds.

(3) The inspection requirements of paragraph (e)(1)(iii) of this section do not apply to reinforced tank shell butt welds until the time of lining removal or application for tank cars with an internal lead, glass, or rubber lining.

(4) Each tank car facility must inspect and test the elements identified in paragraph (e)(1) of this section by one or more of the following methods:

(i) Dye penetrant testing (PT);

(ii) Radiographic examination (RT);

(iii) Magnetic particle testing (MT);

(iv) Ultrasonic testing (UT); and

(v) Direct, remote, or enhanced visual inspection, using, for example, magnifiers, fiberscopes, borescopes, and/or machine vision technology (VT).

(f) *Thickness tests.* (1) The tank car owner must ensure that each tank car facility measures the thickness of the tank car shell, heads, sumps, domes, and nozzles on each tank car by using a device capable of accurately measuring the thickness to within ±0.05 mm (±0.002 inch).

(2) The tank car owner must ensure that each tank car has a thickness test measurement:

(i) At the time of an internal lining or coating application or replacement, or

(ii) At least once every ten (10) years for a tank that does not have an internal lining or coating, or

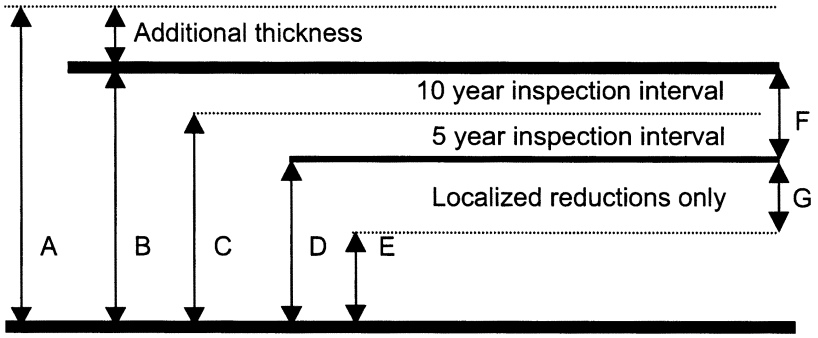
(iii) At least once every five (5) years for a tank that does not have an internal lining or coating when:

(A) The tank is used to transport a material that is corrosive or reactive to the tank (see Appendix D of this part) or service equipment as defined § 180.503, and

(B) The remaining shell and head thickness is at or below line C in Figure A of this paragraph.

Figure A

Tank and Shell Thickness Qualification Frequencies



Where:

A As-built tank shell or head thickness with additional thickness.

B Required minimum tank shell or head thickness after forming per part 179.

C Inspection frequency adjustment point (design minimum shell or head thickness, minus ½ of the table value in paragraph (g) of this section).

D Condemning limit for general corrosion (required minimum shell or head thickness, minus the value in paragraph (g) of this section).

E Condemning limit for localized corrosion (required minimum shell or head thickness, minus the table value in paragraph (g) of this section, minus 1.58 mm (1/16-inch)). See Note 1 in paragraph (g) of this section for diameter limitations and minimum separation distances.

F Allowable shell or head thickness reduction (table value in paragraph (g) of this section).

G Additional thickness reduction for localized areas in paragraph (g) of this section.

(3) For a localized repair of an internal lining or internal coating where a material corrosive to the tank or service equipment as defined § 180.503 has contacted the tank, a qualified individual must verify conformance with paragraph (g) of this section by measuring the shell or head in the area of the repair. The thickness test applies only to the non-lined or coated repaired area, and is not a qualification event.

Modification of the tank stencil is not required.

(4) Operation of a tank car below the condemning limit for general corrosion or the condemning limit for localized corrosion (as shown in Figure A of this section) is prohibited.

(5) For sumps, domes, nozzles, and nozzle reinforcements, the tank car owner must determine if any reduction in wall thickness affects the design levels of reliability and safety built into sump, dome, nozzle, or nozzle reinforcement. Each tank car owner must maintain at its principal place of business documentation describing the allowable thickness reductions for sumps, domes, and nozzles, and nozzle reinforcements. This documentation must be made available to FRA or an authorized representative of the Department upon request.

(6) After repairs, alterations, conversions, modifications, or blasting of tank car that results in a reduction of the tank's thickness, a qualified individual must measure the thickness of the tank in the area of reduced thickness to ensure that the thickness of the tank conforms to paragraph (g) of this section.

(g) *Service life thickness allowance.* A tank car found with a thickness below the required minimum thickness after forming for its specification, as stated in part 179 of this subchapter, may continue in service if any reduction in the required minimum thickness is not more than that provided in the following table:

ALLOWABLE SHELL THICKNESS REDUCTIONS

Marked tank test pressure	Top shell and tank head	Bottom shell
60 psig < 200 psig	3.17 mm	1.58 mm
	1/8 inch	1/16-inch
≥200 psig	0.79 mm	0.79 mm
	1/32 inch	1/32-inch

Note 1. A tank car owner may add an extra 1.58 mm (1/16 inch) to the values in the table for local reductions. Local reductions are those that do not exceed 20.32 linear centimeters (8 linear inches) measured at the longest diameter, and are separated from the other local reductions by at least 40.64 cm (16 inches).

Note 2. Any reduction in the tank car shell thickness may not affect the structural strength of the tank car to the extent that the tank car no longer conforms to Section 6.2 of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter).

Note 3. For DOT 115 class tank cars, shell thickness reductions apply only to the outer shell of the tank car. There is no shell or head thickness reduction authorized for the inner tank.

(h) *Safety system inspections.* Each tank car owner must ensure qualification of the tank car safety systems. However, inspections of foam or cork insulation systems are not required.

(i) *Lining and coating inspection and test.* (1) At a minimum, the owner of a lining or coating applied to protect a tank used to transport a material that is corrosive or reactive to the tank must ensure accomplishment of an inspection adequate to detect defects or other conditions that could reduce the reliability of the tank. In addition, the owner of a lining of tank cars used to transport hazardous materials must ensure the lining complies with § 173.24(b)(2) and (3) of this subchapter.

(2) The owner of the lining or coating must establish and maintain a record of the service life of the lining or coating and commodity combination, that is, the specific hazardous materials that were loaded into a tank and the lining or coating in place at the time of loading. The owner of the lining or coating must use its knowledge of the service life of each lining or coating and commodity combination to establish an appropriate inspection interval for that lining or coating and commodity combination. This interval must not exceed eight (8) years, unless the lining or coating owner can establish, document, and show that the service history or scientific analysis of the lining or coating and commodity pairing supports a longer inspection interval. The owner must maintain at its principal place of business a written procedure for collecting and documenting the life of the lining or coating applied within the tank car. The lining or coating owner must provide this documentation, including inspection and test, repair, removal, and application procedures, to the FRA or car owner upon request. In addition, any person who offers a loaded tank car into transportation must provide commodity information to the car owner and the owner of the lining or coating upon request.

(3) The owner of the lining or coating must provide the test method and acceptance criteria for the lining or coating to the tank car owner and to the person responsible for qualifying the lining or coating. The tank car facility inspecting and testing the lining or coating must follow the inspection and test requirements, including the acceptance requirements, established by the lining or coating owner.

(j) *Leakage pressure test.* Unless the design of the service equipment arrangement precludes it (*e.g.,* there is no fitting to pressurize the tank), each owner of a tank car must ensure that the tank, service equipment, and closures installed, replaced, or reinstalled on the tank car are leak tested. The test may be conducted with the lading in the tank. When the test pressure exceeds the start-to-discharge or burst pressure of a pressure relief device, the device must be rendered inoperative. The written procedures and test method for leak testing must ensure for the sensitivity and reliability of the test method and for the serviceability of components to prevent premature failure. This section does not apply to facilities that remove closures for the sole purpose of loading or unloading the lading (*e.g.,* blind flanges, pipe plugs, *etc.*).

(k) *Service equipment inspection and test.* (1) Each tank car owner must ensure for the qualification of tank car service equipment at least once every ten (10) years. The tank car owner must analyze the service equipment inspection and test results for any given lading and, based on the analysis, adjust the inspection and test frequency to ensure that the design level of reliability and safety of the equipment is met. The owner must maintain at its principal place of business all supporting documentation used to make such analyses and inspection and test frequency adjustments. The supporting documentation must be made available to FRA or an authorized representative of the Department upon request.

(2) Each tank car facility must qualify service equipment, including reclosing pressure relief devices and interior heater systems in accordance with Appendix D of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter).

(l) *Alternative inspection and test procedures.* When approved by the

Associate Administrator for Railroad Safety, FRA, a tank car owner, or a lining or coating owner may use an alternative inspection and test procedure or interval based on a damage-tolerance analysis (that must include a determination of the probable locations and modes of damage due to fatigue, corrosion, and accidental damage), or based on a service reliability assessment (that must be supported by analysis of systematically collected data) in lieu of the other requirements of this section.

(m) *Qualification compliance date for tank cars.* (1) After July 1, 2000, each tank car with a metal jacket or with a thermal protection system must have an inspection and test conforming to this section no later than the date the tank car requires a periodic hydrostatic pressure test (*i.e.,* the marked due date on the tank car for the hydrostatic test).

(2) For insulated or jacketed tank cars on a 20-year periodic hydrostatic pressure test interval (*i.e.,* Class DOT 103W, 104W, 111A60W1, 111A100W1, and 111A100W3 tank cars), the next inspection and the test date is the midpoint between the compliance date in paragraph (m)(1) of this section and the remaining years until the tank would have had a hydrostatic pressure test.

26. In § 180.511, revise the introductory text and paragraphs (d) and (g) and add paragraph (h) to read as follows:

§ 180.511 Acceptable results of inspections and tests.

Provided it conforms to other applicable requirements of this subchapter, a tank car is qualified for use if it successfully passes the inspections and tests set forth below conducted in accordance with this subpart. A representation of that qualification must consist of marking the tank in accordance with § 180.515.

* * * * *

(d) *Safety system inspection.* A tank car successfully passes the safety system inspection when each thermal protection system, tank head puncture resistance system, coupler vertical restraint system, and system used to protect discontinuities (*e.g.,* breakage grooves on bottom outlets and protective housings) on the tank car conform to this subchapter and show no indication of a defect that may reduce reliability before the next inspection and test interval.

* * * * *

(g) *Hydrostatic test.* A Class 107 tank car, the inner tank of a Class 115 tank car, or a riveted tank car successfully passes the hydrostatic test when it shows no leakage, distortion, excessive permanent expansion, or other evidence of weakness that might render the tank car unsafe for transportation service.

(h) *Service equipment.* A tank car successfully passes the service equipment inspection and test when this equipment equipment conforms to this subchapter and AAR Appendix D (IBR, see § 171.7 of this subchapter) and shows no indication of a defect that may reduce reliability before the next inspection and test interval.

27. Revise § 180.513 to read as follows:

§ 180.513 Repairs, alterations, conversions, and modifications.

(a) To work on tank cars, a tank car facility must comply with the applicable requirements of this subpart, the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter), and the owner's requirements.

(b) An owner of a tank car or component is responsible for ensuring that each tank car facility complies with the owner's maintenance program by conducting periodic analyses and surveillance activities.

(c) Unless the exterior tank car shell or interior tank car jacket has a protective coating, after a repair that requires the complete removal of the tank car jacket, the exterior tank car shell and the interior tank car jacket must have a protective coating applied to prevent the deterioration of the tank shell and tank jacket. Previously applied coatings that still provide effective protection need not be covered over.

(d) After repair, replacement, or qualification of tank car service equipment, the tank service equipment must successfully pass the leak test prescribed in § 180.509(j).

28. Revise § 180.515 to read as follows:

§ 180.515 Markings.

(a) When a tank car passes the required inspection and test with acceptable results, the tank car facility must mark the date of the inspection and test and the due date of the next inspection and test qualified on the tank car in accordance with Appendix C of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter). When a tank car facility performs multiple inspections and tests at the same time, one date may be used to satisfy the requirements of this section. One date also may be shown when multiple inspections and test have the same due date. Dates displayed on the ''consolidated stencil'' (see Appendix C of the AAR specifications for Tank Cars) take precedence over dates modified, and not stenciled, pursuant to interval adjustments for service equipment, linings, and granted alternative inspection intervals.

(b) Converted DOT 105, 109, 112, 114, or 120 class tank cars must have the new specification and conversion date permanently marked in letters and figures at least 0.95 cm (0.375 inch) high on the outside of the manway nozzle or the edge of the manway nozzle flange on the left side of the car. The marking may have the last numeral of the specification number omitted (*e.g.,* ''DOT 111A100W'' instead of ''DOT 111A100W1'').

(c) When qualified within six months of installation and protected from deterioration, the test date marking of a reclosing pressure relief device is the installation date on the tank car.

29. In § 180.517, revise paragraph (a), paragraph (b) introductory text, and paragraphs (b)(3). (4), and (7), and add paragraph (b)(8) to read as follows:

§ 180.517 Reporting and record retention requirements.

(a) *Certification and representation.* Each owner of a specification tank car must retain the certificate of construction (AAR Form 4–2) and related papers certifying that the manufacture of the specification tank car identified in the documents is in accordance with the applicable specification. The builder's signature on the certificate of construction, and the marking of the tank car with the tank specification is the representation that all of the appropriate inspections and tests were successfully performed to qualify the tank for use. The owner must retain the documents throughout the period of ownership of the specification tank car and for one year thereafter. Upon a change of ownership, the requirements in Section 1.3.15 of the AAR Specifications for Tank Cars (IBR, see § 171.7 of this subchapter) apply. The builder of the car or a facility performing work on the car may retain copies of relevant records.

(b) *Inspection and test reporting.* Each tank car that is inspected and tested as specified in § 180.509 must have a written report, in English, prepared according to this paragraph. For qualification inspections and tests performed after initial service, marking the tank car with the specification (or retaining the specification marking on the tank) is the representation that all of the appropriate inspections and tests were successfully performed to qualify the car for continued use. The report may be created and retained electronically, but, upon request by FRA for a copy of the report, it must be made

available in common readable form. The owner must retain a copy of the inspection and test reports until successfully completing the next inspection and test of the same type. The inspection and test report must include the following:

* * * * *

(3) Tank car reporting mark and number;

(4) Tank car specification;

* * * * *

(7) The name and address of the tank car facility and the name and signature of inspector; and

(8) The unique code (station stencil) identifying the facility.

30. Add Appendix D to Part 180 to read as follows:

Appendix D to Part 180—Hazardous Materials Corrosive to Tanks or Service Equipment

This list contains materials identified either by proper shipping name in 49 CFR 172.101 or shipped under an ''n.o.s.'' shipping description that, under certain conditions, can corrode carbon steel tanks or service equipment at a rate that will reduce the design level of reliability and safety of the tank or equipment to an unsafe level before the next qualification. Materials identified on this list are considered corrosive to the tank or service equipment.

While every effort was made to identify materials deemed corrosive to the tank or service equipment, owners and operators are cautioned that this list may not be inclusive. Tank car owners and operators are reminded of their duty to ensure that no in-service tank will deteriorate below the specified minimum thickness requirements in this subchapter. See § 180.509(f)(3). In addition, FRA states a tank car owner must designate an interior coating or lining appropriately based on their knowledge of the chemical and not rely simply on this list. Regarding future thickness tests, this list may also be modified based on an analysis of the test results by the car owner, the Department of Transportation, or the Association of American Railroads' Tank Car Committee.

Hazardous Materials Table Proper Shipping Names (See § 172.101)

Acetic acid, glacial *or* Acetic acid solution
Aluminum chloride, solution
Arsenic acid, liquid
Arsenic acid, solid
Butyric acid
Ferric chloride, solution
Fertilizer ammoniating solution (*Nitrogen fertilizer solution*)
Fluoroboric acid
Fluorosilicic acid
Formaldehyde, solutions, flammable
Formaldehyde, solutions
Hydrobromic acid
Hydrochloric acid Hydrochloric acid solution
Hydrofluoric acid and Sulfuric acid mixtures
Hydrofluoric acid
Hydrogen peroxide and peroxyacetic acid mixtures, stabilized
Hydrogen, peroxide, aqueous solutions
Hydrogen peroxide, stabilized *or* Hydrogen peroxide aqueous solutions, stabilized
Hypochlorite solutions
Methyl methacrylate monomer, stabilized
Nitric acid
Phenyl phosphorus dichloride
Phenyl phosphorus thiodichloride
Phosphoric acid solution
Phosphoric acid, solid
Phosphorus trichloride (*Phosphorus chloride*)
Sodium chlorate
Sodium chlorate, aqueous solution
Sodium hydrosulfide
Sulfur, molten
Sulfuric acid
Sulfuric acid, fuming
Sulfuric acid, spent
Zinc chloride, anhydrous
Zinc chloride, solution

Materials Transported Under an ''N.O.S.'' Description

Benzoic acid (Environmentally hazardous substance, liquid, n.o.s., (RQ 5,000 pounds)
Bisulphites, aqueous solution, n.o.s. (Ammonium bisulfide)
Black liquor (Corrosive liquids, n.o.s. (contains sulfuric acid))
Calcium lignosulfonate (not regulated under this subchapter)
Hexanoic acid (Corrosive liquids, n.o.s. (contains hexanoic acid))
Lignin liquor (not regulated under this subchapter)
Lithium chloride (not regulated under this subchapter)
Sodium polyacrylate (not regulated under this subchapter)
Titanium sulfate solution (Corrosive liquids, n.o.s. (contains sulfuric acid))
White liquor (not regulated under this subchapter)

Issued in Washington, DC, on August 10, 2011 under authority delegated in 49 CFR part 106.

R. Ryan Posten,

Senior Director for Hazardous Materials Safety.

[FR Doc. 2011–20863 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–60–P

Notices

Federal Register

Vol. 76, No. 160

Thursday, August 18, 2011

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Document No. AMS–FV–11–0050, FV–11–326]

United States Standards for Grades of Grapefruit Juice

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Agricultural Marketing Service (AMS), prior to undertaking research and other work associated with revising official U.S. grade standards, is soliciting comments on a request to revise the United States Standards for Grades of Grapefruit Juice. AMS received a petition from the Florida Citrus Processors Association asking AMS to consider revising the current U.S. grade standards for grapefruit juice to account for advances in industry processing technology.

DATES: Comments must be received by October 17, 2011.

ADDRESSES: Interested persons are invited to submit written comments on the Internet at *http://www.regulations.gov* or to Brian E. Griffin, Inspection and Standardization Section, Processed Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 0709, South Building; STOP 0247, Washington, DC 20250; telephone (202) 720–4693; fax (202) 690–1527, e-mail *brian.griffin@ams.usda.gov.* Comments should make reference to the date and page number of this issue of the **Federal Register** and will be made available for public inspection at the above office during regular business hours.

Please be advised that all comments submitted in response to this notice will be included in the record and will be made available to the public on the Internet via *http://www.regulations.gov.* Also, the identity of the individuals or entities submitting the comments will be made public. The U.S. Standards for Grades of Grapefruit Juice identified in this notice are available either at the above address or by accessing the AMS Web site at: *http://www.ams.usda.gov/processedinspection.*

FOR FURTHER INFORMATION CONTACT: Brian E. Griffin, Inspection and Standardization Section, Processed Products Branch, Agricultural Marketing Service, U.S. Department of Agriculture, telephone (202) 720–5021; or fax (202) 690–1527.

SUPPLEMENTARY INFORMATION:

Background

AMS received a petition from the Florida Citrus Processors Association, an association of citrus producers, requesting revisions to the United States Standards for Grades of Grapefruit Juice. These standards are issued under the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627). The petitioners are requesting the removal of the maximum limit for ''free and suspended pulp'' (referred to in the industry as ''sinking pulp'') from the U.S. grade standards for all forms of grapefruit juice.

The current grade standards, effective since September 12, 1983, provide that grapefruit juice from concentrate, grapefruit juice, and frozen concentrated grapefruit juice establish limits for maximum free and suspended pulp as follows: Grade A—10 percent by volume, Grade B—15 percent by volume. Concentrated grapefruit juice for manufacturing requirements for maximum free and suspended pulp are as follows: Grade A—10 percent by volume, and Grade B—12 percent by volume.

The petitioners believe that, with respect to maximum values for free and suspended pulp, the existing U.S. Standards for Grades of Grapefruit Juice do not take into account modern extraction and finishing technologies, nor are they supported by evidence of a correlation between these criteria and acceptable flavor. The petitioners are requesting that AMS revise the U.S. Standards for Grades of Grapefruit Juice by removing any parameters for maximum free and suspended pulp.

The petitioners believe that removing the free and suspended pulp values from the grade standards would allow processors to process the entire grapefruit crop without resorting to expensive technologies that increase the cost of juice with no concomitant benefit. More mature grapefruit tends to be sweeter, but when juiced tends to cause the product to exceed maximum free and suspended pulp values. The petitioners have submitted research data covering a six-season period which illustrates levels of sinking pulp vs. naringin, and levels of sinking pulp vs. limonin using various extractor setups. The petitioners have also submitted data on a sensory evaluation performed by the University of Florida on consumer acceptability of grapefruit juice with two free and suspended pulp levels. A copy of the petitioner's request and supporting documentation is located on the Internet at *http://www.regulations.gov* along with the current U.S. Standards for Grades of Grapefruit Juice.

Agricultural Marketing Service

AMS is soliciting comments on the proposed revision of the U.S. Standards for Grades of Grapefruit Juice. In particular, AMS would welcome comments and information regarding the probable impact on processors and growers. Further details are provided in the petition and are available from Brian E. Griffin at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section or can be found on the Internet at *http://www.regulations.gov.* This notice provides for a 60-day comment period for interested parties to comment on the proposed revision of the U.S. Standards for Grades of Grapefruit Juice.

Authority: 7 U.S.C. 1621–1627.

Dated: August 10, 2011.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2011–20787 Filed 8–17–11; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Forest Service

Mendocino Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Mendocino County Resource Advisory Committee will meet September 16, 2011 (RAC) in Willits, California. Agenda items to be covered include: (1) Approval of minutes, (2) Handout Discussion (3) Public Comment, (4) Financial Report (5) Sub-committees (6) Matters before the group (7) Discussion—approval of projects (8) Next agenda and meeting date.

DATES: The meeting will be held on September 16, 2011, from 9 a.m. until 12 noon.

ADDRESSES: The meeting will be held at the Mendocino County Museum, located at 400 E. Commercial St. Willits, California.

FOR FURTHER INFORMATION CONTACT: Roberta Hurt, Committee Coordinator, USDA, Mendocino National Forest, Covelo Ranger District, 78150 Covelo Road, Covelo, CA 95428. (707) 983–6658; *e-mail: windmill@willitsonline.com.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Persons who wish to bring matters to the attention of the Committee may file written statements with the Committee staff by September 10, 2011. Public comment will have the opportunity to address the committee at the meeting.

Dated: August 11, 2011.

Lee Johnson,

Designated Federal Official.

[FR Doc. 2011–21059 Filed 8–17–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Butte County Resource Advisory Committee (RAC)

AGENCY: Forest Service, USDA.

ACTION: Notice of Meeting.

SUMMARY: The Butte County Resource Advisory Committee (RAC) will hold a meeting on August 29, 2011 in Oroville, CA. The purpose of the meeting is to review Cycle 2 project applications for potential funding recommendations to Lassen, Plumas or Mendocino National Forest Supervisors. The funding is made available under Title II provisions of the Secure Rural Schools and Community Self-Determination Act of 2000. This is the last cycle of funding under the current legislation.

DATES & ADDRESSES: The meeting will take place from 6:30–9 p.m. at the Feather River Ranger District Office, 875 Mitchell Avenue, Oroville, CA.

FOR FURTHER INFORMATION CONTACT: (or for special needs): Lee Anne Schramel Taylor, Forest Coordinator, USDA, Plumas National Forest, P.O. Box 11500/159 Lawrence Street, Quincy, CA 95971; (530) 283–7850; or by e-mail *eataylor@fs.fed.us.* Other RAC information may be obtained at *http://www.fs.usda.gov* and *http://www.fs.fed.us/srs.*

Dated: August 11, 2011

Laurence Crabtree,

Deputy Forest Supervisor.

[FR Doc. 2011–21119 Filed 8–17–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Notice of Funds Availability for Section 514 Farm Labor Housing Loans and Section 516 Farm Labor Housing Grants for Off-Farm Housing for Fiscal Year (FY) 2011

AGENCY: Rural Housing Service, USDA.

ACTION: Notice; correction.

SUMMARY: This notice corrects the scoring points available to a Notice published in the **Federal Register** on July 7, 2011 regarding Funds Availability for Section 514 Farm Labor Housing Loans and Section 516 Farm Labor Housing Grants for Off-Farm Housing for FY 2011. The correction changes the scoring under section VI. Pre-Application Review Information, (A)(1)(v)(b) entitled Energy Conservation for Purchase and Substantial Rehabilitation for an existing non-Farm Labor Housing (FLH) property. The scoring has changed to increase the maximum points from 16 points to 32 points.

FOR FURTHER INFORMATION CONTACT: Mirna Reyes-Bible, Finance and Loan Analyst, Multi-Family Housing Preservation and Direct Loan Division, STOP 0781 (Room 1263–S), USDA Rural Development, 1400 Independence Avenue, SW., Washington, DC 20250–0781, *telephone:* (202) 720–1753 (This is not a toll free number), or via *e-mail: Mirna.ReyesBible@wdc.usda.gov.* If you have questions regarding Net Zero Energy Consumption and Energy Generation please contact Carlton Jarratt, Finance and Loan Analyst, Multi-Family Housing Preservation and Direct Loan Division at (804) 287–1524 or via *e-mail: carlton.jarrat@wdc.usda.gov.*

Correction

In the notice beginning on page 39,813 in the issue of July 7, 2011, make the following correction under paragraph (b) entitled Energy Conservation for Purchase and Substantial Rehabilitation for an existing non-FLH property. In the first column for page 39,818 replace the entire paragraph (b) with the following:

(b) *Energy Conservation for Purchase and Substantial Rehabilitation of an Existing Multifamily Property (maximum 32 points).* Pre-applications for the purchase and substantial rehabilitation of non-program MFH and related facilities in rural areas may be eligible to receive 32 points for the following initiatives:

Note: If you are participating in (1) The Green Communities program, you may not receive additional points for items listed under (2). In other words, you may participate in (1) and (3) or (2) and (3), but not all three:

(1) Participation in the Green Communities program by the Enterprise Community Partners, *http://www.enterprisecommunity.org,* will be awarded 30 points for any project that qualifies for the program. (30 points) At least 30 percent of the points needed to qualify for the Green Communities program must be earned under the Energy Efficiency section of the Green Communities qualification program; *or*,

(2) Energy conservation points can be awarded for the following energy conservation measures only when the applicant is not enrolled in Green Communities and conservation measures are listed in the preliminary plans for substantial rehabilitation. (maximum 20 points).

- Replacement of heating, ventilation and air conditioning (HVAC) equipment with Energy Star qualified heating, HVAC equipment. (3 points).
- Replacement of windows and doors with Energy Star qualified windows and doors. (3 points).
- Additional insulation is added to the property to exceed the required R–Value of those building elements in that area of the country per the International Energy Conservation Code 2009. Two points will be awarded if all exterior walls exceed insulation code and 1 point will be awarded if attic insulation exceeds code for a maximum of 3 points. (maximum 3 points).
- Reduction in building shell air leakage by at least 15 percent as determined by pre- and post-rehabilitation blower door testing on a sample of units. Building shell air leakage may be reduced through materials such as caulk, spray foam, gaskets, and house-wrap. Sealing of duct work with mastic, foil-backed tape, or aerosolized duct sealants can also help reduce air leakage. (3 points).

• 100 percent of installed appliances and exhaust fans are Energy Star qualified. (2 points).

• 100 percent of installed water heaters as Energy Star qualified. (2 points).

• 100 percent of toilets with flush capacity of more than 1.6 gallon flush capacity are replaced with new toilets with 1.6 gallon capacity or less, with Environmental Protection Agency (EPA) Water Sense label. (1 point).

• 100 percent of showerheads are replaced with new showerheads with EPA Water Sense label. (1 point).

• 100 percent of faucets are replaced with new faucets with EPA Water Sense label. (1 point).

• 100 percent Energy-efficient lighting including Energy Star qualified fixtures, compact fluorescent replacement bulbs in standard incandescent fixtures, and Energy Star Ceiling Fans. (1 point); *and*,

(3) Participation in local green/energy efficient building standards. Applicants, who participate in a city, county or municipality program, will receive an additional 2 points. The applicant should be aware of and look for additional requirements that are sometimes embedded in the third-party program's rating and verification systems. (2 points).

Dated: August 11, 2011.

Robert Lewis,,

Acting Administrator, Housing and Community Facilities Programs.

[FR Doc. 2011–21013 Filed 8–17–11; 8:45 am]

BILLING CODE 3410–XV–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

On Behalf of the Accessibility Committee of the Federal Chief Information Officers Council; Listening Session Regarding Improving the Accessibility of Government Information

AGENCY: Federal Chief Information Officers Council, Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of meeting.

SUMMARY: This notice announces a listening session that the Federal Chief Information Officers Council will be conducting to hear from the public on ways the federal government can take stronger steps toward improving the acquisition and implementation of accessible technology for people with disabilities. In order to better understand the needs of diverse communities, the Federal Chief Information Officers Council, in collaboration with the Chief Acquisition Officers Council, the General Services Administration Office of Governmentwide Policy, and the U.S. Access Board, will hold a virtual listening session, where participants may either call in or log onto a Web site to participate and express concerns and propose ideas.

DATES: The listening session will be held on September 8, 2011 from 2 p.m. to 5 p.m. Eastern Time (E.T.).

ADDRESSES: The listening session will be held by telephone and online. Instructions on how to participate are at: *http://www.access-board.gov/sec508/session-instructions.htm.*

FOR FURTHER INFORMATION CONTACT: Tim Creagan, Office of Technical and Information Services, Architectural and Transportation Barriers Compliance Board, 1331 F Street, NW., Suite 1000, Washington, DC 20004–1111. Telephone (202) 272–0016 (voice) or (202) 272–0074 (TTY). e-mail address *creagan@access-board.gov.*

SUPPLEMENTARY INFORMATION: In 1998, Congress amended the Rehabilitation Act of 1973 to require Federal agencies to make their electronic and information technology accessible to people with disabilities. Inaccessible technology interferes with an ability to obtain and use information quickly and easily. Section 508 of the Rehabilitation Act (29 U.S.C. 794d) was created to eliminate barriers in information technology, open new opportunities for people with disabilities, and encourage development of technologies that will help achieve these goals. The law applies to all federal agencies when they develop, procure, maintain, or use electronic and information technology. Under Section 508, agencies must give employees with disabilities and members of the public with disabilities access to information that is comparable to access available to others without disabilities.

Effective implementation of Section 508 is an essential element of President Obama's principles of open government, requiring that all government and data be accessible to all citizens. In order for the goal of open government to be meaningful for persons with disabilities, technology must also be accessible, including digital content.

On July 19, 2010, the Office of Management and Budget (OMB) took steps to assure that the Federal government's progress in implementing Section 508 is stronger and achieves results more quickly by releasing a memorandum to agencies, titled ''Improving the Accessibility of Government Information'' (see *http://www.whitehouse.gov/sites/default/files/omb/assets/procurement_memo/improving_accessibility_gov_info_07192010.pdf*).

The OMB has directed that a series of listening sessions be held to gain feedback on ways to improve Section 508 performance. The Federal Chief Information Officers Council, in collaboration with the Chief Acquisition Officers Council, the General Services Administration Office of Governmentwide Policy, and the U.S. Access Board, have held four listening sessions to engage citizens and federal employees and hear their concerns and ideas. Transcripts from the previous listening sessions can be found on the Federal Chief Information Officers Council Accessibility Committee webpage (*http://www.cio.gov/pages.cfm/page/Listening-Sessions*). This final listening session will be a virtual session, where participants may either call in or log onto a website to participate. The listening session will focus on what steps the federal government can take to increase the accessibility and usability of government information and data for persons with disabilities. Input from private industry is sought on the following questions:

• What is private industry doing to implement information technology (IT) accessibility that the federal government should follow?

• How can implementation of Section 508 be improved?

• What could the federal government ask for that would allow vendors to better show that their products meet accessibility provisions?

• What support do newly emerging technology companies need to build in accessibility in their product and service offerings?

Input is also sought on the following questions:

• What can the federal government do to use technology better or in new ways?

• What can the federal government do to make technology more accessible?

• What emerging technologies does the federal government use that you cannot?

• What technologies should the federal government use that would enhance your interactions with government agencies?

• What are state and local governments doing to implement information technology accessibility that the federal government should follow?

• What is academia doing to implement IT accessibility that the federal government should follow?

• What can the federal government do to influence technology accessibility?

• What can the federal government do to support the availability of effective communities of practice on IT accessibility?

• Would the IT industry benefit from a professional certification or credential that denotes a company's expertise in accessibility? If so, how could it be implemented and what role should the government play?

Feedback from the listening session will be used by, and shared across agencies to improve accessibility and usability of electronic and information technology. The listening session will be accessible. Computer assisted real-time transcription (CART) will be provided. Persons wishing to participate in the virtual listening session can either call in and speak their comments over the telephone or go online and type them on the afternoon of the listening session. Callers should dial 1–877–939–0745 and then enter 51300082 # to join the session; callers must use a touch-tone telephone. Persons going online should go to the Access Board's Web site at *http://www.access-board.gov/sec508/session-instructions.htm* for instructions.

David M. Capozzi,

Executive Director.

[FR Doc. 2011–21144 Filed 8–17–11; 8:45 am]

BILLING CODE 8150–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Pacific Islands Region Vessel and Gear Identification Requirements.

OMB Control Number: 0648–0360.

Form Number(s): NA.

Type of Request: Regular submission (revision and extension of a current information collection).

Number of Respondents: 295.

Average Hours per Response: Vessel marking, 45 minutes or 75 minutes, depending on type of vessel; gear-marking, 2 minutes per each piece of gear.

Burden Hours: 1,110.

Needs and Uses: This request is for revision and extension of a current information collection.

Regulations at 50 CFR part 665, and at 50 CFR part 300 subparts D and O, require that all vessels (and their gear) with permits issued under authority of the National Marine Fishery Service's (NMFS) Fishery Management Plan for United States (U.S.) Pacific Island Region Fisheries display the vessel's official number. The numbers must be of a specific size and format and located at specified locations. The display of the identifying number aids in fishery law enforcement.

Affected Public: Business or other for-profit organizations.

Frequency: Annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: *OIRA_Submission@omb.eop.gov.*

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov.*

Dated: August 15, 2011.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–21037 Filed 8–17–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Alaska Prohibited Species Donation Program.

OMB Control Number: 0648–0316.

Form Number(s): NA.

Type of Request: Regular submission (revision and extension of a current information collection).

Number of Respondents: 1.

Average Hours per Response: 40.

Burden Hours: 13.

Needs and Uses: This request is for revision and extension of a currently approved information collection.

A prohibited species donation (PSD) program for Pacific salmon and Pacific halibut has effectively reduced regulatory discard of salmon and halibut by allowing fish that would otherwise be discarded to be donated to needy individuals through tax-exempt organizations. Vessels and processing plants participating in the donation program voluntarily retain and process salmon and halibut bycatch. An authorized, tax-exempt distributor, chosen by NMFS, is responsible for monitoring the retention and processing of fish donated by vessels and processors. The authorized distributor also coordinates the processing, storage, transportation, and distribution of salmon and halibut.

The PSD program requires a collection-of-information so that the National Marine Fisheries Service (NMFS) can monitor the authorized distributors' ability to effectively supervise program participants and ensure that donated fish are properly processed, stored, and distributed.

Affected Public: Not-for-profit institutions.

Frequency: Every three years.

Respondent's Obligation: Voluntary.

OMB Desk Officer: *OIRA_Submission@omb.eop.gov.*

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov.*

Dated: August 15, 2011.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–21038 Filed 8–17–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of

information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Annual Retail Trade Survey.

OMB Control Number: 0607–0013.

Form Number(s): . SA–44, SA–44A, SA–44C, SA–44E, SA–44N, SA–44S, SA–45, SA–45C, SA–721A, SA–721B, SA–721E, SA–721F, SA–722A and SA–722E.

Type of Request: Revision of a currently approved collection.

Burden Hours: 33,416.

Number of Respondents: 21,775.

Average Hours per Response: 1 hour and 32 minutes.

Needs and Uses: The Annual Retail Trade Survey (ARTS) covers employer firms with establishments located in the United States and classified in retail trade and/or accommodation and food services sector as defined by the North American Industry Classification System (NAICS). The survey requests firms to provide annual sales, e-commerce sales, year-end inventories held inside and outside the United States, total operating expenses, purchases, and accounts receivable. We also request, for selected industries, sales by merchandise line, percent of sales by class of customer, and percent of e-commerce sales to customers located outside the United States. These data are collected to provide a sound statistical basis for the formation of policy by various government agencies, as well as to serve as a benchmark for the estimates compiled from the Monthly Retail Trade Report (OMB No. 0607–0717). Results will be made available, at the United States summary level, for selected retail trade, accommodation and food services industries approximately fifteen months after the end of the reference year.

For the 2011 ARTS the Census Bureau will request two years of data to link our old and new samples, ensuring that our published estimates continue to be reliable and accurate. For the 2012 ARTS the Census Bureau will request data on detailed operating expenses. These data items were previously requested under a separate supplemental mailing that was conducted every 5 years. The last supplemental mailing was conducted in conjunction with the 2007 ARTS under OMB No. 0607–0942. While the retail portion of that program will be collapsed into the ARTS, we will continue to ask only the additional detailed expense questions every 5 years.

The Bureau of Economic Analysis (BEA) uses the data to estimate the change in private inventories component of gross domestic product (GDP) and output in both the benchmark and annual input-output (I–O) accounts and GDP by industry. Data on sales taxes are also used to prepare estimates of GDP by industry and to derive industry output for the I–O accounts. Data on detailed operating expenses, which will now be collected on this survey quinquennially, are used to produce national estimates of value added, gross output, and intermediate inputs and serve as a benchmark for the annual industry accounts, which provide the control totals for the GDP-by-state accounts. The Bureau of Labor Statistics uses the data as input to its Producer Price Indexes and in developing productivity measurements. Private businesses use the estimates in computing business activity indexes. Other government agencies and businesses use the data to satisfy a variety of public and business needs such as economic market analysis, company performance, and forecasting future demands.

Affected Public: Business or other for-profit.

Frequency: Annually.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C., Sections 182, 224, and 225.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or e-mail (*bharrisk@omb.eop.gov*).

Dated: August 15, 2011.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–21086 Filed 8–17–11; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Survey of Housing Starts, Sales, and Completions.

OMB Control Number: 0607–0110.

Form Number(s): SOC–QI/SF.1, SOC–QI/MF.1.

Type of Request: Extension of a currently approved collection.

Burden Hours: 14,630.

Number of Respondents: 22,200.

Average Hours per Response: 5 minutes.

Needs and Uses: The U. S. Census Bureau is requesting an extension of the currently approved collection for the Survey of Housing Starts, Sales, and Completions, otherwise known as the Survey of Construction (SOC). Government agencies and private companies use statistics from SOC to monitor and evaluate the large and dynamic housing construction industry. Data for two principal economic indicators are produced from the SOC: New Residential Construction (housing starts and housing completions) and New Residential Sales. In addition, a number of other statistical series are produced, including extensive information on the physical characteristics of new residential buildings, and indexes measuring rates of inflation in the price of new buildings. These statistics are based on a sample of residential buildings in permit-issuing places and a road canvass in a sample of land areas not covered by building permit systems.

Census Bureau field representatives (FRs) mail forms SOC–QI/SF.1 and SOC–QI/MF.1 to new respondents to complete. A few days later, the FRs either call or visit the respondents to enter their survey responses into a laptop computer using the Computer Assisted Personal Interviewing (CAPI) software. The respondents are home builders, real estate agents, rental agents, or new homeowners of sampled residential buildings. FRs contact respondents multiple times based on the number of projects in the sample and the number of months required to complete the project.

The Census Bureau uses the information collected in the SOC to publish estimates of the number of new residential housing units started, under construction, completed, and the number of new houses sold and for sale. The Census Bureau also publishes many financial and physical characteristics of new housing units. Government agencies use these statistics to evaluate economic policy, measure progress towards the national housing goal, make policy decisions, and formulate

legislation. For example, the Board of Governors of the Federal Reserve System uses data from this survey to evaluate the effect of interest rates in this interest-rate sensitive area of the economy. The Bureau of Economic Analysis uses the data in developing the Gross Domestic Product (GDP). The private sector uses the information for estimating the demand for building materials and the many products used in new housing and to schedule production, distribution, and sales efforts. The financial community uses the data to estimate the demand for short-term (construction loans) and long-term (mortgages) borrowing.

Affected Public: Individuals or households; business or other for-profit.

Frequency: Monthly.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Sections 131 and 182.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or e-mail (*bharrisk@omb.eop.gov*).

Dated: August 15, 2011.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–21138 Filed 8–17–11; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Annual Wholesale Trade Survey.

OMB Control Number: 0607–0195.

Form Number(s): Forms SA–42, SA–42A, SA–42(MSBO), SA–42A(MSBO), SA–42(AGBR), SA–42A(AGBR).

Type of Request: Revision of a currently approved collection.

Burden Hours: 10,442.

Number of Respondents: 8,176.

Average Hours per Response: 1 hour and 16 minutes.

Needs and Uses: The Annual Wholesale Trade Survey (AWTS) covers employer firms with establishments located in the United States and classified in wholesale trade as defined by the North American Industry Classification System (NAICS). This sector comprises two main types of wholesalers: (1) Merchant wholesalers that sell goods on their own account (including sales offices and sales branches, except retail stores, maintained by manufacturing, refining, or mining enterprises apart from their plants or mines for the purpose of marketing their products) and (2) business to business electronic markets, agents, and brokers that arrange sales for purchases for others generally for a commission or fee.

Respondents are separated into three classifications: (1) Merchant wholesale establishments, excluding manufacturers' sales branches and offices; (2) manufacturers' sales branches and offices; and (3) agents, brokers, and business to business electronic markets. The first classification is asked to provide sales, e-commerce, inventories, method of inventory valuation, inventories held outside the United States, purchases, and operating expenses. The second classification is asked to provide sales, e-commerce, inventories, method of inventory valuation, inventories held outside the United States, and operating expenses. The third classification is asked to provide commissions, sales on their own account, and operating expenses. These data are collected to provide a sound statistical basis for the formation of policy by various government agencies, as well as to serve as a benchmark for the estimates compiled from the Monthly Wholesale Trade Survey (OMB No. 0607–0190). Results will be made available, at the United States summary level, for selected wholesale industries approximately fourteen months after the end of the reference year.

For the 2011 AWTS the Census Bureau will request two years of data to link our old and new samples, ensuring that our published estimates continue to be reliable and accurate. For the 2012 AWTS the Census Bureau will request data on detailed operating expenses. These data items were previously requested under a separate supplemental mailing that was conducted every 5 years. The last supplemental mailing was conducted in conjunction with the 2007 AWTS under OMB No. 0607–0942. While the wholesale portion of that program will be collapsed into the AWTS, we will continue to ask only the additional detailed expense questions every 5 years. These detailed expense questions are only applicable to the merchant wholesale establishments, excluding manufacturers' sales branches and offices. Additionally, the 2012 AWTS will collect data on sales taxes, which is done once every 5 years.

The Bureau of Economic Analysis (BEA) uses the data to estimate the change in private inventories component of gross domestic product (GDP) and output in both the benchmark and annual input-output (I–O) accounts and GDP by industry. Data on sales taxes, which are collected on this survey quinquennially, are also used to prepare estimates of GDP by industry and to derive industry output for the I–O accounts. Data on detailed operating expenses, which will now be collected on this survey quinquennially, are used to produce national estimates of value added, gross output, and intermediate inputs and serve as a benchmark for the annual industry accounts, which provide the control totals for the GDP-by-state accounts. The Bureau of Labor Statistics uses the data as input to its Producer Price Indexes and in developing productivity measurements. Private businesses use the estimates in computing business activity indexes. Other government agencies and businesses use the data to satisfy a variety of public and business needs such as economic market analysis, company performance, and forecasting future demands.

Affected Public: Business or other for-profit.

Frequency: Annually.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C., Sections 182, 224, and 225.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or e-mail (*bharrisk@omb.eop.gov*).

Dated: August 15, 2011.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–21091 Filed 8–17–11; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Survey of Residential Building or Zoning Permit Systems.

OMB Control Number: 0607–0350.

Form Number(s): C–411(V), C–411(M), C–411(C).

Type of Request: Revision of a currently approved collection.

Burden Hours: 500.

Number of Respondents: 2,000.

Average Hours per Response: 15 minutes.

Needs and Uses: The Census Bureau produces statistics used to monitor activity in the large and dynamic construction industry. These statistics help state and local governments and the federal government, as well as private industry, to analyze this important sector of the economy. The accuracy of the Census Bureau statistics regarding the amount of construction authorized depends on data supplied by building and zoning officials throughout the country. The Census Bureau uses Form C–411 to obtain information from state and local building permit officials needed for updating the universe of permit-issuing places which serves as the sampling frame for the Report of Privately-Owned Residential Building or Zoning Permits Issued (OMB number 0607–0094), also known as the Building Permits Survey (BPS), and the Survey of Housing Starts, Sales, and Completions (OMB number 0607–0110), also known as Survey of Construction (SOC). These two sample surveys provide widely used measures of construction activity, including the principal economic indicators New Residential Construction and New Home Sales. Data from the BPS and SOC are also used by the Bureau of Economic Analysis (BEA) in the calculation of estimates of the Residential Fixed Investment portion of the Nation's Gross Domestic Product (GDP). In addition, data from the BPS are used by the Census Bureau in the calculation of annual population estimates; these estimates are widely used by government agencies to allocate funding and other resources to local governments.

The questions on Form C–411 pertain to the legal requirements for issuing building or zoning permits in the local jurisdictions. Information is obtained on such items as geographic coverage and types of construction for which permits are issued.

We have redesigned the form to create three versions: C–411(V) for verification of coverage for jurisdictions with existing permit systems; C–411(M) for municipalities where a new permit system may have been established; and C–411(C) for counties where new permit systems may have been established.

This will clarify the instructions and the information requested in each of these situations but will not affect respondent burden.

The appropriate form is sent to a jurisdiction when we have reason to believe that a new permit system has been established or an existing one has changed. This is based on information from a variety of sources including survey respondents, regional councils and our own efforts to keep abreast of changes in corporate status.

We use the information to verify the existence of new permit systems or changes to existing systems. Based on the information, we add new permit-issuing places to the universe, delete places no longer issuing permits, and make changes to the universe to reflect those places that have merged.

Failure to maintain the universe of permit-issuing places would result in deficient samples and inaccurate statistics. This in turn jeopardizes the accuracy of the above mentioned economic indicators. These indicators are closely monitored by the Board of Governors of the Federal Reserve System and other economic policy makers because of the sensitivity of the housing industry to changes in interest rates.

Affected Public: State, local or Tribal Government.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, Sections 9(b), 161, and 182.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or e-mail (*bharrisk@omb.eop.gov*).

Dated: August 15, 2011.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–21066 Filed 8–17–11; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 54–2011]

Foreign-Trade Zone 72—Indianapolis, IN; Application for Manufacturing Authority, Brevini Wind USA, Inc., (Wind Turbine Gear Boxes), Yorktown, IN

A request has been submitted to the Foreign-Trade Zones Board (the Board) by the Indianapolis Airport Authority, grantee of FTZ 72, requesting manufacturing authority on behalf of Brevini Wind USA, Inc. (Brevini), to manufacture wind turbine gear boxes under FTZ procedures within FTZ 72. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on August 11, 2011.

The Brevini facility (approximately 400 employees, 20 acres) is located at 2400 Priority Way, within the Muncie Delaware County Park One Industrial Park in Yorktown, Indiana. The facility is used to manufacture and repair wind turbine gear boxes and related winches (up to 2,000 units of each per year) for the U.S. market and export. Components and materials sourced from abroad (representing 25% of the value of the finished products) include: parts of gear boxes, seals (rubber, metal), fasteners, pumps, filters, valves, bearings, shafts, gears, parts of gear boxes, clutches, brakes, cooling units, covers, discs, flanges, housings, sprockets, heating units, hoses, hydraulic parts, lubrication units, pinions, planet carriers, reduction stages, rotor lock discs, and electric motors (duty rate ranges from free to 5.8%).

FTZ procedures could exempt Brevini from customs duty payments on the foreign materials and components used in export production. The company

anticipates that some 30 percent of the plant's shipments will be exported. On its domestic sales, Brevini would be able to choose the duty rates during customs entry procedures that apply to wind turbine gear boxes and winches (duty rates—free, 2.5%) for the foreign-origin inputs noted above. FTZ designation would further allow Brevini to realize logistical benefits through the use of weekly customs entry procedures. Customs duties also could possibly be deferred or reduced on foreign status production equipment. Brevini would also be exempt from duty payments on foreign inputs that become scrap during the production process. The application indicates that the savings from FTZ procedures would help improve the facility's international competitiveness.

In accordance with the Board's regulations, Pierre Duy of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for receipt of comments is October 17, 2011. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to November 1, 2011.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *http://www.trade.gov/ftz.*

For further information, contact Pierre Duy at *Pierre.Duy@trade.gov* or (202) 482–1378.

Dated: August 11, 2011.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2011–21143 Filed 8–17–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

Aerospace Executive Service Trade Mission (AESTM) to Seoul, Korea

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY:

Mission Description

The U.S. Department of Commerce, International Trade Administration (ITA), Aerospace & Defense Technologies Team and the U.S. Commercial Service in Seoul (CS Korea) are organizing an Aerospace Executive Service Trade Mission (AESTM) to Seoul in conjunction with the Seoul ADEX 2011 (International Aerospace & Defense Exhibition) (*http://www.seoulairshow.com*).

The AESTM, to be led by a senior official of the Department of Commerce, will include representatives from a variety of U.S. aerospace and defense industry manufacturers and service providers. These mission participants will be introduced to international agents, distributors and end-users whose capabilities are targeted to each U.S. participant's needs. Mission participants will also be briefed by key local industry players and Joint U.S. Military Affairs Group—Korea (JUSMAG–K) who can advise on local market conditions and opportunities.

Commercial Setting

The Republic of Korea (Korea) is an economic leader in East Asia. Korea is the 7th largest market for U.S. exports as well as the 9th largest market for U.S. aerospace exports with $3.0 billion of U.S. aerospace exports in 2010. Korea is a growing market for the aerospace and defense industry, with U.S. aerospace exports growing 51% from 2004 and 2010. With the world's sixth largest military, and continued spending for new weapon systems as part of its defense modernization program, Korea continues to attract the interest of U.S. defense suppliers. In addition to its traditional focus on air power, Seoul ADEX 2011 will also incorporate land forces technology.

Seoul ADEX is one of the world's premier aerospace and defense technology events. The 2009 ADEX show was the largest to date and featured 273 exhibitors from 27 countries, 72 VIPs from 41 countries, and approximately 20,000 trade visitors. Encompassing all civil and military sectors of the international aerospace and ground support industry, Seoul ADEX is the foremost platform for companies to showcase their products and services in the region. Attendees and visitors to the Seoul ADEX include foreign and Korean VIPs, government officials, senior company managers, and high-level executives involved in the aerospace and defense market in Korea and the rest of the region.

With a close working relationship between the U.S. and Korean governments and private aerospace and defense companies, the AESTM service at this major aerospace and defense show will assist American companies in making important contact with the industry's key players in this region.

The U.S.-Korea Trade Agreement (KORUS) would provide significant commercial opportunities to U.S. aerospace exporters, including duty-free treatment for all U.S. aerospace exports to Korea within three years of implementation of KORUS (Korean aerospace tariffs currently average 3.5 percent, ranging up to 8 percent).

Mission Goals

The goal of the AESTM at the Seoul ADEX 2011 is to facilitate an effective presence for small- and medium-sized companies while combining aspects of a trade mission, such as one on one pre-scheduled business-to-business meetings, trade show participation, and networking activities, in one package.

The AESTM Program enables U.S. aerospace companies to familiarize themselves with this important trade fair, to conduct market research and to explore export opportunities through pre-arranged meetings with potential partners. AESTM participants will be supported by knowledgeable Commercial Service specialists focused on furthering their company-specific objectives.

Mission Scenario

Participants will have individual company kiosk space within the U.S. Pavilion where they can display company literature and conduct meetings with visitors to the air show. Company information and literature will be forwarded by the companies to CS Korea in advance whereupon CS Korea will search for relevant partners and coordinate logistics with respect to arranging meetings for each participant at the show. Prior to the end of the AESTM program, CS Korea staff will undertake a debriefing session with mission participants as well as counsel and coordinate with them on appropriate follow-up procedures.

In summary, participation in the AESTM Program includes:

- Pre-show Outreach and Press Release by CS Korea;
- Pre-show breakfast briefing on October 17, 2011, by CS Korea and other inter agencies in American Embassy such as JUSMAG–K;

- Daily Transportation between AESTM hotel and ADEX 2011 and vice versa;
- Pre-scheduled meetings with potential partners, distributors, and/or end users and on-site meeting if requested;
- One show entry pass per company representative;
- Participation in U.S. Exhibitors Welcome Reception on October 17 by the show organizer;
- One invitation to the U.S. VIP reception per participant by the U.S. Ambassador to Korea;
- Access to Official U.S. Pavilion/Business Information Office amenities, including meeting area;
- Individual kiosk space within the U.S. Pavilion for display of company literature, poster and meetings;
- Copy of the official ADEX 2011 Air Show Exhibitor's Directory;
- Copy of AES Trade Mission Directory;
- On-site AESTM program coordinator.

Proposed Timetable

Mission Timetable: ITA Aerospace & Defense Technologies Team members arrive in Seoul prior to the show. The proposed program is below:

October 16 (Sunday)	AES Participants Arrive.
A.M., October 17 (Monday)	Program and pre-show briefing at hotel.
P.M., October 17 (Monday)	1-on-1 meeting (2–3 meetings) at hotel.
Evening, October 17 (Monday)	Show Organizer's Welcome Reception at official hotel of the show organizer (6:30–8:30 p.m.).
A.M., October 18 (Tuesday)	Show Opens.
P.M., October 18 (Tuesday)	1-on-1 meeting at Seoul ADEX 2011.
Evening, October 18 (Tuesday)	Welcome Reception (subject to date change) by the U.S. Ambassador.
A.M., October 19 (Wednesday)	1-on-1 meeting at Seoul ADEX 2011.
P.M., October 19 (Wednesday)	Follow-Up meetings.
October 20 (Thursday)	On site meeting with exhibitors upon request.
October 21 (Friday)	On your own schedule.
October 22–23 (Saturday–Sunday)	Public Days.

Participation Requirements

All parties interested in participating in the Aerospace Executive Service Trade Mission must complete and submit an application for consideration by the Department of Commerce. All applicants will be evaluated on their ability to meet certain conditions and best satisfy the selection criteria as outlined below. A minimum of 8 and a maximum of 11 companies will be selected to participate in the mission from the applicant pool. U.S. companies already doing business in Korea as well as U.S. companies seeking to enter the market for the first time are encouraged to apply.

Fees and Expenses

After a company has been selected to participate in the mission, a payment to the Department of Commerce in the form of a participation fee is required. The participation fee will be $5,000 for a small or medium-sized enterprise (SME) [1] and $5,500 for large firms. The fee for each additional firm representative (SME or large) is $300. Expenses for travel, lodging, meals, and incidentals will be the responsibility of each trade mission participant.

[1] An SME is defined as a firm with 500 or fewer employees or that otherwise qualifies as a small business under SBA regulations. *See http://www.sba.gov/contractingopportunities/owners/basics/whatismallbusiness/index.html.* Parent companies, affiliates, and subsidiaries will be considered when determining business size. The dual pricing reflects the Commercial Service's user fee schedule that became effective May 1, 2008. *See http://www.export.gov/newsletter/march2008/initiatives.html.*

Conditions for Participation

- An applicant must submit a completed and signed mission application and supplemental application materials, including adequate information on the company's products and/or services, primary market objectives, and goals for participation. If the U.S. Department of Commerce receives an incomplete application, the Department may reject the application, request additional information, or take the lack of information into account when evaluating the applications.
- Each applicant must also certify that the products and services it seeks to export through the mission are either produced in the United States, or, if not, marketed under the name of a U.S. firm and have at least 51 percent U.S. content of the value of the finished product or service.

Selection Criteria for Participation

- Suitability of the company's products or services to the Korean market.
- Consistency of the applicant's goals and objectives with the stated scope and design of the mission.
- Applicant's potential for business in Korea, including likelihood of exports resulting from the mission.

Referrals from political organizations and any documents containing references to partisan political activities (including political contributions) will be removed from an applicant's submission and not considered during the selection process.

Timeframe for Recruitment and Applications

Mission recruitment will be conducted in an open and public manner, including publication in the **Federal Register** (*http://www.gpoaccess.gov/fr*), posting on ITA's trade mission calendar—*http://www.trade.gov/trade-missions*—and other Internet Web sites, press releases to general and trade media, direct mail, broadcast fax, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows.

Recruitment for the mission will begin August 8, 2011, and conclude August 26, 2011. The U.S. Department of Commerce will review applications and make selection decisions on a rolling basis, and will inform all applicants of selection decisions as soon as possible. Applications received after the August 26 deadline will be considered only if space and scheduling constraints permit.

Contacts

Jason Sproule, Senior International Trade Specialist, Irvine U.S. Export Assistance Center, 2302 Martin Court, Irvine, California 92612, *Tel:* 949–660–7105, *Fax:* 949–660–1338, *Jason.sproule@trade.gov.*

Elnora Moye,

U.S. Department of Commerce, Commercial Service/GTP.

[FR Doc. 2011–21108 Filed 8–17–11; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA645

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice of receipt and request for comment.

SUMMARY: Notice is hereby given that NMFS has received an application from the Washington Department of Fish and Wildlife (WDFW), for a direct take permit pursuant to the Endangered Species Act of 1973, as amended (ESA). The duration of the proposed Permit is ten years. This document serves to notify the public of the availability for comment of the permit application. All comments received will become part of the public record and will be available for review pursuant to the ESA.

DATES: Written comments on the application must be received at the appropriate address or fax number (see **ADDRESSES**) no later than 5 p.m. Pacific time on *September 19, 2011.*

ADDRESSES: Written responses to the application should be sent to Brian Allee, National Marine Fisheries Services, Salmon Management Division, 1201 N.E. Lloyd Boulevard, Suite 1100, Portland, OR 97232. Comments may also be submitted by e-mail to: *LowerColumbiaWeirs.nwr@noaa.gov.* Include in the subject line of the e-mail comment the following identifier: Comments on three weirs in the Lower Columbia. Comments may also be sent via facsimile (fax) to (503) 872–2737. Requests for copies of the permit applications should be directed to the National Marine Fisheries Services, Salmon Management Division, 1201 NE. Lloyd Boulevard, Suite 1100, Portland, OR 97232. The documents are also available on the Internet at *http://www.nwr.noaa.gov.* Comments received will also be available for public inspection, by appointment, during normal business hours by calling (503) 230–5412.

FOR FURTHER INFORMATION CONTACT: Brian Allee at (503) 231–2009 or *e-mail: brian.allee@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

Chinook salmon (*Oncorhynchus tshawytscha*): threatened, naturally produced and artificially propagated Lower Columbia River.

Chum salmon (*O. keta*): threatened, naturally produced and artificially propagated Columbia River.

Coho salmon (*O. kisutch*): threatened, naturally produced and artificially propagated Lower Columbia River.

Steelhead (*O. mykiss*): threatened, naturally produced and artificially propagated Lower Columbia River.

Background

Section 9 of the ESA and Federal regulations prohibit the ''taking'' of a species listed as endangered or threatened. The term ''take'' is defined under the ESA to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. NMFS may issue permits to take listed species for any act otherwise prohibited by section 9 for scientific purposes or to enhance the propagation or survival of the affected species, under section 10(a)(1)(A) of the ESA. NMFS regulations governing permits for threatened and endangered species are promulgated at 50 CFR 222.307.

In an application dated May 2, 2011, and updated on May 23, 2011, the Washington Department of Fish and Wildlife proposes to install weirs in the Grays River and Elochoman River, both tributaries of the Columbia River, and the Coweeman River, a tributary of the Cowlitz River in southwest Washington State. The weir on the Grays River would represent a re-location of an existing weir. The weirs are intended to address adult salmonid monitoring needs outlined in the Lower Columbia Fish Recovery Board's Watershed Conservation Plan through development of accurate and precise abundance estimates, and remove hatchery fall Chinook salmon from naturally spawning tule fall Chinook salmon populations.

Authority

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate each application, associated documents, and comments submitted thereon to determine whether the applications meet the requirements of section 10(a)(1)(A) of the ESA. If it is determined that the requirements are met, the permit will be issued to WDFW for the purpose of carrying out the installation, operation, and management of the weirs. NMFS will publish a record of its final action in the **Federal Register.**

Dated: August 15, 2011.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011–21111 Filed 8–17–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA513

Taking and Importing Marine Mammals: Taking Marine Mammals Incidental to Navy Operations of Surveillance Towed Array Sensor System Low Frequency Active Sonar

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

ACTION: Notice; issuance of four Letters of Authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, and implementing regulations, notification is hereby given that NMFS has issued four one-year Letters of Authorization (LOAs) to take marine mammals by harassment incidental to the U.S. Navy's operation of Surveillance Towed Array Sensor System Low Frequency Active (SURTASS LFA) sonar operations to the Chief of Naval Operations, Department of the Navy, 2000 Navy Pentagon, Washington, DC 20350 and persons operating under his authority.

DATES: Effective from August 16, 2011, through August 15, 2012.

ADDRESSES: Electronic copies of the Navy's March 31, 2011, LOA application letter, the LOAs, the Navy's 2010 annual report are available by writing to P. Michael Payne, Chief, Permits, Conservation, and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225, by telephoning the contact listed here (see **FOR FURTHER INFORMATION CONTACT**), or online at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications.* Documents cited in this notice may be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Jeannine Cody, Office of Protected Resources, NMFS (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1361 *et seq.*) directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of marine mammals by U.S. citizens who engage in a military readiness activity if certain findings are made and regulations are issued.

Authorization may be granted for periods of five years or less if NMFS finds that the taking will have a negligible impact on the species or stock(s), and will not have an unmitigable adverse impact on the availability of the species or stock(s) for certain subsistence uses. In addition, NMFS must prescribe regulations that include permissible methods of taking and other means effecting the least practicable adverse impact on the species and its habitat, and on the availability of the species for subsistence uses, paying particular attention to rookeries, mating grounds, and areas of similar significance. The regulations also must include requirements pertaining to the monitoring and reporting of such taking.

Regulations governing the taking of marine mammals incidental to the U.S. Navy's operation of SURTASS LFA sonar were published on August 21, 2007 (72 FR 46846) and remain in effect through August 15, 2012. They are codified at 50 CFR part 216 subpart Q. These regulations include mitigation, monitoring, and reporting requirements for the incidental taking of marine mammals by the SURTASS LFA sonar system. For detailed information on this action, please refer to the August 21, 2007 **Federal Register** document and 50 CFR part 216 subpart Q.

Summary of LOA Request

NMFS received an application from the U.S. Navy for four LOAs, one covering the USNS VICTORIOUS (T–AGOS 19), one covering the USNS ABLE (T–AGOS 20), one covering the USNS EFFECTIVE (T–AGOS 21), and one covering the USNS IMPECCABLE (T–AGOS 23), under the regulations issued on August 21, 2007 (72 FR 46846). (**Note:** The R/V CORY CHOUEST has been retired and has been replaced by the USNS ABLE.) The Navy requested that these LOAs become effective on August 16, 2011. The application requested authorization, for a period not to exceed one year, to take, by harassment, marine mammals incidental to employment of the SURTASS LFA sonar system for training, testing and routine military operations on the aforementioned ships in areas of the Pacific Ocean, as described in the 2007 regulations.

Monitoring and Reporting

In compliance with NMFS' 2007 SURTASS LFA sonar regulations, the Navy submitted an annual report (No. 3) for SURTASS LFA sonar operations during 2009–2010. The Navy also submitted a comprehensive report on SURTASS LFA sonar operations and the mitigation and monitoring activities conducted under the LOAs issued under its previous rule for the 2002 through 2007 period. A copy of these reports can be viewed and/or downloaded at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications*. Based on these reports, the Navy has conducted the specified activities in the manner described in the regulations and LOAs, and has implemented the required mitigation and monitoring measures. Additionally, marine mammal detections and behavioral observations suggest that the actual impacts of SURTASS LFA sonar operation and training fall within the scope and nature of those analyzed and anticipated by the regulations and LOAs.

In accordance with the current SURTASS LFA sonar regulations (50 CFR 216.186), the Navy has submitted classified quarterly mission reports. Under the first three LOA periods in the current rule, the Navy has not exceeded the take authorized by NMFS. Based on the submitted quarterly reports for the 2010 LOAs, NMFS does not expect the Navy to exceed authorized take (requested and authorized) based on the Navy's 2010 application. The annual report (No. 4) for the 2010–2011 LOAs is due on September 30, 2011. Upon receipt, NMFS will post this annual report at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications*.

Authorization

NMFS has issued four LOAs to the U.S. Navy, authorizing the incidental harassment of marine mammals, incidental to operating the four SURTASS LFA sonar systems for training, testing and routine military operations. Issuance of these four LOAs is based on findings, described in the preamble to the final rule (72 FR 46846, August 21, 2007) and supported by information contained in the Navy's required reports on SURTASS LFA sonar, that the activities described under these four LOAs will have no more than a negligible impact on marine mammal stocks and will not have an unmitigable adverse impact on the availability of the affected marine mammal stocks for subsistence uses.

These LOAs remain valid through August 15, 2012, provided the Navy remains in conformance with the conditions of the regulations and the LOAs, and the mitigation, monitoring, and reporting requirements described in 50 CFR 216.184–216.186 (72 FR 46846, August 21, 2007) and in the LOAs are undertaken.

Dated: August 12, 2011.

James H. Lecky,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011–21110 Filed 8–17–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Navy

Nominations for Membership on the Ocean Research Advisory Panel

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Ocean Research Advisory Panel (ORAP) is soliciting nominations for new members.

DATES: Nominations should be submitted no later than September 15, 2011.

ADDRESSES: Nominations should be submitted via e-mail to CDR Stephen D. Martin, U.S. Navy, at *stephen.d.martin@navy.mil*.

Contact Information: Office of Naval Research, 875 North Randolph Street Suite 1425, *Attn:* ONR Code 322B Room 1075, Arlington, VA 22203, telephone 703–696–4395.

FOR FURTHER INFORMATION CONTACT: Dr. Charles L. Vincent, Office of Naval Research, 875 North Randolph Street Suite 1425, Arlington, VA 22203–1995, telephone 703–696–4120.

SUPPLEMENTARY INFORMATION: ORAP is a statutorily mandated federal advisory committee that provides senior advice to the National Ocean Research Leadership Council (NORLC), the governing body of the National Oceanographic Partnership Program (NOPP). Under the National Ocean Policy, the National Ocean Council (NOC) Deputy-level Committee has assumed the responsibilities of the NORLC. ORAP provides independent advice and guidance to the NOC. The NOC routinely provides guidance and direction on the areas for which it seeks advice and recommendations from ORAP. ORAP also advises on selection of projects and allocation of funds for NOPP.

Panel Member Duties and Responsibilities: Members of the panel

represent the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, ocean industries, state governments, academia and others, including individuals who are eminent in the fields of marine science, marine policy, or related fields, including ocean resource management. Members are appointed annually and may serve a term of four years, and are not normally compensated except for travel expenses and per diem while away from their homes in performance of services for the panel.

The panel meets for at least one two-day public meeting per year, but possibly meets three times per year, on dates agreeable by the panel members; attendance at meetings is expected. Intercessional activities not involving formal decisions or recommendations may be carried out electronically, and the panel may establish sub-panels composed of less than full membership to carry out panel duties.

Nominations: Any interested person or organization may nominate qualified individuals (including one's self) for membership on the panel. Nominated individuals should have extended expertise and experience in the field of ocean science and/or ocean resource management. Nominations should be identified by name, occupation, position, address, telephone number, e-mail address, and a brief paragraph describing their qualifications in the context of the ORAP Charter, that can be found on-line at (*http://www.nopp.org/committees/orap/*), and ability to represent a stakeholder group. Nominations should also include a résumé or curriculum vitae.

Process and Deadline for Submitting Nominations: Submit nominations via e-mail to CDR Stephen Martin (*stephen.d.martin@navy.mil*) no later than September 15, 2011. ORAP nomination committees under the direction of the National Ocean Council will evaluate the nominees identified by respondents to this Federal Register notice and down-select to a short-list of available candidates (150% of the available open positions for consideration). These selected candidates will be required to fill-out the ''Confidential Financial Disclosure Report'' OGE form 450. This confidential form will allow Government officials to determine whether there is a statutory conflict between a person's public responsibilities and private interests and activities, or the appearance of a lack of impartiality, as defined by federal regulation. The form and additional guidance may be viewed at: (*http://www.usoge.gov/forms/oge450_pdf/oge450_automated.pdf).*

In accordance with section 7903 of title 10, United States Code, the short-list of candidates will then be submitted for approval by the Secretaries of the Navy and Defense who are the appointing officials for their consideration. At this time, six openings are envisioned on the Panel and the final set of nominees will seek to balance a range of geographic and sector representation and experience. Applicants must be U.S. citizens. Successful nominees must provide detailed information required to evaluate potential conflicts of interest. Typically the time required to achieve the final appointments to the Panel is 10–12 months. Members of the Panel serve as Special Government Employees who volunteer their time but whose travel costs for Panel business is provided by the Government. ORAP is a Federal Advisory Committee and operates under the principles of open and transparent development of advice to the government.

The selection of new panel members will be based on the nominee's qualifications to provide senior advice to the NOC; the availability of the potential panel member to fully participate in the panel meetings; absence of any conflict of interest or appearance of lack of impartiality, and lack of bias; the candidates' areas of expertise and professional qualifications; and achieving an overall balance of different perspectives, geographic representation, and expertise on the panel.

Dated: August 11, 2011.

J. M. Beal

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2011–21116 Filed 8–17–11; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Comment Request.

SUMMARY: The Department of Education (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collection of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before October 17, 2011.

ADDRESSES: Comments may be submitted electronically to *FAFSA.Comments@ed.gov*. We ask that you copy them to *ICDocketMgr@ed.gov* or mail to U.S. Department of Education, UCP Building, 1830 First Street, NE., Washington, DC 20202–4357. Please note that written comments received in response to this notice will be considered public records.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: August 12, 2011.

Darrin A. King,

Director, Information Collection Clearance Division, Privacy, Information and Records Management Services.

As required by the Paperwork Reduction Act of 1995, this notice requests comments on the 2012–2013 versions of the forms used by individuals applying for Federal student aid including the Free Application for Federal Student Aid (FAFSA) and the Student Aid Report (SAR).

Title: 2012–2013 Federal Student Aid Application.

Type of Review: Revision.

OMB Number: 1845–0001.

Frequency: Annually.

Respondents: Individuals.

Annual Respondents: 24,705,864.

Annual Responses: 46,447,024.

Annual Burden Hours: 29,357,853.

Abstract: Section 483 of the Higher Education Act of 1965, as amended (HEA), mandates that the Secretary of Education ''* * * shall produce, distribute, and process free of charge common financial reporting forms as described in this subsection to be used for application and reapplication to determine the need and eligibility of a student for financial assistance.''

The determination of need and eligibility are for the following Title IV, HEA, Federal student financial assistance programs: the Federal Pell Grant Program; the Campus-Based programs (Federal Supplemental Educational Opportunity Grant (FSEOG), Federal Work-Study (FWS), and the Federal Perkins Loan Program); the William D. Ford Federal Direct Loan Program; the Teacher Education Assistance for College and Higher Education (TEACH) Grant; and the Iraq and Afghanistan Service Grant.

Federal Student Aid, an office of the U.S. Department of Education (hereafter ''the Department''), developed an application process to collect and process the data necessary to determine a student's eligibility to receive Title IV, HEA program assistance. The application process involves an applicant's submission of the *Free Application for Federal Student Aid* (FAFSA). After submission of the FAFSA, an applicant receives a *Student Aid Report* (SAR) which is a summary of the data they submitted on the FAFSA. The applicant reviews the SAR, and, if necessary, will make corrections or updates to their submitted FAFSA.

The Department seeks OMB approval of all application components as a single ''collection of information''. The aggregate burden will be accounted for under OMB Control Number 1845–0001. The specific application components, descriptions and submission methods for each are listed in Table 1.

TABLE 1—FEDERAL STUDENT AID APPLICATION COMPONENTS

Component	Description	Submission method
Initial Submission of FAFSA		
FAFSA on the Web (FOTW)	Online FAFSA that offers applicants a customized experience..	Submitted by the applicant via *http://www.fafsa.gov.*
FOTW—Renewal	Online FAFSA for applicants who have previously completed the FAFSA.	
FOTW–EZ	Online FAFSA for applicants who qualify for the Simplified Needs Test (SNT) or Automatic Zero (Auto Zero) needs analysis formulas.	
FOTW–EZ Renewal	Online FAFSA for applicants who have previously completed the FAFSA and who qualify for the SNT or Auto Zero needs analysis formulas.	
FAFSA on the Phone (FOTP)	The Federal Student Aid Information Center (FSAIC) representatives assist applicants by filing the FAFSA on their behalf through FOTW.	Submitted through *http://www.fafsa.gov* for applicants who call 1–800–4–FED–AID.
FOTP–EZ	FSAIC representatives assist applicants who qualify for the SNT or Auto Zero needs analysis formulas by filing the FAFSA on their behalf through FOTW.	
FAA Access	Online tool that a financial aid administrator (FAA) utilizes to submit a FAFSA..	Submitted through *http://www.faaacess.ed.gov* by a FAA on behalf of an applicant.
FAA Access—Renewal	Online tool that a FAA can utilize to submit a Renewal FAFSA.	
FAA Access—EZ	Online tool that a FAA can utilize to submit a FAFSA for applicants who qualify for the SNT or Auto Zero needs analysis formulas.	
FAA Access—EZ Renewal	Online tool that a FAA can utilize to submit a FAFSA for applicants who have previously completed the FAFSA and who qualify for the SNT or Auto Zero needs analysis formulas.	
Electronic Other	This is a submission done by a FAA, on behalf of the applicant, using the Electronic Data Exchange (EDE).	The FAA may be using their mainframe computer or software to facilitate the EDE process.
PDF FAFSA or Paper FAFSA	The paper version of the FAFSA printed by the Department for applicants who are unable to access the Internet or the online PDF FAFSA for applicants who can access the Internet but are unable to complete the form using FOTW.	Mailed by the applicant.
Correcting Submitted FAFSA Information and Reviewing FAFSA Information		
FOTW–Corrections	Any applicant who has a Federal Student Aid PIN (FSA PIN)—regardless of how they originally applied—may correct using FOTW Corrections.	Submitted by the applicant via *http://www.fafsa.gov.*
Electronic Other—Corrections	With the applicant's permission, corrections can be made by a FAA using the EDE.	The FAA may be using their mainframe computer or software to facilitate the EDE process.

TABLE 1—FEDERAL STUDENT AID APPLICATION COMPONENTS—Continued

Component	Description	Submission method
Paper SAR—This is a SAR and an option for corrections.	The full paper summary that is mailed to paper applicants who did not provide an e-mail address, to applicants who did not sign their application and to applicants whose records were rejected during processing because the Social Security Number did not match with the SSA. Applicants can write corrections directly on the paper SAR and mail for processing.	Mailed by the applicant.
FAA Access—Corrections	An institution can use FAA Access to correct the FAFSA	Submitted through *http://www.faaacess.ed.gov* by a FAA on behalf of an applicant.
Internal Department Corrections	The Department will submit an applicant's record for system-generated corrections.	There is no burden to the applicants under this correction type as these are system-based corrections.
FSAIC Corrections	Any applicant, with their Data Release Number (DRN), can change the postsecondary institutions listed on their FAFSA or change their address by calling FSAIC.	These changes are made directly in the CPS system by a FSAIC representative.
SAR Electronic (eSAR)	This is the PDF version of the SAR for applicants who applied electronically or by paper and provided an e-mail address.	Cannot be submitted for processing.
SAR Acknowledgment	This is the condensed paper SAR that is mailed to applicants who applied electronically but did not provide an e-mail address.	

This information collection also documents an estimate of the annual public burden as it relates to the application process for Federal student aid. The Applicant Burden Model (ABM), measures applicant burden through an assessment of the activities each applicant conducts in conjunction with other applicant characteristics. The ABM has been designed to accurately describe, in terms of burden, the average applicant's experience. Key determinants of the ABM include:

- The total number of applicants that will potentially apply for Federal student aid;
- How the applicant chooses to complete and submit the FAFSA, *e.g.,* by paper or electronically via FOTW;
- How the applicant chooses to submit any corrections and/or updates (*e.g.,* the paper SAR or electronically via FOTW Corrections);
- The type of SAR document the applicant receives (paper SAR, SAR acknowledgment, or the eSAR);
- The formula applied to determine the applicant's EFC (full need analysis formula, Simplified Needs Test or Automatic Zero); and
- The average amount of time involved in preparing to complete the application.

The ABM is largely driven by the number of potential applicants for the application cycle. The total application projection for 2012–2013 is based upon two factors—estimates of the total enrollment in all degree-granting institutions and the percentage change in FAFSA submissions for the last completed application cycle. The ABM is also based on the application options available to students and parents. The Department accounts for each application component based on web trending tools, survey information, and other Department data sources.

For 2012–2013, the Department is reporting a net burden reduction of 2,881,475 hours. The reduction is a reflection of the effects of simplifying FAFSA on the Web, which is utilized by the majority of applicants who apply for aid. For example, data reported in the 2011–2012 burden estimates reflected that an applicant that completed FOTW and had the ability to use a renewal version of the application (see FOTW—Renewal component in Table 1) would take approximately 1.20 hours (72 minutes). The most recent statistics reflect that on average that renewal applicant would actually spend about 1.08 hours (64.8 minutes).

Updated completion times were calculated for each component and have been used to estimate the burden, excluding the change in the applicant volume. The results demonstrate that the burden for all applicants would have decreased by almost 13 percent or 4,181,899 hours, if the application volume had remained constant.

If the Department had not simplified the application process, thus reducing the time required to complete the FAFSA, the new burden estimates would only need to account for the change in applicants. The 4.63% increase in applicants would result in an increase in burden of 1,300,424 hours.

Accounting for both the increase in total applicants and the decrease in individual applicant burden, the net change is an overall decrease of almost 9 percent or 2,881,475 hours. The following Table shows the net burden change and total cost for applicants. The change in total annual responses is also listed in the Table. Total annual responses include the original FAFSA submission, which is counted as one response for each applicant; and also includes a response for any subsequent correction generated by the applicant.

TABLE 2—NET BURDEN CHANGE

	2011–2012	2012–2013	Change	% Change	Burden disposition
		Accounting for change in applicant burden and change in applicants			

TABLE 2—NET BURDEN CHANGE—Continued

	2011–2012	2012–2013	Change	% Change	Burden disposition
Total Applicants	23,611,500	24,705,864	+1,094,364	+4.63	Net decrease in burden. The increase in applicants is offset by the results of the Department's simplification changes. This has created an overall decrease in burden of 8.94% or 2,881,475 hours.
Total Applicant Burden	32,239,328	29,357,853	−2,881,475	−8.94	
Total Annual Responses	32,239,328	46,447,024	+14,207,696	+44.07	
Cost for All Applicants	$159,370.20	$234,804.24	$75,434.04	+47.33	

The Department is proud that efforts to simplify the FAFSA submission process have resulted in a continued decrease in the burden associated with the application process, even as the Department serves more students each year. The results demonstrate the significant improvements that have been made to the application process. The Department believes that these changes will contribute to more students completing the FAFSA and will assist more students with their pursuit of postsecondary education.

Request for Copies: Comments should be submitted to the Department as indicated. All comments will become a matter of public record. Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 4703. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request. Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m. Eastern time, Monday through Friday.

[FR Doc. 2011–20992 Filed 8–17–11; 8:45 am]

BILLING CODE

DEPARTMENT OF ENERGY

Notice of Availability: American Assured Fuel Supply

AGENCY: The U.S. Department of Energy.

ACTION: Notice of availability.

SUMMARY: The U.S. Department of Energy (DOE) is creating 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 DOE's nuclear nonproliferation objectives by supporting civil nuclear energy development while minimizing proliferation risks. This notice announces the availability of the AFS and the DOE policy and process for eligible recipients to purchase LEU from the AFS.

FOR FURTHER INFORMATION CONTACT: Rich Goorevich, Senior Policy Advisor, Office of Nonproliferation and International Security, National Nuclear Security Administration, U.S. Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585, *Tel:* 202–586–0589, *Fax:* 202–586–1348.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of Energy is authorized pursuant to the Atomic Energy of 1954, as amended (Pub. L. 83–703), and the Nuclear Non-Proliferation Act of 1978 (NNPA) (Pub. L. 95–242) to encourage the widespread use of atomic energy for peaceful purposes, and 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. Consistent with those responsibilities and missions, in 2005, Secretary of Energy Samuel Bodman announced that the United States would set aside 17.4 metric tons of surplus highly-enriched uranium (HEU) to be down-blended to LEU and held in reserve to address disruptions in the nuclear fuel supply of foreign recipients that have good nonproliferation credentials. This initiative was originally referred to as the Reliable Fuel Supply Initiative, and more recently renamed the American Assured Fuel Supply (AFS).

Congress appropriated $49,540,000 in the Consolidated Appropriations Act, 2008 (Pub. L. 110–161) to fund a portion of 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, 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 the LEU set-aside initiated pursuant to Secretary Bodman's 2005 announcement, 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 AFS is intended to complement the INFB. Specifically, the AFS will support countries that pursue peaceful civilian nuclear programs by providing a back-up source of fuel in the event of a supply disruption that threatens the normal operation of their programs. In addition, in accordance with the congressional request, the AFS will be available to address supply disruptions affecting domestic nuclear power plants. The AFS reserve is modest in size and designed to not disrupt or replace market mechanisms. Rather, it is to be drawn upon only in the event of

demonstrated need and after all other market options are exhausted.

The National Nuclear Security Administration (NNSA), a semi-autonomous agency within DOE, is responsible for the administration and implementation of the AFS. Down-blending of the 17.4 metric tons of surplus HEU began in 2007 and is scheduled for completion in 2012. When complete, the down-blending will result in approximately 290 metric tons of LEU, of which approximately 230 metric tons will form the reserve. The remainder will be used to pay for the down-blending and processing costs.

For additional information on the potential environmental impacts of DOE's ongoing HEU disposition activities and the AFS initiative in particular, please see ''Amended Record of Decision: Disposition of Surplus Highly Enriched Uranium Environmental Impact Statement,'' also published in today's **Federal Register**.

II. Policy and Process for Accessing AFS Material

DOE intends to implement the following policies and processes to evaluate requests for purchases and the sale of LEU from the AFS.

Policy. DOE intends for the AFS to be made available to eligible recipients that meet certain nonproliferation criteria in the case of supply disruptions in the nuclear fuel market. DOE will sell LEU from the AFS consistent with applicable laws, regulations, and Departmental policies concerning excess uranium disposition. DOE will sell LEU to U.S. persons who will in turn sell to domestic or foreign recipients only where DOE has confirmed that there is a fuel supply disruption that cannot be addressed by normal market mechanisms. If foreign reactor operators face a supply disruption, the AFS will be available to them through their U.S. suppliers.

The sale of LEU from the AFS will be conducted consistent with 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. In all cases, the U.S. person purchasing the LEU must meet all applicable licensing requirements and other authorizations for the possession, use, and transportation of nuclear materials. If the AFS is used to supply a foreign recipient, the U.S. person exporting the LEU must obtain or possess an appropriate license from the Nuclear Regulatory Commission. DOE will establish the price of the LEU at the time of delivery using commercially acceptable market indices, to the extent practical, and ensure that reasonable value is obtained. All proceeds from the sale will be deposited in the U.S. Treasury.

Process. Any U.S. person requesting to purchase LEU from the AFS must submit a request in writing to the NNSA Office of Nonproliferation and International Security. The request must set forth facts demonstrating that there is a fuel supply disruption for which fuel cannot be obtained through normal market conditions and that the end-user, if foreign, has good nonproliferation credentials. In addition, the request must include specific information about the purchase, including but not limited to: the time and place of delivery; the desired quantity and composition of LEU; the recipient and associated country of final end-use; confirmation of qualification for an export license, as required; and, if applicable, information on any intermediate consignee and country. Any foreign persons requesting to purchase LEU from the AFS can do so through their U.S. supplier.

The U.S. person purchasing LEU from the AFS will be solely responsible for transportation, insurance, safety, and liability issues once title to the LEU transfers. The LEU will be in the form of uranium hexafluoride at a specific assay (generally 4.95% U–235); DOE will assume no responsibility beyond certification that the LEU meets ASTM International, formerly American Society for testing (ASTM), specifications and is of a certain quantity and assay.

DOE will respond to requests within a reasonable time period, consistent with the requester's needs, the circumstances surrounding the request, and other relevant and necessary governmental interests. DOE reserves the right to prioritize requests, and to seek additional information as necessary to review the request.

DOE will establish an AFS Committee, which will be responsible for reviewing requests for LEU in the AFS and make recommendations to the Secretary of Energy on the sale of LEU from the AFS. The Committee will be chaired by the NNSA Office of Nonproliferation and International Security and include representatives from NNSA's Office of Fissile Material Disposition, DOE's Office of Nuclear Energy, DOE's Office of Environmental Management, and the DOE and NNSA Offices of General Counsel. For transactions that trigger the requirements of section 3112(d) of the USEC Privatization Act, DOE will assess the impact of a sale from the AFS on the domestic uranium market, and will provide its recommendation to the Secretary to make the requisite determination that the transfer will not have an adverse material impact on the domestic uranium enrichment, conversion, or mining industries.

DOE will receive concurrence from the Department of State, and consult with the Department of Commerce and the Department of Defense, prior to the approval and sale of AFS material to a U.S. person for use in a foreign country. For all sales from the AFS, DOE will notify other federal agencies (e.g., U.S. Nuclear Regulatory Commission, Department of State, Department of Commerce and the Department of Defense) prior to the sale, as appropriate.

III. Projected Timeline

The LEU for the AFS will come from down-blending 17.4 metric tons of HEU. When complete, the down-blending will result in approximately 290 metric tons of LEU, of which approximately 230 metric tons will form the reserve. The remainder will be used to pay for the down-blending and processing costs. This will leave the AFS with approximately 6 reloads for an average 1000 MW reactor. The down-blending will be completed in 2012.

As of the publication of this notice, most of the down-blending for the AFS has been completed. DOE will begin accepting requests for purchases of the AFS material pursuant to the above-stated policy and process at this time.

Issued in Washington, DC, this 13th day of May, 2011.

Steven Chu,

Secretary, U.S. Department of Energy.

[FR Doc. 2011–21067 Filed 8–17–11; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration Amended Record of Decision: Disposition of Surplus Highly Enriched Uranium Environmental Impact Statement

AGENCY: National Nuclear Security Administration, U.S. Department of Energy.

ACTION: Amended Record of Decision.

SUMMARY: The National Nuclear Security Administration (NNSA), a semi-autonomous agency within the U.S. Department of Energy (DOE), is amending the August 5, 1996, Record of Decision (the 1996 ROD) (61 FR 40619) for the *Disposition of Surplus Highly Enriched Uranium Environmental*

Impact Statement (HEU EIS) (DOE/EIS–0240). The 1996 ROD included DOE's decision to implement a program to render a nominal 200 metric tons of surplus highly-enriched uranium (HEU) non-weapons-usable by blending it down to low-enriched uranium (LEU) and selling as much of the resulting LEU as possible (up to 85 percent) for use as reactor fuel. In 2007, NNSA prepared a Supplement Analysis (DOE/EIS–0240–SA1) to the HEU EIS but did not make a decision at that time. The Supplement Analysis analyzed the potential environmental impacts associated with ongoing HEU disposition activities and potential changes to those activities: supplying LEU to reactors in foreign countries through U.S. persons under certain circumstances; establishing new pathways for disposing of HEU materials that would not be converted to LEU for reactor fuel; and down-blending additional quantities of HEU for use as reactor fuel. NNSA now is amending the 1996 ROD to make decisions regarding each of these proposals.

FOR FURTHER INFORMATION CONTACT: For further information about the Surplus HEU Disposition Program and the American Assured Fuel Supply, contact: Robert M. George, HEU Disposition Program Manager, Office of Fissile Materials Disposition, National Nuclear Security Administration, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585; (202) 586–1530.

For general information concerning the DOE National Environmental Policy Act (NEPA) process, contact: Ms. Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance (GC–54), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585; (202) 586–4600; leave a message at (800) 472–2756; or send an e-mail to *askNEPA@hq.energy.gov.* Additional information regarding DOE NEPA activities and access to many DOE NEPA documents are available on the Internet through the DOE NEPA Web site at *http://nepa.energy.gov.* Some of these documents, including the HEU EIS referenced in this Amended ROD, are available upon request as described at *http://nepa.energy.gov/nepa_request.cfm.*

SUPPLEMENTARY INFORMATION:

Background

Following the end of the Cold War, the United States identified a surplus of weapons-usable HEU. HEU has a concentration of 20 percent or more of uranium-235, which is a fissile material that can be used to make nuclear weapons. In 1994, the United States declared 174 metric tons of HEU to be surplus to defense needs. In the HEU EIS, DOE analyzed alternatives to disposition a nominal 200 metric tons of surplus HEU in order to reduce the threat of nuclear weapons proliferation in an environmentally safe manner by reducing stockpiles of weapons-usable fissile materials, setting a nonproliferation example for other nations, and allowing peaceful beneficial re-use of the material.

Alternatives analyzed in the HEU EIS involved the continued storage of HEU or mixing the surplus HEU with other uranium materials (LEU, natural uranium, or depleted uranium) to lower the concentration of uranium-235 so that it is not weapons-usable, a process called ''down-blending.'' DOE analyzed a range of scenarios regarding how much HEU would be down-blended (to approximately four percent uranium-235) for use in commercial reactors as opposed to blending to approximately 0.9 percent uranium-235 for disposal as low-level radioactive waste (LLW).

The HEU EIS evaluated the potential environmental impacts of down-blending at up to four existing U.S. facilities: DOE's Y–12 National Security Site in Oak Ridge, Tennessee; DOE's Savannah River Site (SRS) in Aiken, South Carolina; The Babcock & Wilcox Company (now B&W Nuclear Operations Group, Inc. [B&W NOG]) in Lynchburg, Virginia; and Nuclear Fuel Services, Inc., (NFS) in Erwin, Tennessee. These sites were considered because they have technically viable HEU conversion and blending capabilities and could down-blend surplus HEU to LEU for use in commercial fuel or for disposal as waste. B&W NOG and NFS, which is now owned by B&W NOG, are both licensed by the U.S. Nuclear Regulatory Commission (NRC) to process HEU.

As described in the 1996 ROD (61 FR 40619; August 5, 1996), DOE planned to down-blend as much surplus HEU as possible (then assumed to be up to 85 percent of the 200 metric tons, *i.e.,* approximately 170 metric tons) into LEU for use as commercial reactor fuel. The remainder (approximately 30 metric tons) would be down-blended and then disposed of as low-level waste (LLW). DOE planned to use a combination of the four sites and estimated that the blend-down program would be completed in about 15–20 years. This alternative was identified in the 1996 ROD as the environmentally preferable alternative. To date, almost 15 years after the ROD was issued, DOE has down-blended approximately 120 metric tons of surplus HEU to LEU and provided all the LEU for use in commercial or research reactors.

In the fall of 2005, up to an additional 200 metric tons of HEU were declared surplus to nuclear weapon program needs. Of this, up to 160 metric tons were designated for the U.S. Naval Reactors Program for use as reactor fuel. However, based on historical data, DOE anticipated that up to approximately 32 metric tons of this HEU might be unsuitable for use as naval reactor fuel, and proposed to down-blend rejected material to LEU. Another 20 metric tons of the 200 metric ton declaration were designated for down-blending. Down-blending this HEU began in 2009, consistent with the 1996 ROD.

American Assured Fuel Supply Initiative

In 2005, the Secretary of Energy announced that DOE would set aside a stockpile of LEU derived from 17.4 metric tons of surplus HEU to be held in reserve to address potential disruptions in the nuclear fuel supply of eligible foreign recipients that meet certain nonproliferation criteria. In the Explanatory Statement accompanying the House Appropriations Committee Print for the Consolidated Appropriations Act, 2008 (Pub. L. 110–161), which was given the same effect as a joint explanatory statement, Congress recommended that DOE also make the LEU available to domestic reactors in the event of a supply disruption. This effort to establish and manage an LEU reserve was originally referred to as the Reliable Fuel Supply Initiative, but now is called the American Assured Fuel Supply (AFS).

Proposed Action and Program Changes

NNSA proposes to implement the AFS initiative and modify certain elements of the existing surplus HEU disposition program:

(1) *American Assured Fuel Supply.* Under the AFS, a portion of LEU derived from down-blending surplus HEU would be held in reserve to respond, through U.S. intermediaries, to disruptions in the foreign or domestic supply of nuclear fuel. In the 2007 Supplement Analysis, this initiative was referred to as the Reliable Fuel Supply Initiative and was limited in scope to ensuring that foreign countries with good nonproliferation credentials have access to the nuclear fuel market and the benefits of nuclear power. Under the current proposal, the AFS would supply LEU in the event of a supply disruption both to recipients in foreign countries through a U.S. person or recipients in the United States. This would further nuclear nonproliferation objectives by

supporting civilian nuclear energy development while minimizing proliferation risks.

Down-blending the 17.4 metric tons of surplus HEU commenced in 2007 and is scheduled to be completed by 2012.[1] These operations are the same as analyzed in the HEU EIS and are consistent with the existing ROD. The down-blending will result in approximately 290 metric tons of LEU, of which approximately 230 metric tons will form the AFS. The remainder of the LEU will be used to pay for the down-blending and processing costs. Forty metric tons of LEU will be stored in existing facilities at the Westinghouse fuel fabrication facility in Columbia, South Carolina, and the rest of the DOE-owned LEU will be available for the facility's working inventory subject to contract conditions for providing LEU upon request by DOE.

The sale of LEU from the AFS will be conducted consistent with 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.[2] In all cases, the U.S. persons purchasing the LEU must meet all applicable licensing requirements and other authorizations for the possession, use, and transportation of nuclear materials. If the AFS is used to supply a foreign recipient, the U.S. persons exporting the LEU will obtain a license from the NRC. DOE will establish the price of the LEU at the time of delivery using commercially acceptable market indices, to the extent practical, and ensure that reasonable value is obtained. All proceeds from the sale will be deposited in the U.S. Treasury.

The U.S. persons purchasing LEU from the AFS will be solely responsible for transportation, insurance, safety, and liability issues once title is transferred. The LEU will be in the form of uranium hexafluoride (UF_6) at a specific assay (generally 4.95% U–235); DOE assumes no responsibility beyond certification that the LEU meets ASTM International, formerly American Society for Testing Materials (ASTM), specifications and is of a certain quantity and assay.

For additional information on the policies and process for use of the AFS, please see ''Notice of Availability: American Assured Fuel Supply,'' also published in today's **Federal Register**.

(2) *New Disposition Pathways for HEU Discard Material.* The HEU EIS analyzed the down-blending of low-equity[3] HEU materials to an enrichment level of 0.9 percent uranium-235, and disposing of the resulting LEU at a low-level radioactive waste facility. NNSA now proposes instead to directly dispose of these materials only if they meet acceptance criteria for disposal as LLW.[4] Most disposal would occur at DOE's Nevada National Security Site (NNSS) (formerly the Nevada Test Site).

(3) *Down-blending Additional HEU Over a Longer Period of Time.* The quantity of surplus HEU available for disposition and the expected period of program implementation both have increased since the 1996 ROD. Additional quantities of surplus HEU primarily derive from two sources: new material declared excess to weapons needs in 2005, and HEU returned to DOE from foreign research reactor and domestic research reactor programs. NNSA proposes to down-blend these additional quantities of HEU to LEU for use in fabricating fuel for nuclear power plants, research reactors and isotope production facilities. The 1996 ROD foresaw HEU down-blending activities continuing for 15–20 years. NNSA now anticipates that down-blending may continue over an extended period, out to at least 2050, based on the pace of ongoing activities and because the material addressed by the 2005 declaration is coming from nuclear weapon dismantlement over the coming decades.

Down-blending of HEU from foreign or domestic research reactor spent nuclear fuel would occur only if DOE decides to chemically process, (reprocess) that fuel, which would separate the HEU from other components of the fuel. DOE currently plans to accept research reactor spent nuclear fuel through 2019, as announced in amended RODs (69 FR 69901; December 1, 2004 and 74 FR 4173; January 23, 2009) for the *Environmental Impact Statement on a Proposed Nuclear Weapons Nonproliferation Policy Concerning Foreign Research Reactor Spent Nuclear Fuel* (FRR SNF EIS) (DOE/EIS–0218).

Associated reprocessing operations are evaluated in the *Savannah River Site Spent Nuclear Fuel Management Final Environmental Impact Statement* (SRS SNF EIS) (DOE/EIS–0279 2000). DOE has no plans to reprocess spent nuclear fuel solely for the purpose of extracting HEU. However, activities associated with managing the fuel for the purposes of stabilization, facility cleanup, treatment, waste management, safe disposal, or environment, safety, and health protection could result in the separation of HEU in weapons-usable form that could pose a proliferation threat. If HEU is recovered from spent fuel for one or more of these reasons, it would be available for down-blending consistent with the 1996 ROD for the HEU EIS.

Basis for Decision and Associated Environmental Impacts

The Council on Environmental Quality (CEQ) regulations implementing NEPA at 40 CFR 1502.9(c) require Federal agencies to prepare a supplement to an EIS when an agency makes substantial changes in the proposed action that are relevant to environmental concerns or when there are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts. DOE NEPA Implementing Procedures at 10 CFR 1021.314(c) direct that a supplement analysis be prepared to assist in making that determination when it is unclear whether a supplement to an EIS is required. NNSA prepared the *Supplement Analysis for the Disposition of Surplus Highly Enriched Uranium* (DOE/EIS–0240–SA1) in 2007 in accordance with these CEQ and DOE procedures.

In the HEU Supplement Analysis, NNSA analyzed the potential environmental impacts from the ongoing HEU disposition program, as well as potential impacts from port activities and transportation of LEU by ship across the global commons (ocean) to support the proposal to make LEU available to reactors in foreign countries. The Supplement Analysis did not identify an end date for implementation of the proposed activities because, as noted above, receipt of surplus HEU into the disposition program is ongoing.

The Supplement Analysis assumed the continued availability of the four facilities identified in the HEU EIS for continued blend down of HEU.

[1] NNSA awarded the contract for down-blending to a team consisting of WesDyne International (a subsidiary of Westinghouse Electric Company) and NFS. NFS is down-blending the surplus HEU to LEU at its facility in Erwin, Tennessee.

[2] These documents are available on the internet at: *http://www.ne.doe.gov/pdfFiles/Excess%20Uranium%20Inventory.pdf* and *http://www.ne.doe.gov/pdfFiles/inventory_plan_unclassified.pdf.*

[3] Low-equity items include materials with varying enrichments that are no longer needed to meet programmatic needs, have no further defined use, and are commonly considered uneconomical for recovery due to low concentration of HEU or due to impurities.

[4] The Supplement Analysis also analyzes the potential environmental impacts of direct disposal in a geologic repository of 15 metric tons of spent nuclear fuel containing HEU. That fuel currently is in safe and secure storage along with a much larger quantity of spent nuclear fuel at Idaho National Laboratory, and DOE is not proposing any change at this time in the management of that material.

Potential impacts were based on processing 10 metric tons of HEU per year at each facility.

The potential impacts would remain similar to those analyzed in the HEU EIS and Supplement Analysis. NNSA expects that there would be changes over time due to factors such as normal population fluctuations among work forces and in communities near the involved facilities. These changes would not create any significant new circumstances or information related to the proposed actions. Activities would continue in existing, appropriately licensed or approved facilities. Potential environmental impacts would remain small and within applicable regulatory and other limits.

For AFS, which was not envisioned in the HEU EIS, potential impacts of the domestic program would be identical to those associated with the ongoing HEU disposition program. Prior to delivery to a reactor, one or more commercial nuclear fuel fabrication facilities would accommodate the LEU for the AFS reserve in its working inventory and existing storage capacity. This activity would be consistent with the facilities' existing NRC operating licenses and would not require additional construction. In addition, as analyzed in the Supplement Analysis, transportation activities to provide LEU to foreign reactors would add small potential impacts associated with transfer activities at the port of departure and overseas shipments through the global commons.

Disposal of certain HEU materials as LLW would result in potential impacts associated with transportation and disposal. Nevada National Security Site (NNSS) is the most likely disposal site for this LLW. The HEU EIS included an analysis of transporting 0.9 percent LEU to NNSS for disposal. Without down-blending, the low-equity HEU materials would have a higher concentration of uranium-235, but with approved packaging and other required controls, the potential impacts would be similar to the transportation and disposal of 0.9 percent LEU at NNSS. DOE also has analyzed transportation of low-level radioactive wastes to NNSS in the *Environmental Impact Statement for the Nevada Test Site and Off-Site Locations in the State of Nevada* (DOE/EIS–0243). That EIS also included analysis of waste disposal activities and resulted in a ROD identifying the NNSS as available for the disposal of LLW if it meets the NNSS waste acceptance criteria (61 FR 65551, December 13, 1996). If NNSA were to use a different facility for disposal, the transportation impacts would be similar to those associated with use of NNSS (*i.e.,* similar distances and population distributions would be involved), and disposal would occur in existing, licensed facilities so that impacts would be consistent with approved operations at the facility. Recognizing the potential for disposal at other sites, the HEU EIS identified the analysis of transportation impacts to NNSS as representative of other possible routes. In addition, DOE has analyzed the transportation and disposal of LLW in other NEPA analyses, including the *Waste Management Programmatic Environmental Impact Statement for Managing Treatment, Storage, and Disposal of Radioactive and Hazardous Waste* (DOE/EIS–0200, 1997).

Amended Decision

Consistent with the decisions announced in the ROD issued pursuant to the HEU EIS (61 FR 40619; August 5, 1996), NNSA will continue ongoing surplus HEU disposition program activities. NNSA has decided to also make the following changes to the HEU disposition program:

(1) Implement the AFS, including storage of LEU and, as needed, transportation of the LEU by ship across the ocean for use in foreign reactors.

(2) Dispose of certain HEU materials as low-level radioactive waste without prior down-blending if the materials meet applicable waste acceptance criteria.

(3) Increase the quantity of HEU available for down-blending and continue down-blending operations beyond the 20 years anticipated in the 1996 HEU EIS.

NNSA will use all practicable means to avoid or minimize environmental harm when implementing the actions described in this Amended ROD. NNSA operates pursuant to a number of Federal laws including environmental laws, DOE Orders, and Federal, State, and local controls and agreements. Also, the commercial activities associated with the down-blending, transportation, and storage of HEU and LEU are regulated by the NRC and the Department of Transportation. Many of these requirements mandate actions that serve to mitigate potential adverse environmental impacts.

For transactions that trigger the requirements of section 3112(d) of the United States Enrichment Corporation Privatization Act, DOE will assess the impact of a release from the AFS on the domestic market, and will provide its recommendation to the Secretary to make the appropriate determination as to whether the transfer will have an adverse material impact on the domestic uranium enrichment, conversion, or mining industries.

Issued in Washington, DC, this 29th day of April, 2011.

Thomas P. D'Agostino,

Administrator, National Nuclear Security Administration.

[FR Doc. 2011–21069 Filed 8–17–11; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Department of Energy (DoE).

ACTION: Notice of Open Meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, September 28, 2011; 1 p.m.–7 p.m.

ADDRESSES: Sagebrush Inn and Conference Center, 1508 Paseo de Pueblo Sur, Taos, New Mexico.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board (NNMCAB), 1660 Old Pecos Trail, Suite B, Santa Fe, NM 87505. Phone (505) 995–0393; Fax (505) 989–1752 or *e-mail: msantistevan@doeal.gov.*

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

1 p.m. Call to Order by Co-Deputy Designated Federal Officers (DDFO), Ed Worth and Lee Bishop;
Establishment of a Quorum: Roll Call and Excused Absences;
Welcome and Introductions, Ralph Phelps;
Welcome to Taos, Mayor Darren Cordova;
Approval of Agenda and July 27, 2011 Meeting Minutes.

1:30 p.m. Public Comment Period.

1:45 p.m. Old Business;
- Written Reports;
- Other Items.

2 p.m. New Business:
- Report from Nominating Committee (Section V, F. of NNMCAB Bylaws), Deb Shaw;

- Election of Chair and Vice Chair for Fiscal Year (FY) 2012;
- Consideration and Action on FY 2012 Work Plans, Ralph Phelps;
- Discuss NNMCAB Meeting Locations for 2012;
- Appoint Ad Hoc Committee for Annual Self Evaluation;
- Other items.

2:45 p.m. Items from DDFOs, Ed Worth and Lee Bishop.
3:15 p.m. Presentation on Long-Term Stewardship, Tom Longo.
4:30 p.m. Discussion of Draft Recommendation(s) to DOE.
5 p.m. Dinner Break.
6 p.m. Public Comment Period.
6:15 p.m. Consideration and Action on Draft Recommendation(s), Ralph Phelps.
- Draft Recommendation 2011–06 (Tabled 7/20/11) .

6:45 p.m. Open Forum for Board Members.
7 p.m. Adjourn, Ed Worth and Lee Bishop.

Public Participation: The EM SSAB, Northern New Mexico, 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 Menice Santistevan at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Menice Santistevan at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Menice Santistevan at the address or phone number listed above. Minutes and other Board documents are on the Internet at: *http://www.nnmcab.org/.*

Issued at Washington, DC, on August 12, 2011.

LaTanya R. Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2011–21165 Filed 8–17–11; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Nevada

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Nevada. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register.**

DATES: Wednesday, September 14, 2011, 4 p.m.

ADDRESSES: Atomic Testing Museum, 755 East Flamingo Road, Las Vegas, Nevada 89119.

FOR FURTHER INFORMATION CONTACT: Denise Rupp, Board Administrator, 232 Energy Way, M/S 505, North Las Vegas, Nevada 89030. *Phone:* (702) 657–9088; Fax (702) 295–5300 or *E-mail: ntscab@nv.doe.gov.*

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

1. Update—Site-Specific Environmental Impact Statement Committee.
2. Update—Transportation Working Group.
3. Fiscal Year 2011 Work Plan Development.
4. Election of Officers.

Public Participation: The EM SSAB, Nevada, 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 Denise Rupp at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral presentations pertaining to agenda items should contact Denise Rupp at the telephone number listed above. The request must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing to Denise Rupp at the address listed above or at the following Web site: *http://nv.energy.gov/nssab/MeetingMinutes.aspx.*

Issued at Washington, DC on August 11, 2011.

LaTanya R. Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2011–21162 Filed 8–17–11; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2007–1121; FRL9452–6]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping and Reporting Requirements for Motor Vehicle and Non-Road Diesel Fuel

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a request to renew an existing Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR is scheduled to expire on December 31, 2011. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before October 17, 2011.

ADDRESSES: Submit your comments, clearly identified as referring to Docket ID No. EPA–HQ–OAR–2007–1121, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-Docket@epa.gov.*
- *Fax:* (202) 566–9744.
- *Mail:* Air and Radiation Docket, Environmental Protection Agency, Mail Code: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may telephone the Air and Radiation Docket at 202–566–1742.
- *Hand Delivery:* The Public Reading Room is located at the EPA West Building, 1301 Constitution Avenue, NW., Room 3334, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special

arrangements should be made for deliveries of boxed information. You may telephone the Air and Radiation Docket at 202–566–1742.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2007–1121. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://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 e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail 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 *http://www.epa.gov/epahome/dockets.htm.*

FOR FURTHER INFORMATION CONTACT: Anne-Marie C. Pastorkovich, Attorney/Advisor, Mail Code: 6406J, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; *telephone number:* 202–343–9423 *fax number:* 202–343–2801; *e-mail address: pastorkovich.anne-marie@epa.gov.*

SUPPLEMENTARY INFORMATION:

How can I access the docket and/or submit comments?

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OAR–2007–1121, which is available for online viewing at *http://www.regulations.gov*, or in person viewing at the Air and Radiation Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202–566–1744, and the telephone number for the Air Docket is 202–566–1742.

Use *http://www.regulations.gov* to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified in this document.

What information is EPA particularly interested in?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable us to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) enhance the quality, utility, and clarity of the information to be collected; and

(iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

What should I consider when I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Offer alternative ways to improve the collection activity.
6. Make sure to submit your comments by the deadline identified under **DATES.**
7. To ensure proper receipt by EPA, be sure to identify the Docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

What information collection activity or ICR does this apply to?

Affected entities: Entities potentially affected by this action (*with SIC Code/2002 NAICS Code indicated in parentheses*) are refiners (2911/324110), importers (5172/424720), pipelines (4613), petroleum marketers and other distributors (5171, 5172/424710, 424720), terminals (5171/424710), fuel oil dealers (5172/424720), fuel additive manufacturers (2911/424720), petroleum retailers and wholesale purchaser-consumers (5171, 5172/424710, 424720) and laboratories (8734/541380).

Title: Recordkeeping and Reporting Requirements for Motor Vehicle and Non-Road Diesel Fuel.

ICR numbers: EPA ICR No. 1718.09, OMB Control No. 2060–0308.

ICR status: This ICR is currently scheduled to expire December 31, 2011. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9. They are also displayed by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This ICR covers recordkeeping and reporting requirements for motor vehicle diesel fuel and non-road, locomotive and marine diesel fuel. It also includes recordkeeping and reporting associated with the placement of codes on dyed diesel fuel (the dye is required under IRS regulations). The main purpose for recordkeeping and reporting is to ensure compliance with the regulations at 40 CFR part 80, *Subpart I—Motor Vehicle, Non-Road, Locomotive, and Marine Diesel Fuel.* Most reporting is mandatory. Parties may assert a claim of business confidentiality and

submissions covered by such a claim will be treated in accordance with procedures at 40 CFR part 2 and established Agency procedures.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average less than one hour per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

A document entitled ''Proposed Supporting Statement—Part A: Recordkeepking and Reporting Related to Fuel Quality Regulations for Diesel Fuel Sold in 2001 & Later Years; for Tax-Exempt (Dyed) Highway Diesel Fuel; and Non-Road Locomotive & Marine Diesel Fuel: Renewal'' has been placed in Docket No. EPA–HQ–OAR–2007–1121. This draft document provides a more detailed explanation of the Agency's estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 6,806.

Frequency of response: Annual, quarterly and/or on occasion.

Estimated total number of responses: 265,406.

Estimated total average number of responses for each respondent: 39.

Estimated total annual burden hours: 18,950.

Estimated total annual costs: $2,044,300.

Are there changes in the estimates from the last approval?

There is a decrease in the total estimated respondent burden and cost compared to the currently approved ICR. Most of the decrease is because motor vehicle diesel reporting requirements are no longer applicable and because virtually all laboratory qualifications for test methods have already been submitted to, and acted upon by, EPA.

What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

Dated: August 12, 2011.

Lori Stewart,

Acting Director, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2011–21102 Filed 8–17–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9452–7]

Notification of a Public Teleconference of the Science Advisory Board Panel for the Review of the Great Lakes Restoration Initiative Action Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) Science Advisory Board (SAB) Staff Office announces a public teleconference of the SAB Panel to discuss its draft advisory report on the interagency *Great Lakes Restoration Initiative Action Plan FY 2010–2014.*

DATES: The teleconference will be held on September 16, 2011 from 1 p.m. to 5 p.m. (Eastern Daylight Time).

ADDRESSES: The public teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this teleconference meeting may contact Mr. Thomas Carpenter, Designated Federal Officer (DFO), SAB Staff Office, by telephone/voice mail at (202) 564–4885; by fax at (202) 565–2098 or via e-mail *carpenter.thomas@epa.gov.* General information concerning the EPA Science Advisory Board can be found at the EPA SAB Web site at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDAA), codified at 42 U.S.C. 4365 to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. Pursuant to FACA and EPA policy, notice is hereby given that an *ad hoc* SAB Panel will hold a public teleconference to discuss its draft advisory report on the Great Lakes Restoration Initiative Action Plan. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: EPA is leading an interagency Great Lakes Restoration Initiative (GLRI) to protect and restore the chemical, biological, and physical integrity of the Great Lakes. The GLRI Action Plan is designed to target the most significant environmental problems in the region, as documented in extensive scientific studies, conferences and workshops. To guide the efforts of the GLRI, EPA and its Federal partners, through the Great Lakes Interagency Task Force, developed a comprehensive multi-year Action Plan. The GLRI Action Plan identifies outcome-oriented performance goals, objectives, measurable ecological targets, and specific actions for five major focus areas: toxic substances and areas of concern; invasive species; near-shore health and nonpoint source pollution; habitat and wildlife protection and restoration; and accountability, education, monitoring, evaluation, communication, and partnerships. EPA is seeking SAB review and comment regarding the Great Lakes Restoration Initiative's Action Plan. Additional information describing the scientific background and basis for the Action Plan can be found at *http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/Review%20of%20GLRI%20Action%20Plan?OpenDocument.*

The panel held a public meeting on July 12 and 13, 2011 (76 FR 115, 34977–34978 and 76 FR 131 40355) to discuss their comments on the Action Plan. The purpose of the September 16, 2011 teleconference is for the Panel to discuss their draft advisory report.

Availability of Meeting Materials: The agenda and the draft Advisory Report on the Great Lakes Restoration Initiative Action Plan will be available on the SAB Web site at *http://www.epa.gov/sab* in advance of the meeting.

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and

panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit comments for a Federal advisory committee to consider as it develops advice for EPA. Input from the public to the SAB will have the most impact if it consists of comments that provide specific scientific or technical information or analysis for SAB panels to consider or if it relates to the clarity or accuracy of the technical information included. Members of the public wishing to provide comment should contact the Designated Federal Officer for the relevant advisory committee directly.

Oral Statements: In general, individuals or groups requesting an oral presentation at this public teleconference will be limited to three minutes per speaker. Interested parties should contact Mr. Thomas Carpenter, DFO, in writing (preferably via e-mail), at the contact information noted above, by September 12, 2011 to be placed on the list of public speakers for the meeting.

Written Statements: Written statements should be received in the SAB Staff Office by September 12, 2011 so that the information may be made available to the SAB Oil Spill Research Review Panel for their consideration. Written statements should be supplied to the DFO in the following formats: one hard copy with original signature and one electronic copy via e-mail (acceptable file format: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM–PC/Windows 98/2000/XP format). Submitters are requested to provide two versions of each document submitted: One each with and without signatures, because the SAB Staff Office does not publish documents with signatures on its Web sites. It is the SAB Staff Office general policy to post written comments on the Web page for the advisory meeting or teleconference. Members of the public should be aware that their contact information, if included in any written comments, will appear on the web. Furthermore, special care should be taken not to include copy-righted material.

Accessibility: For information on access or services for individuals with disabilities, please contact Mr. Thomas Carpenter at the phone number or e-mail address noted above, preferably at least ten days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: August 10, 2011.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2011–21100 Filed 8–17–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9452–8]

Notification of a Public Teleconference of the Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public teleconference of the CASAC Lead Review Panel to discuss its draft letter reviewing EPA's *Integrated Science Assessment for Lead (First External Review Draft—May 2011).*

DATES: The CASAC Lead Review Panel teleconference will be held on Thursday, September 15, 2011, from 12 p.m. to 3 p.m. (Eastern Time).

ADDRESSES: The public teleconference will take place by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain general information concerning the public teleconference may contact Mr. Aaron Yeow, Designated Federal Officer (DFO), via telephone at (202) 564–2050 or e-mail at *yeow.aaron@epa.gov*. General information concerning the EPA CASAC can be found on the EPA Web site at *http://www.epa.gov/casac.*

SUPPLEMENTARY INFORMATION: The CASAC was established pursuant to the Clean Air Act (CAA) Amendments of 1977, codified at 42 U.S.C. 7409D(d)(2), to provide advice, information, and recommendations to the Administrator on the scientific and technical aspects of issues related to the criteria for air quality standards, research related to air quality, sources of air pollution, and the strategies to attain and maintain air quality standards and to prevent significant deterioration of air quality. The CASAC is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. The CASAC Lead Review Panel and the CASAC will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Section 109(d)(1) of the CAA requires that the Agency periodically review and revise, as appropriate, the air quality criteria and the NAAQS for the six ''criteria'' air pollutants, including lead. EPA is currently reviewing the primary (health-based) and secondary (welfare-based) NAAQS for lead. The Lead Review Panel held a face-to-face meeting on July 20–21, 2011 (as noticed in 76 FR 36120–36121) to provide a peer review of EPA's draft *Integrated Science Assessment for Lead (First External Review Draft—May 2011)* and to provide consultative advice on EPA's *Review of the National Ambient Air Quality Standards for Lead: Risk and Exposure Assessment Planning Document.* Information about this review activity may be found on the CASAC Web site at *http://www.epa.gov/casac/*. Pursuant to FACA and EPA policy, notice is hereby given that the CASAC Lead Review Panel will hold a follow-up public teleconference to discuss the NAAQS review process and its draft letter reviewing EPA's *Integrated Science Assessment for Lead (First External Review Draft—May 2011).*

Availability of Meeting Materials: Agendas and materials in support of the meeting will be placed on the CASAC Web site at *http://www.epa.gov/casac* in advance of the meeting. For technical questions and information concerning EPA's *Integrated Science Assessment for Lead (First External Review Draft),* please contact Dr. Ellen Kirrane of EPA's Office of Research and Development at (919) 541–1340, or *kirrane.ellen@epa.gov*.

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit comments for a federal advisory committee to consider as it develops advice for EPA. Input from the public to the CASAC will have the most impact if it provides specific scientific or technical information or analysis for CASAC panels to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the Designated Federal Officer directly.

Oral Statements: In general, individuals or groups requesting an oral

presentation at a teleconference will be limited to three minutes. Interested parties should contact Mr. Aaron Yeow, DFO, in writing (preferably via e-mail) at the contact information noted above by September 8, 2011, to be placed on the list of public speakers for the meeting.

Written Statements: Written statements should be supplied to the DFO via e-mail at the contact information noted above by September 8, 2011 for the meeting so that the information may be made available to the Panel members for their consideration. Written statements should be supplied in one of the following electronic formats: Adobe Acrobat PDF, MS Word, MS PowerPoint, or Rich Text files in IBM–PC/Windows 98/2000/XP format. It is the SAB Staff Office general policy to post written comments on the Web page for the advisory meeting or teleconference. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the CASAC Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Mr. Aaron Yeow at (202) 564–2050 or *yeow.aaron@epa.gov*. To request accommodation of a disability, please contact Mr. Yeow preferably at least ten days prior to the teleconference to give EPA as much time as possible to process your request.

Dated: August 11, 2011.

Vanessa Vu,

Director, EPA Science Advisory Staff Office.

[FR Doc. 2011–21101 Filed 8–17–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Update to Notice of Financial Institutions for Which the Federal Deposit Insurance Corporation Has Been Appointed Either Receiver, Liquidator, or Manager

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Update Listing of Financial Institutions in Liquidation.

SUMMARY: Notice is hereby given that the Federal Deposit Insurance Corporation (Corporation) has been appointed the sole receiver for the following financial institutions effective as of the Date Closed as indicated in the listing. This list (as updated from time to time in the **Federal Register**) may be relied upon as ''of record'' notice that the Corporation has been appointed receiver for purposes of the statement of policy published in the July 2, 1992 issue of the **Federal Register** (57 FR 29491). For further information concerning the identification of any institutions which have been placed in liquidation, please visit the Corporation Web site at *http://www.fdic.gov/bank/individual/failed/banklist.html* or contact the Manager of Receivership Oversight in the appropriate service center.

Dated: August 15, 2011.

Federal Deposit Insurance Corporation.

Pamela Johnson,

Regulatory Editing Specialist.

INSTITUTIONS IN LIQUIDATION

[In alphabetical order]

FDIC ref. No.	Bank name	City	State	Date closed
10388	The First National Bank of Olathe	Olathe	KS	8/12/2011

[FR Doc. 2011–21089 Filed 8–17–11; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

[Notice 2011–12]

Filing Dates for the Oregon Special Election in the 1st Congressional District

AGENCY: Federal Election Commission.

ACTION: Notice of filing dates for special election.

SUMMARY: Oregon has scheduled elections on November 8, 2011, and January 31, 2012, to fill the U.S. House seat in the 1st Congressional District vacated by Representative David Wu.

Committees required to file reports in connection with the Special Primary Election on November 8, 2011, shall file a 12-day Pre-Primary Report. Committees required to file reports in connection with both the Special Primary and Special General Election on January 31, 2012, shall file a 12-day Pre-Primary Report, a consolidated 12-day Pre-General Report and Year-End Report, and a 30-day Post-General Report.

FOR FURTHER INFORMATION CONTACT: Mr. Greg J. Scott, Information Division, 999 E Street, NW., Washington, DC 20463; *Telephone:* (202) 694–1100; Toll Free (800) 424–9530.

SUPPLEMENTARY INFORMATION:

Principal Campaign Committees

All principal campaign committees of candidates who participate in the Oregon Special Primary and Special General Elections shall file a 12-day Pre-Primary Report on October 27, 2011; a consolidated 12-day Pre-General and Year-End Report on January 19, 2012; and a 30-day Post-General Report on March 1, 2012. (See chart below for the closing date for each report.)

All principal campaign committees of candidates participating *only* in the Special Primary Election shall file a 12-day Pre-Primary Report on October 27, 2011. (See chart below for the closing date for each report).

Note that these reports are in addition to the campaign committee's regular quarterly filings. (See chart below for the closing date for each report.)

Unauthorized Committees (PACs and Party Committees)

Political committees filing on a semi-annual basis in 2011 or a quarterly basis in 2012 are subject to special election reporting if they make previously undisclosed contributions or expenditures in connection with the Oregon Special Primary or Special General Election by the close of books for the applicable report(s). (See chart below for the closing date for each report).

Since disclosing financial activity from two different calendar years on one report would conflict with the calendar year aggregation requirements stated in the Commission's disclosure rules, unauthorized committees that trigger the filing of the consolidated Pre-General & Year-End Report will be

required to file this report on two separate forms: One form to cover 2011 activity, labeled as the Year-End Report; and the other form to cover only 2012 activity, labeled as the Pre-General Report. Both forms must be filed by January 19, 2012.

Committees filing monthly that make contributions or expenditures in connection with the Oregon Special Primary or General Elections will continue to file according to the monthly reporting schedule.

Additional disclosure information in connection with the Oregon Special Election may be found on the FEC Web site at *http://www.fec.gov/info/report_dates.shtml.*

Disclosure of Lobbyist Bundling Activity

Campaign committees, party committees and Leadership PACs that are otherwise required to file reports in connection with the special elections must simultaneously file FEC Form 3L if they receive two or more bundled contributions from lobbyists/registrants or lobbyist/registrant PACs that aggregate in excess of the lobbyist bundling disclosure threshold during the special election reporting periods (see charts below for closing date of each period). 11 CFR 104.22(a)(5)(v).

The lobbyist bundling disclosure threshold for calendar year 2011 is $16,200. This threshold amount may change in 2012 based upon the annual cost of living adjustment (COLA). As soon as the adjusted threshold amount is available, the Commission will publish it in the **Federal Register** and post it on its Web site. 11 CFR 104.22(g) and 110.17(e)(2). For more information on these requirements, see **Federal Register** Notice 2009–03, 74 FR 7285 (February 17, 2009).

CALENDAR OF REPORTING DATES FOR OREGON SPECIAL ELECTION

Report	Closed of books[1]	Reg./cert. & overnight mailing deadline	Filing deadline
Committees Involved in Only the Special Primary (11/08/11) Must File:			
Pre-Primary	10/19/11	10/24/11	10/27/11
Year-End	12/31/11	01/31/12	01/31/12
Committees Involved in Both the Special Primary (11/08/11) and Special General (01/31/12) Must File:			
Pre-Primary	10/19/11	10/24/11	10/27/11
Pre-General & Year-End[2]	01/11/12	[3] 01/16/12	01/19/12
Post-General	02/20/12	03/01/12	03/01/12
April Quarterly	03/31/12	04/15/12	[4]04/15/12
Committees Involved in Only the Special General (01/31/12) Must File:			
Pre-General & Year-End[2]	01/11/12	[3]01/16/12	01/19/12
Post-General	02/20/12	03/01/12	03/01/12
April Quarterly	03/31/12	04/15/12	[4]04/15/12

[1] These dates indicate the end of the reporting period. A reporting period always begins the day after the closing date of the last report filed. If the committee is new and has not previously filed a report, the first report must cover all activity that occurred before the committee registered as a political committee with the Commission up through the close of books for the first report due.

[2] Committees should file a consolidated Pre-General & Year-End Report by the filing deadline of the Pre-General Report.

[3] Notice that the registered/certified & overnight mailing deadline falls on a Federal holiday. The report should be postmarked on or before that date.

[4] Notice that this filing deadline falls on a weekend. Filing deadlines are not extended when they fall on nonworking days. Accordingly, reports filed by methods other than Registered, Certified or Overnight Mail, or electronically, must be received before the Commission's close of business on the last business day before the deadline.

Dated: August 11, 2011.

On behalf of the Commission.

Cynthia L. Bauerly,

Chair, Federal Election Commission.

[FR Doc. 2011–21036 Filed 8–17–11; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 11–12]

China Shipping Container Lines Co., Ltd.; COSCO Container Lines Company Limited; Evergreen Line A Joint Service Agreement; Hanjin Shipping Co., Ltd.; Horizon Lines, LLC; Kawasaki Kisen Kaisha, Ltd.; Nippon Yusen Kaisha; United Arab Shipping Company (S.A.G.); and Yang Ming Marine Transport Corporation v. The Port Authority of New York and New Jersey; Notice of Filing of Complaint and Assignment

Notice is given that a complaint has been filed with the Federal Maritime Commission (Commission) by China Shipping Container Lines Co., Ltd.; COSCO Container Lines Company Limited; Evergreen Line A Joint Service Agreement; Hanjin Shipping Co., Ltd.; Horizon Lines, LLC; Kawasaki Kisen Kaisha, Ltd.; Nippon Yusen Kaisha; United Arab Shipping Company (S.A.G.); and Yang Ming Marine Transport Corporation, hereinafter ''Complainants,'' against the Port Authority of New York and New Jersey, hereinafter ''Respondent''. Complainants are each ocean common carriers. Complainants allege that Respondent is a marine terminal operator that ''owns and operates marine terminal facilities in the New York and New Jersey area, including leased marine terminal facilities and public berths.''

Complainants allege that Respondent violated the Shipping Act of 1984, 46 U.S.C. 41102(c) and 41106(2) because

through adoption and implementation of its published Tariff's provisions the Port ''(a) has failed and continues to fail to establish, observe, and enforce just and reasonable regulations and practices relating to or connected with receiving, handling, storing, or delivering property; and (b) has given and continues to give undue and unreasonable preference and advantage or impose undue or unreasonable prejudice or disadvantage with respect to persons.'' In particular, Complainants allege that the Port has adopted a ''Cargo Facility Charge'' (CFC) which is ''unlawful because Complainants do not receive services commensurate with the fee; because it severely and unreasonably prejudices Complainants while unduly preferring other users of the Port's facilities; and because the Cargo Facility Charge and the rules applying it provide for unlawful expulsion of Complainants from the Port.'' Complainants request that the Commission issue an order ''declaring Respondent's CFC and Section H [of Respondent's tariff] to be unlawful, and commanding Respondent: to cease and desist from the aforesaid violations; to establish and put in force such practices as the Commission determines to be lawful and reasonable; to pay to Complainants by way of reparations for the unlawful conduct herein described a sum to be determined, with interest and attorney's fees and such other sums as the Commission may determine to be proper as an award of reparations; and that such other and further order or orders be made as the Commission determines to be proper in the premises.'' The full text of the complaint can be found in the Commission's Electronic Reading Room at *http://www.fmc.gov.*

This proceeding has been assigned to the Office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by August 13, 2012 and the final decision of the Commission shall be issued by December 11, 2012.

Karen V. Gregory,

Secretary.

[FR Doc. 2011–21016 Filed 8–17–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 12, 2011.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *C–B–G, Inc.,* West Liberty, Iowa; to acquire up to 50.01 percent of the voting shares of Washington Bancorp, and thereby indirectly acquire voting shares of Federation Bank, both in Washington, Iowa.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Community Bank Partners, Inc.,* Denver, Colorado; to acquire 100 percent of the voting shares of First National Bancshares, Inc., and thereby indirectly acquire voting shares of First National Bank, both in Goodland, Kansas.

Board of Governors of the Federal Reserve System, August 15, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–21075 Filed 8–17–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Government in the Sunshine Meeting Notice

AGENCY: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:30 a.m., Monday, August 22, 2011.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed

MATTERS TO BE CONSIDERED:

1. Personnel Matter.

FOR MORE INFORMATION PLEASE CONTACT: Michelle Smith, Director, or Dave Skidmore, Assistant to the Board, Office of Board Members at 202–452–2955.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: August 15, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–21184 Filed 8–16–11; 4:15 pm]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

SES Performance Review Board

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given of the appointment of members to the FTC Performance Review Board.

FOR FURTHER INFORMATION CONTACT: Karen Leydon, Chief Human Capital Officer, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–3633.

SUPPLEMENTARY INFORMATION: Publication of the Performance Review

Board (PRB) membership is required by 5 U.S.C. 4314(c)(4). The PRB reviews and evaluates the initial appraisal of a senior executive's performance by the supervisor, and makes recommendations regarding performance ratings, performance awards, and pay-for-performance pay adjustments to the Chairman.

The following individuals have been designated to serve on the Commission's Performance Review Board:

Eileen Harrington, Executive Director, Chair.

Willard K. Tom, General Counsel.

Pauline M. Ippolito, Deputy Director, Bureau of Economics.

Richard A. Feinstein, Director, Bureau of Competition.

Jessica L. Rich, Deputy Director, Bureau of Consumer Protection.

By direction of the Commission.

Richard C. Donohue,

Acting Secretary.

[FR Doc. 2011–21021 Filed 8–17–11; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Biodefense Science Board

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) will be holding a public meeting. The meeting is open to the public.

DATES: The NBSB will hold a public meeting on September 22, 2011 from 9 a.m. to 5 p.m. E.S.T. The agenda is subject to change as priorities dictate.

ADDRESSES: Almas Temple—Sphinx Grand Ballroom; 1315 K Street, NW., Washington, DC 20005 (adjacent to the Hamilton Crowne Plaza Washington). To attend by teleconference, please check the NBSB September meeting webpage, *http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Pages/110922meeting.aspx.* Individuals who wish to attend the meeting in person should send an e-mail to *NBSB@HHS.GOV* with ''NBSB Registration'' in the subject line.

FOR FURTHER INFORMATION: *e-mail: NBSB@HHS.GOV*

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (*42 U.S.C. 247d–7f*) and section 222 of the Public Health Service Act (*42 U.S.C. 217a*), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the Assistant Secretary for Preparedness and Response on other matters related to public health emergency preparedness and response.

Background: The majority of this public meeting will be dedicated to a discussion of the findings of the NBSB's Anthrax Vaccine Working Group. Subsequent agenda topics will be added as priorities dictate. Any additional agenda topics will be available on the Board's September meeting webpage prior to the public meeting.

Availability of Materials: The meeting agenda and materials will be posted prior to the meeting on the September meeting webpage at *http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Pages/110922meeting.aspx.*

Procedures for Providing Public Input: Any member of the public providing oral comments at the meeting must sign-in at the registration desk and provide his/her name, address, and affiliation. All written comments must be received prior to September 21, 2011 and should be sent by e-mail to *NBSB@HHS.GOV* with ''NBSB Public Comment'' as the subject line. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should e-mail *nbsb@hhs.gov.*

Dated: August 8, 2011.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2011–21163 Filed 8–17–11; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Low Income Home Energy Assistance Program (LIHEAP) Household Report.

OMB No.: 0970–0060.

Description: This report is an annual activity required by statute (42 U.S.C. 8629) and Federal reguations (45 CFR 96.92) for the Low Income Home Energy Assistance Program (LIHEAP). Submission of the completed report is one requirement for LIHEAP grantees applying for Federal LIHEAP block grant funds. States, the District of Columbia, and the Commonwealth of Puerto Rico are required to report statistics for the previous Federal fiscal year on:

- Assisted and applicant households, by type of LIHEAP assistance;
- Assisted and applicant households, by type of LIHEAP assistance and poverty level;
- Assisted households, regardless of the type(s) of LIHEAAP assistance;
- Assisted households, by type of LIHEAP assistance, having at least one vulnerable member broken out; by a person at least 60 years or younger, disabled person, or a child five years older or younger;
- Assisted households, by type of LIHEAP assistance, with at least one member age 2 years or under;
- Assisted households, by type of LIHEAP assistance, with at least one member ages 3 years through 5 years; and
- Assisted households, regardless of the type(s) of LIHEAP assistance, having at least one member 60 years or older, disabled, or five years old or younger.

Insular areas (other than the Commonwealth of Puerto Rico) and Indian Tribal Grantees are required to submit data only on the number of households receiving heating, cooling, energy crisis, or weatherization benefits.

The information is being collected for the Department's annual *LIHEAP Report to Congress.* The data also provide information about the use of LIHEAP funds. Finally, the data are used in the calculation of LIHEAP performance measures under the Government Performance and Results Act of 1993. The data elements will allow the accuracy of measuring LIHEAP targeting performance and LIHEAP cost efficiency.

Respondents: State Governments, Tribal Governments, Insular Areas, the District of Columbia, and the Commonwealth of Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Assisted Household Report—Long Form	52	1	25	1,300
Assisted Household Report—Short Form	164	1	1	164
Applicant Household Report	52	1	13	676

Estimated Total Annual Burden Estimates: 2,140.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address: infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–21107 Filed 8–17–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0424]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Temporary Marketing Permit Applications

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 September 19, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0133. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i)—(OMB Control Number 0910–0133)—Extension

Section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity for food ''[w]henever * * * such action will promote honesty and fair dealing in the interest of consumers * * *.'' Under section 403(g) of the FD&C Act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (§ 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) enables the Agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions and standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

In the **Federal Register** of June 10, 2011 (76 FR 34080), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
130.17(c)	13	2	26	25	650

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
130.17(i)	1	2	2	2	4
Total					654

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated number of temporary marketing permit applications and hours per response is an average based on the Agency's experience with applications received for the past 3 years, and information from firms that have submitted recent requests for temporary marketing permits. Based on this information, we estimate that there will be, on average, approximately 13 firms submitting requests for two temporary marketing permits per year over the next 3 years.

Thus, FDA estimates that 13 respondents will submit 2 requests for temporary marketing permits annually under § 130.17(c). The estimated number of respondents for § 130.17(i) is minimal because this section is seldom used by the respondents; therefore, the Agency estimates that there will be one or fewer respondents annually with two or fewer requests for extension of the marketing permit under § 130.17(i). The estimated number of hours per response is an average based on the Agency's experience and information from firms that have submitted recent requests for temporary marketing permits. We estimate that 13 respondents each will submit 2 requests for temporary marketing permits under § 130.17(c) and that it will take a respondent 25 hours per request to comply with the requirements of that section, for a total of 650 hours. We estimate that one respondent will submit two requests for extension of its temporary marketing permits under § 130.17(i) and that it will take a respondent 2 hours per request to comply with the requirements of that section, for a total of 4 hours.

Dated: August 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21039 Filed 8–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0425]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Recall Regulations

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 September 19, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0188. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, and 107.280—(OMB Control Number 0910–0188)—Extension

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the FD&C Act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the FD&C Act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations in part 107 (21 CFR part 107) implement these statutory provisions.

Section 107.230 requires each recalling firm to conduct an infant formula recall with the following elements: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct-account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 requires the recalling firm to conduct an infant formula recall with the following elements: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation

for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market.

In the **Federal Register** of June 7, 2011 (76 FR 32976), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA has added a new table 2 to this document to comply with the new requirement to report third-party disclosure burden hours in a separate table. The third-party disclosure burden hours were previously reported in the 60-day notice under the reporting burden table (table 1). In compliance with the new requirement, we have broken out the third-party disclosure burden hours in a new third-party disclosure burden table (table 2). FDA has moved 50 hours per recall from line 1 of table 1 to line 1 of table 2, and 25 hours per recall from line 4 of table 1 to line 2 of table 2. This is being done to show the third-party disclosure burden previously disclosed in table 1. The total estimated burden of this collection remains unchanged at 12,864 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
107.230	2	1	2	4,450	8,900
107.240	2	1	2	1,482	2,964
107.250	2	1	2	120	240
107.260 [2]	1	1	1	625	625
Total					12,729

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

The reporting and third-party disclosure burden estimates are based on Agency records, which show that there are five manufacturers of infant formula and that there have been, on average, two infant formula recalls per year for the past 3 years. Based on this information, we estimate that there will be, on average, approximately two infant formula recalls per year over the next 3 years.

Thus, FDA estimates that two respondents will conduct recalls annually under §§ 107.230, 107.240, and 107.250. The estimated number of respondents for § 107.260 is minimal because this section is seldom used by FDA; therefore, the Agency estimates that there will be one or fewer respondents annually for § 107.260.

The estimated number of reporting burden hours per response is an average based on the Agency's experience and information from firms that have conducted recalls. We estimate that two respondents will conduct infant formula recalls under § 107.230 and that it will take a respondent 4,450 hours to comply with the requirements of that section, for a total of 8,900 hours. In the 60-day notice, we estimated that it will take a respondent 4,500 hours per recall to comply with § 107.230 for a total of 9,000 hours. As noted, we have added a new table 2 to report third-party disclosure burden hours. The new lower figure of 4,450 hours per recall reflects that 50 hours are being reported in new table 2. We estimate that two respondents will conduct infant formula recalls under § 107.240 and that it will take a respondent 1,482 hours to comply with the requirements of that section, for a total of 2,964 hours. We estimate that two respondents will submit recommendations for termination of infant formula recalls under § 107.250 and that it will take a respondent 120 hours to comply with the requirements of that section, for a total of 240 hours. Finally, we estimate that one respondent will need to carry out additional effectiveness checks and issue additional notifications under § 107.260, for a total of 625 hours. In the 60-day notice, we estimated that it will take a respondent 650 hours per recall to comply with § 107.260 for a total of 650 hours. As noted, we have added a new table 2 to report third-party disclosure burden hours. The new lower figure of 625 hours per recall reflects that 25 hours are being reported in new table 2.

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
107.230	2	1	2	50	100
107.260	1	1	1	25	25
Total					125

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

New table 2 reports the Agency's third-party disclosure burden estimates for §§ 107.230 and 107.260. The estimated burden hours per disclosure is an average based on the Agency's experience. The third-party disclosure burden in § 107.230 is the requirement to promptly notify each affected direct-account (customer) about the recall and if the recalled formula presents a risk to human health, the requirement that the recalling firm must also request that each establishment that sells the recalled formula post (at the point of purchase) a notice of the recall. We estimate that two respondents will conduct infant formula recalls under § 107.230 and that it will take a respondent 50 hours to comply with the third-party disclosure requirements of that section, for a total of 100 hours. The third-party disclosure burden in § 107.260 is the requirement to issue additional notifications where the recall strategy or implementation is determined to be deficient. We estimate that one respondent will issue additional notifications under § 107.260 and that it will take a respondent 25 hours to comply with the third-party disclosure requirements of that section, for a total of 25 hours.

Dated: August 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21040 Filed 8–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0402]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Petitions for Exemption From Preemption

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 September 19, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0277. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

State Petitions for Exemption From Preemption—21 CFR 100.1(d) (OMB Control Number 0910–0277)—Extension

Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343–1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard of identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the State food labeling or standard of identity requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from Federal preemption.

In the **Federal Register** of June 10, 2011 (76 FR 34082), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.1(d)	1	1	1	40	40

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for § 100.1(d) is minimal because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, FDA has not received any new petitions for exemption from preemption; therefore, the Agency estimates that one or fewer petitions will be submitted annually. Although FDA has not received any new petitions for exemption from preemption in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State or local

government to petition for an exemption from preemption under the provisions of section 403A of the FD&C Act.

Dated: August 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21041 Filed 8–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0012]

Direct Discovery of HLA Associated Influenza Epitopes Isolated From Human Cells for Vaccine and Therapeutic Evaluation and Development (U01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of a sole source cooperative agreement with the University of Oklahoma Health Sciences Center. The goal of the FDA, Center for Drug Evaluation and Research, Office of Chief Scientist, is to develop technology to molecularly characterize peptide epitopes that are processed and presented on soluble HLA (human leucocyte antigen) expressed by human cells. Initial studies will examine and characterize influenza peptides isolated from several different soluble Class I HLAs produced from influenza infected human lung cell lines. There is a growing interest in developing universal vaccines for influenza by targeting conserved internal proteins to stimulate cross-protective CTLs (cytolytic T lymphocyte) to provide long-lasting immunity. It is therefore critically important to identify which viral epitopes are generated by antigen processing in influenza infected lung cells, the target cells of cell mediated immune response to respiratory viruses. FDA seeks a collaboration to develop this technology for this purpose which can then be applied to identifying and characterizing other HLA-presented epitopes in viral infections, cancer, and immune toxicities.

DATES: Important dates are as follows:

1. The application due date is September 1, 2011.
2. The anticipated start date is November 1, 2011.
3. The opening date is August 18, 2011.
4. The expiration date is November 2, 2011.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

For Programmatic questions and concerns contact: Michael Norcross, Center for Drug Evaluation and Research, Food and Drug Administration, 9000 Rockville Pike, N29B, Rm. 4NN (HFD 122), Bethesda, MD 20892, *Telephone:* 301–827–0793; *E-mail: Michael.norcross@fda.hhs.gov.*

For Financial and Administrative questions and concerns contact: Gladys M. Bohler, Food and Drug Administration, Office of Acquisitions and Grant Services, 5630 Fisher's Lane, Rm. 1078 (HFA 500), Rockville, MD 20857, *Telephone:* 301–827–7175, *E-mail: gladys.bohler@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at: *http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm088761.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Funding Opportunity Number: RFA–FD–12–001.

Catalog of Federal Domestic Assistance Number: 93.103.

A. Background

Knowledge on how viral and self proteins are processed and presented in HLA molecules is important to understand how the body defends itself from infection and how immune responses can lead to tissue toxicities. Developing technology to allow direct identification of epitopes bound by HLA molecules is critical to vaccine and therapeutic immune strategies. FDA is interested in collaborative research to develop and implement this technology which will be valuable in evaluation and review of vaccines and therapeutics. Initial studies will address identifying epitopes from influenza that are presented by different HLA alleles in infected lung cells.

Influenza virus infection affects a significant proportion of the population and is associated with serious morbidity and mortality. Although many epitopes can be predicted by computer programs and by screening peripheral blood cells with panels of viral peptides from influenza, the peptides that are presented on the infected target cells in the tissues and the infiltrating T cells that recognize the HLA-peptide complexes are the critical elements to control and recover from infection. The technology of directly identifying viral epitopes in HLA can elucidate viral targets for T cells and provide the foundation for new approaches for rapid development of effective vaccines. More effective vaccines to prevent and control influenza infections will have broad public health benefits by reducing morbidity and mortality of this infectious disease.

B. Research Objectives

For this purpose, a direct epitope elution approach is needed to allow milligram quantities of HLA-peptide complexes to be purified from influenza infected lung cells lines that express soluble HLA. Human lung cell lines engineered to secrete soluble HLA from three supertypes (A*01, A*03, and B*27) should be infected with at least two current influenza strains and HLA collected during infection. HLA will be purified and bound peptides eluted. Influenza peptides should be systematically identified by mass spectrometry analysis and sequencing. Synthetic viral peptides can then be tested for binding to recombinant HLA to verify binding specificity and affinity. Influenza epitopes identified in this initial phase of the project can be evaluated for immunogenicity and antigenicity in follow up studies.

This project will provide the regulatory science to facilitate development and evaluation of direct discovery of HLA presented epitopes. The direct epitope methodology will be applied to current influenza strains initially, but has the flexibility to address novel pandemic strains and other pathological agents.

Goal 1: Identify virus-encoded class I HLA peptides presented during influenza infection of human lung cells.

Goal 2: In vitro validation of class I HLA-presented influenza peptides.

Goal 3: Develop HLA-epitope direct-discovery technology for use in FDA laboratories.

C. Eligibility Information

The technology requires extensive infrastructure for growing cells, purifying HLA from culture supernatants, and for mass spectrometry analysis. Staff at the University of Oklahoma Health Sciences Center are leaders in this technology and have published the first reports on applying this method to influenza. Support of this project will allow the extension of the methodology to examine other HLA types. FDA believes this is a novel and valuable methodology that should be implemented at FDA. Funding this collaborative initiative will allow FDA to acquire the proteomic expertise, training, and tissue culture support to establish a laboratory in the field of immunoproteomics. The direct

identification of viral epitopes is critically important to understanding immune responses to infection and vaccination, and there are currently no comparable methods besides the classic screening of vast arrays of overlapping viral peptides on blood lymphocytes. Peptide screening methods only identify possible target epitopes, but do not define which epitopes are expressed in lung tissue. The technology will be valuable for vaccine development and evaluation, and has the flexibility to allow rapid analysis of novel pandemic strains for immunogenic epitopes. The technology can be applied to other infectious diseases, cancer, and immunotoxicities.

II. Award Information/Funds Available

A. Award Amount

Only one grant award will be made in fiscal year (FY) 2012. The application budget is not limited, but it needs to reflect the actual needs of the proposed project. However, presently for FY 2012, the funds are available in the amount of $400,000 (total cost), and are subject to change based on the availability of funds.

B. Length of Support

The maximum period is 1 year with the option of 4 more years of budget support depending on the availability of funds.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at *http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm088761.htm.* Persons interested in applying for a grant may obtain an application at *http://grants2.nih.gov/grants/funding/phs398/phs398.html.* For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number.
- Step 2: Register With Central Contractor Registration.
- Step 3: Register With Electronic Research Administration (eRA) Commons.

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 3, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit paper applications to: Gladys Bohler, Grants Management Specialist (see **FOR FURTHER INFORMATION CONTACT** section of this document).

Dated: August 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21043 Filed 8–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Dialogues in Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following Office of Women's Health and Society for Women's Health Research jointly sponsored meeting: Dialogues in Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials. The purpose of this symposium is to facilitate the broader discussion and dissemination of innovative strategies for increasing the recruitment and retention of women and minority subpopulations into clinical trials. The overarching goal of this symposium is to use a best practices learning exchange to share information and encourage successful methods and/or model implementation within a broad research community—industry, academia, and government.

Date and Time: The meeting will be held on September 22, 2011, from 8 a.m. to 9 a.m. (registration); 9 a.m. to 5:30 p.m. (program); 5:30 p.m. to 6:30 p.m. (reception); and September 23, from 8 a.m. to 1:30 p.m.

Location: The meeting will be held at L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW., Washington, DC 20024.

Contact: Deborah Kallgren, FDA Office of Women's Health, 10903 New Hampshire Ave., Bldg. 32, Rm. 2314, Silver Spring, MD 20993–0002, 301–796–9442, *Fax:* 301–847–8604, *e-mail: deborah.kallgren@fda.hhs.gov.*

Registration: Registration is free, but seating is limited to 200. Registration will be accepted online and is available at *http://www.swhr.org* through September 16, 2011. For information regarding registration contact: Rachel Griffith, Society for Women's Health Research (SWHR), 1025 Connecticut Ave., NW., Suite 701, Washington, DC 20036, 202–496–5001, *Fax:* 202–833–3472, *e-mail: rachel@swhr.org.*

If you need special accommodations due to a disability, please contact Rachel Griffith at least 7 days in advance.

Dated: August 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21042 Filed 8–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, codified at 5 U.S.C. App. 2), notice is hereby given of the following meeting:

Name: Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: September 22, 2011, 8:30 a.m. to 5 p.m.; September 23, 2011, 8:30 a.m. to 3:30 p.m.

Place: Renaissance Washington, DC DuPont Circle Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Status: The meeting will be open to the public with attendance limited due to space availability. Participants are asked to register for the meeting by going to the registration Web site at *http://altarum.cvent.com/event/SACHDNC092011.* The registration deadline is Tuesday, September 20, 2011. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate their needs on the registration website. The deadline for special accommodation requests is Friday, September 19, 2011. If there are technical problems gaining access to the Web site, please contact Maureen Ball, Meetings Coordinator, at *conferences@altarum.org.*

Purpose: The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (Advisory Committee) was established by Congress to advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having (or at risk) for heritable disorders. The Advisory Committee, as authorized by Public Law 106–310, which added

section 1111 of the Public Health Service Act, codified at 42 U.S.C. 300b–10, also provides advice and recommendations concerning grants and projects authorized under section 1109 of the Public Health Service Act (42 U.S.C. 300b–8).

Agenda: The meeting will include a review and reflection of the previous 24 meetings and a look forward. The agenda will include topics related to the past, present, and future work of the Committee, including: (1) A presentation of the previous, current and future endeavors of the External Review Workgroup's activities; (2) an update from the Evidence Evaluation and Methods workgroup's progress on developing the Decision Process Tree; (3) review of previous reports, workgroups and publications from the Committee and next steps for public health genetics; and (4) discussion and presentations on the previous and continued work and reports of the Advisory Committee's subcommittees on laboratory standards and procedures, follow-up and treatment, and education and training. Proposed agenda items are subject to change as priorities dictate. You can locate the Agenda, Committee Roster and Charter, presentations, and meeting materials at the home page of the Advisory Committee's Web site at *http://www.hrsa.gov/heritabledisorderscommittee/.*

Public Comments: This meeting will include an extended public comment period during the morning session on September 22, 2011. Members of the public can submit written comments and/or present oral comments during the public comment period of the meeting. Those individuals who want to make oral comments are requested to register online by Tuesday, September 20, 2011, at *http://altarum.cvent.com/event/SACHDNC092011.* Requests should contain the name, address, telephone number, and any professional or business affiliation of the person desiring to make an oral comment. Groups having similar interests are requested to combine their comments and present them through a single representative. Written comments should be e-mailed no later than Tuesday, September 20, 2011 for consideration. Oral and written public comment will be included in the transcripts of the meeting and will be posted to the committee's Web site. Written comments should contain the name, address, telephone number, and any professional or business affiliation of the author. Submit written comments to Maureen Ball, Meetings Coordinator, Conference and Meetings Management, Altarum Institute, 1200 18th Street, NW., Suite 700, Washington, DC 20036, telephone: 202 828–5100; fax: 202 785–3083, or e-mail: *conferences@altarum.org.*

Contact Person: Anyone interested in obtaining other relevant information should write or contact Alaina M. Harris, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0721, *aharris@hrsa.gov.* More information on the Advisory Committee is available at *http://mchb.hrsa.gov/heritabledisorderscommittee.*

Dated: August 12, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011–21092 Filed 8–17–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301–496–7057; *fax:* 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Quantitative Measurement of Syndesmophytes in Ankylosing Spondylitis Using Computed Tomography (CT)

Description of Technology: Syndesmophyte (abnormal bone) growth in the spine is a hallmark of Ankylosing Spondylitis, a type of inflammatory arthritis. Syndesmophyte growth is currently monitored using semi-quantitative scoring of radiographs, but radiographs consider only a small part of the vertebra, and the method is subject to reader error. Because syndesmophytes grow slowly, radiographs also lack sensitivity. The invention provides a method to measure syndesmophytes using data from computed tomography scans of the lumbar spine. It provides computer algorithm that fully quantitates syndesmophyte volumes in three-dimension space. This method allows precise and accurate measurement of the presence and rate of growth of syndesmophytes over time, which for the first time will permit testing of whether any treatments can slow the progression of this type of spinal arthritis.

Potential Commercial Applications:

- The method would be useful for clinical trials of drugs against Syndesmophyte growth.
- Because of the improved precision, achieving statistical significance in assessing the efficacy of a drug would require smaller samples.

Competitive Advantages:

- The present method is more automated than existing methods.
- The method is more precise and sensitive than existing methods, thus providing more reliable statistical analysis and improved planning in treatment regimen.

Development Stage: In vivo data available (human).

Inventors: Sovira Tan (NIAMS), *et al.*

Publication: Tan S, Yao J, Ward MM, Yao L, Summers RM. Computer aided evaluation of ankylosing spondylitis using high-resolution CT. IEEE Trans Med Imaging 2008 Sep;27(9):1252–1267. [PMID 18779065].

Intellectual Property: HHS Reference No. E–167–2011/0—Software. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich, *Esq.;* 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Arthritis and Musculoskeletal and Skin Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Brian W. Bailey, Ph.D. at *bbailey@mail.nih.gov.*

An Automated Method for Precise Measurement of Vertebral Body Height and Intervertebral Disk Height Using Computed Tomography

Description of Technology: Vertebral fractures due to osteoporosis result in loss of vertebral height. Degenerative disk disease in the spine results in loss of disk height. Currently, radiography and magnetic resonance imaging are used to assess vertebral and disk height, and measurements are done manually. The present invention offers improved method to measure vertebral and disk heights. The invention provides computer algorithm that substantially automates the task, and uses computed tomography. The advantage of computed tomography over radiography is that of 3D imaging over 2D imaging. Computed tomography's advantage over MRI is better image resolution. The combination of automation and superior imaging capability makes the method substantially more precise than previous ones. This allows better detection of changes in vertebral height and disk height over time, and thus aids in the planning of appropriate medical treatment in cases associated with the loss of vertebral or disk heights, such as in osteoporosis for example.

Potential Commercial Applications:

- The method would be useful for clinical trials of drugs for osteoporosis.
- Because of the improved precision, achieving statistical significance in assessing the efficacy of a drug would require smaller samples.

Competitive Advantages:

- The present method is semi-automated.
- The method is more precise and sensitive than existing methods, thus providing more reliable statistical analysis and improved planning in treatment regimen.

Development Stage: In vivo data available (human).

Inventors: Sovira Tan (NIAMS), *et al.*

Intellectual Property: HHS Reference No. E–166–2011/0—Software. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich, *Esq.;* 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Arthritis and Musculoskeletal and Skin Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Brian W. Bailey, Ph.D. at *bbailey@mail.nih.gov.*

Monoclonal Antibodies Against Poliovirus

Description of Technology: Early work by Hammond et al. showed gamma globulin to be effective for the prevention of poliomyelitis. Therefore, passive immunotherapy could be another way to treat chronic excretors. Even though prior attempts to use intravenous immunoglobulin (IVIG) and breast milk were unsuccessful, there is reason to think that higher doses of antipoliovirus antibodies could result in complete clearance of poliovirus from chronically infected individuals. Six poliovirus-neutralizing MAbs were recovered from a combinatorial Fab phage display library constructed from bone marrow-derived lymphocytes of immunized chimpanzees. The six MAbs neutralized vaccine strains and virulent strains of poliovirus. Five MAbs were serotype specific, while one MAb cross-neutralized serotypes 1 and 2. Both serotype 2-specific antibodies recognized antigenic site 1. No escape mutants to serotype 3-specific MAbs could be generated. The administration of a serotype 1-specific MAb to transgenic mice susceptible to poliovirus at a dose of 5 μg/mouse completely protected them from paralysis after challenge with a lethal dose of wild-type poliovirus. Moreover, MAb injection 6 or 12 h after virus infection provided significant protection. This application claims the antibodies described above and methods for their use.

Potential Commercial Applications:

- Prophylaxis/therapeutic for poliovirus.
- Post-exposure emergency prophylaxis of poliovirus.

Competitive Advantages:

- No humanization required.
- Highly potent neutralizing antibodies.
- Biological materials available.

Development Stage:

- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Zhaochun Chen, Robert H. Purcell, Konstantin Chumakov (NIAID).

Publication: Chen Z, *et al.* Chimpanzee-human monoclonal antibodies for treatment of chronic poliovirus excretors and emergency postexposure prophylaxis. J Virol. 2011 May;85(9):4354–4362. [PMID: 21345966].

Intellectual Property: HHS Reference No. E–076–2011/0—U.S. Provisional Application No. 61/443,915 filed 17 Feb 2011.

Licensing Contact: Peter Soukas, J.D.; 301–435–4646; *soukasp@mail.nih.gov.*

Methods of Treating Giardiasis Using FDA-Approved Compounds

Description of Technology: This technology includes a group of at least twenty-nine, diverse, commercially available compounds that are newly identified for activity against *Giardia lamblia* parasites. At least six of the candidate compounds, Bortezomib, Decitabine, Hydroxocobalamin, Amlexanox, Idarubicin, and Auranofin have preexisting FDA approval for human use for other (non-Giardia) conditions. Another three compounds, Fumagillin, Nitarsone and Carbadox have preexisting approval for veterinary use for non-Giardia conditions. Additional active compounds identified include: Acivicin, Riboflavin butyrate, BTO–1, GW9662, Dinitroph-dfgp, Deserpidine, Tetramethylthiuram disulsulfide, Disulfiram, Mitoxantrone, Ecteinascidin 743, 17-allyaminogeldanamycin, Carboquone and Nocodazole. The anti-Giardial activity of these compounds presents a cost saving opportunity for the rapid development of new, better tolerated treatments for the most prevalent human intestinal parasite infection in the United States and the world.

Potential Commercial Applications:

- Treatment of Giardia in humans.
- Treatment of Giardia in animals—dogs and cats.

Competitive Advantages: These compounds have currently been approved for human and veterinary uses of other indications which provides an opportunity to greatly reduce risk and pre-market investments both in terms of time and costs associated with development and regulatory approval for new Giardia applications including the drug resistant Giardiasis.

Development Stage:

- Early-stage.
- Pre-clinical.
- In vitro data available.

Inventors:

- Wei Zheng, Catherine Chen, Juan J. Marugan, Noel T. Southall, Christopher P. Austin (NHGRI).
- Osnat Hertzberg, Luidmila Kulakova, Andrey Galkin (Institute for Bioscience & Biotechnology Research, University of Maryland).

Publication: Chen CZ, et al. High-throughput Giardia lamblia viability assay using bioluminescent ATP content measurements. Antimicrob Agents Chemother. 2011 Feb;55(2):667–675. [PMID 21078930].

Intellectual Property: HHS Reference No. E–211–2010/1—U.S. Provisional Application No. 61/411,509 filed 09 Nov 2010.

Licensing Contact: Tedd Fenn; 301–435–5031; *Tedd.Fenn@nih.gov.*

Collaborative Research Opportunity: The NHGRI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Novel Compounds for Treatment of Giardiasis. For collaboration opportunities, please contact Claire Driscoll, NHGRI, at *cdriscol@mail.nih.gov.*

Dated: August 12, 2011.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2011–21155 Filed 8–17–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Amended Notice of Meeting

Notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism, September 12, 2011, 3:30 p.m. to 5:30 p.m., September 13, 2011, 9 a.m. to 1 p.m., National Institutes of Health, Building 1, 1 Center Drive, Wilson Hall, Bethesda, MD 20892 which was published in the **Federal Register** on June 29, 2011, 76FRN2011–16858.

The meeting time has changed on September 12, 2011 from 2:45 p.m. to 5:30 p.m. The location of the meeting will remain the same.

Dated: August 11, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21126 Filed 8–17–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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 on Deafness and Other Communication Disorders Special Emphasis Panel, P50 Review.

Date: September 27, 2011.

Time: 3 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Christine A. Livingston, PhD, Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Bethesda, MD 20892, (301) 496–8683, *livingsc@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: August 12, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21150 Filed 8–17–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Board of Scientific Advisors.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Board of Scientific Advisors, caBIG Oversight Ad hoc Subcommittee.

Date: August 25, 2011.

Time: 11 a.m. to 1 p.m.

Agenda: New Business, caBIG Initiatives and Oversight Interaction.

Place: National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Rm. 8018, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: John Czajkowski, MPA, Deputy Director for Management, Office of the Director, National Cancer Institute, National Institutes of Health, 31 Center Drive, Rm. 11A48, Bethesda, MD 20892, 301–435–2455, *john.czajkowski@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/bsa.htm,* where an agenda and any additional information for the meeting will be posted when available.

(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: August 12, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21146 Filed 8–17–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, September 13, 2011, 9 a.m. to September 13, 2011, 5 p.m., National Institutes of Health National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892 which was published in the **Federal Register** on August 10, 2011, 76 FR 49493.

This notice is amended to add the National Cancer Advisory Board Ad hoc Subcommittee on Global Cancer Research meeting. The meeting will convene on September 12, 2011 from 6:30 to 8:30 p.m. in the Diplomat/Ambassador room at the Bethesda Regency Hyatt, One Metro Center, Bethesda, MD 20814.

Dated: August 12, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21137 Filed 8–17–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–09–155: Translational Research in Pediatric and Obstetric Pharmacology.

Date: September 14, 2011.

Time: 10 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John Bleasdale, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301–435–4514, *bleasdaleje@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Integrative Physiology of Obesity and Diabetes Study Section.

Date: September 22, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Reed A Graves, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, MSC 7892, Bethesda, MD 20892, (301) 402–6297, *gravesr@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group Biochemistry and Biophysics of Membranes Study Section.

Date: September 26–27, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

Contact Person: Nuria E. Assa-Munt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Cell Biology.

Date: September 27, 2011.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Wallace Ip, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, 301–435–1191, *ipws@mail.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group, Dissemination and Implementation Research in Health Study Section.

Date: September 28, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jacinta Bronte-Tinkew, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3164, MSC 7770, Bethesda, MD 20892, (301) 806–0009, *brontetinkewjm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, AREA Applications: Cardiovascular and Respiratory Sciences.

Date: September 28–29, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Maqsood A. Wani, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2114, MSC 7814, Bethesda, MD 20892, 301–435–2270, *wanimaqs@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 12, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21135 Filed 8–17–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health 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 Mental Health Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: September 23, 2011.

Open: 8:30 a.m. to 12:30 p.m.

Agenda: Presentation of NIMH Director's report and discussion on NIMH program and policy issues.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Conference Room C/D/E, Rockville, MD 20852.

Closed: 1:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Conference Room C/D/E, Rockville, MD 20852.

Contact Person: Jane A. Steinberg, PhD, Director, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–5047.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed

and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, 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/Center's home page: *http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: August 11, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21134 Filed 8–17–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a conference call of the Interagency Autism Coordinating Committee (IACC).

The IACC Full Committee will be having a conference call on Wednesday, September 7, 2011. The committee plans to discuss a draft letter to the Secretary of Health and Human Services on issues related to seclusion and restraint. This conference call will be accessible to the public through a call-in number and access code.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Conference Call.

Date: September 7, 2011.

Time: 3 to 5 p.m. *Eastern Time*—Approximate end time.

Agenda: The committee will discuss a draft letter to the Secretary of Health and Human Services on issues related to seclusion and restraint.

Place: No in-person meeting; conference call only.

Conference Call: Dial: 800–369–1673, *Access code:* 2298100.

Cost: The conference call is free and open to the public.

Contact Person: Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC, Room 8185a, Rockville, MD 20852, *Phone:* (301) 443–6040, *E-mail: IACCPublicInquiries@mail.nih.gov.*

Please Note:

The conference call will be accessible to the public through a call-in number and access code. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the conference call, please e-mail *IACCTechSupport@acclaroresearch.com* or call the IACC Technical Support Help Line at 443–680–0098.

Individuals who participate by using this electronic service and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least 7 days prior to the meeting.

Schedule subject to change.

Information about the IACC and a registration link for this meeting are available on the Web site: *http://www.iacc.hhs.gov.*

Dated: August 11, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21133 Filed 8–17–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental 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: National Institute of Mental Health Initial Review Group, Interventions Committee for Disorders Involving Children and Their Families.

Date: October 3, 2011.

Time: 10:30 a.m. to 5 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: David I. Sommers, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Initial Review Group, Mental Health Services in Non-Specialty Settings.

Date: October 11, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Contact Person: Aileen Schulte, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, *aschulte@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Initial Review Group, Interventions Committee for Adult Disorders.

Date: October 12, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: David I. Sommers, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Initial Review Group, Mental Health Services in MH Specialty Settings.

Date: October 14, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications,

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Contact Person: Marina Broitman, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892–9608, 301–402–8152, *mbroitma@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: August 11, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21131 Filed 8–17–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Drug Abuse.

Date: September 12–13, 2011.

Closed: September 12, 2011, 3:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Conference Rooms C & D, Rockville, MD 20852.

Open: September 13, 2011, 8:30 a.m. to 1 p.m.

Agenda: This portion of the meeting will be open to the public for announcements and reports of administrative, legislative and program developments in the drug abuse field.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Conference Rooms C & D, Rockville, MD 20852.

Contact Person: Teresa Levitin, PhD, Director, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4243, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–89550, (301) 443–2755, *tlevitin.nida.nih.gov*.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.drugabuse.gov/NACDA/NACDAHome.html*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: August 12, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21130 Filed 8–17–11; 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 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 SEDAPA R25.

Date: September 22, 2011.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Gerald L. McLaughlin, PhD, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4238, MSC 9550, 6001 Executive Blvd., Bethesda, MD 20892–9550, 301–402–6626, *gm145a@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Grand Opportunity for Medication Development.

Date: September 30, 2011.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mark R. Green, PhD, Deputy Director, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4241, MSC 9550, 6001 Executive Blvd., Bethesda, MD 20892–9550, 301–435–1431, *mgreen1@nida.nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Training and Career Development Subcommittee.

Date: November 2–3, 2011.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Eliane Lazar-Wesley, PhD, Health Scientist Administrator, 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, *e16r@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: August 12, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21128 Filed 8–17–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Refugee Resettlement

Supplemental Awards to Seven Unaccompanied Alien Shelter Care Providers

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: The Office of Refugee Resettlement announces the award of single-source expansion supplement grants to seven Unaccompanied Alien Shelter Care Providers.

CFDA Number: 93.676.

Statutory Authority: Awards announced in this notice are authorized by Section 462 of the Homeland Security Act, Public Law 6 U.S.C. 279(b)(A)–(J) and Section 235(a)(5)(C); 235(d); of the Trafficking Victims Protection Reauthorization Act of 2008, (8 U.S.C. 1232).

Project Period: October 1, 2010—September 30, 2011.

Summary: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR) announces the award of single-source expansion supplement grants to seven unaccompanied alien shelter care providers for a total of $5,016,218. The additional funding provided by the awards will support services to refugees through September 30, 2011.

These grants will support the expansion of bed capacity to meet the number of unaccompanied alien children referrals from the Department of Homeland Security (DHS). The funding program is mandated by Section 462 of the Homeland Security Act to ensure appropriate placement of all referrals from the DHS. ORR's ability to meet this mandate is often a challenge since the program is completely tied to DHS apprehension strategies and the sporadic number of border crossers.

The program has specific requirements for the provision of services. Existing grantees are the only entities with the infrastructure, licensing, experience and appropriate level of trained staff to meet the service requirements and the urgent need for expansion. The program's ability to avoid a backlog of children waiting in border patrol stations for placement can only be accommodated through the expansion of existing programs through this supplemental award process.

The single-source expansion supplement recipients are:

Grantee	Location	Award amount
Heartland Alliance	Chicago, IL	$232,380
Southwest Key	TX and CA	2,123,131
Morrison Child and Family Services	Portland, OR	487,986
Catholic Charities Houston	Houston, TX	473,405
Catholic Charities Miami-Boystown	Miami, FL	320,940
International Education Services-Harlingen	Harlingen, TX	206,616
His House	Miami, FL	1,171,760

FOR FURTHER INFORMATION CONTACT: Kenneth Tota, Deputy Director, Office of Refugee Resettlement, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447, Telephone (202) 401–4858.

Dated: August 11, 2011.

Eskinder Negash,

Director, Office of Refugee Resettlement.

[FR Doc. 2011–21032 Filed 8–17–11; 8:45 am]

BILLING CODE 4120–27–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–566; Extension of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review: Form I–566, Interagency Record of Request, A, G, or NATO Dependent Employment Authorization or Change/Adjustment of Status To/From A, G, or NATO Status.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for 60 days until October 17, 2011.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Products Division, Office of the Executive Secretariat, 20 Massachusetts Avenue, NW., Washington, DC 20529–2020. Comments may also be submitted to DHS via facsimile to 202–272–0997 or via e-mail at *USCISFRComment@dhs.gov.* When submitting comments by e-mail please add the OMB Control Number 1615–0027 in the subject box.

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check ''My Case Status'' online at: *https://egov.uscis.gov/cris/Dashboard.do*, or call the USCIS National Customer Service Center at 1–800–375–5283.

Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Interagency Record of Request, A, G, or NATO Dependent Employment Authorization or Change/Adjustment of Status To/From A, G, or NATO Status.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–566; U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. This information collection facilitates processing of applications for benefits filed by dependents of diplomats, international organizations, and NATO personnel by U.S. Citizenship and Immigration Services, and the Department of State.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 5,800 responses at 15 minutes (0.25 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,450 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: *http://www.regulations.gov/.*

We may also be contacted at: USCIS, Regulatory Products Division, Office of the Executive Secretariat, 20 Massachusetts Avenue, NW., Room 5012, Washington, DC 20529–2020, Telephone number 202–272–8377.

Dated: August 12, 2011.

Sunday A. Aigbe,

Chief, Regulatory Products Division, Office of the Executive Secretariat, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2011–21017 Filed 8–17–11; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management, Regulation and Enforcement

[Docket No. BOEM–2011–0049]

Commercial Leasing for Wind Power on the Outer Continental Shelf (OCS) Offshore Rhode Island and Massachusetts—Call for Information and Nominations (Call)

AGENCY: Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE), Interior.

ACTION: Call for Information and Nominations for Commercial Leasing for Wind Power on the OCS Offshore Rhode Island and Massachusetts.

SUMMARY: BOEMRE invites the submission of nominations for one or more commercial leases that would allow a lessee to propose the construction of a wind energy project(s) on the OCS offshore Rhode Island and Massachusetts and to develop a project if further environmental review is successful. Although this announcement is not itself a leasing announcement, the area described herein may be subject to future leasing, and BOEMRE will use the responses to this Call for Information and Nominations (Call) to gauge specific interest in acquiring commercial wind leases in some or all of the area described, and to determine whether competitive interest exists in any particular area, as required by 43 U.S.C. 1337(p)(3). Parties wishing to submit a nomination in response to this Call should submit detailed and specific information in response to the requirements described in the section entitled, ''Required Nomination Information.''

This announcement also requests that interested and affected parties comment and provide information about site conditions, resources and multiple uses within the area identified in this notice that would be relevant to BOEMRE's review of the nominations submitted and any subsequent decision to offer all or part of the area for commercial wind leasing. The information that BOEMRE is requesting is described below in the section entitled, ''Requested Information from Interested or Affected Parties.''

This notice is published pursuant to subsection 8(p)(3) of the OCS Lands Act, 43 U.S.C. 1337(p)(3), as well as the implementing regulations at 30 CFR Part 285.

The area under consideration for this Call (Call Area) is located on the OCS off the coast of Rhode Island and Massachusetts within the Area of Mutual Interest (AMI), as described by a Memorandum of Understanding (MOU) between the Governors of Rhode Island and Massachusetts.

The Call Area is divided into two areas which are separated by an existing Traffic Separation Scheme (TSS). The first section of the Call Area is northwest of the TSS beginning approximately 9 nautical miles (nmi) southeast of Point Judith, Rhode Island, and extending approximately 2 nmi seaward (Northwest section). This section of the Call Area is approximately 1.25 square nmi and contains 1 partial OCS lease block. The second section of the Call Area is southeast of the TSS beginning approximately 10 nmi south of the Newport, Rhode Island coast, and extending approximately 20 nmi seaward (Southeast section). This section of the Call Area is approximately 246 square nmi and contains 31 whole OCS lease blocks as well as 10 partial OCS lease blocks.

The Call Area was identified by BOEMRE in consultation with the State of Rhode Island and the Commonwealth of Massachusetts, and further delineated in consultation with the BOEMRE/Rhode Island and BOEMRE/Massachusetts Renewable Energy Task Forces. A detailed description of the area and how it was identified is found later in this notice.

DATES: BOEMRE must receive your nomination describing your interest in this potential commercial leasing area postmarked by October 3, 2011 for your nomination to be considered. BOEMRE requests comments or other submissions of information by this same date. BOEMRE will consider only the nominations we receive by that time.

Submission Procedures: If you are submitting a nomination for a lease in response to this Call, please submit your nomination by mail to the following address: Bureau of Ocean Energy Management, Regulation and Enforcement, Office of Offshore Alternative Energy Programs, 381 Elden Street, Mail Stop 4090, Herndon, Virginia 20170. In addition to a paper copy of the nomination, please include an electronic copy of the nomination on a compact disc (CD). Nominations must be postmarked by October 3, 2011 to be considered by BOEMRE. BOEMRE will list the parties that submitted nominations and the location of the proposed lease areas (i.e., OCS blocks nominated) on the BOEMRE Web site after the 45-day comment period has closed.

Comments and other submissions of information may be submitted by either of the following two methods:

1. Federal eRulemaking Portal: *http://www.regulations.gov.* In the entry entitled, ''Enter Keyword or ID,'' enter BOEM–2011–0049, and then click ''search''. Follow the instructions to submit public comments and view supporting and related materials available for this notice. BOEMRE will post all comments which are not marked ''Contains Confidential Information.''

2. By U.S. Postal Service or other delivery service, sending your comments and information to the following address: Bureau of Ocean Energy Management, Regulation and Enforcement, Office of Offshore Alternative Energy Programs, 381 Elden Street, Mail Stop 4090, Herndon, Virginia 20170. All responses will be reported on *http://www.regulations.gov.*

If you wish to protect the confidentiality of your nomination or comments, clearly mark the relevant sections and request that BOEMRE treat them as confidential. Please label privileged or confidential information with ''Contains Confidential Information,'' and consider submitting such information as a separate attachment. Treatment of confidential information is addressed in the section of this Call entitled, ''Privileged or Confidential Information.'' Information that is not labeled as privileged or confidential will be regarded by BOEMRE as suitable for public release.

FOR FURTHER INFORMATION CONTACT: Jessica Bradley, Project Coordinator, BOEMRE, Office of Offshore Alternative Energy Programs, 381 Elden Street, Mail Stop 4090, Herndon, Virginia 20170, (703) 787–1320.

SUPPLEMENTARY INFORMATION:

Purpose of the Call for Information and Nominations

The OCS Lands Act requires BOEMRE to award leases competitively, unless BOEMRE makes a determination that there is no competitive interest (43 U.S.C. 1337(p)(3)). The issuance of this notice is not intended to indicate that BOEMRE has determined that competitive interest exists in the area identified. Rather, this notice is the first step in the renewable energy planning and leasing process in the AMI offshore Rhode Island and Massachusetts. The responses to this notice will assist BOEMRE in determining if there is any competitive interest in the area identified. This notice also requests information from interested and affected parties on issues relevant to BOEMRE's review of nominations for potential leasing in the area identified.

BOEMRE is issuing a Call instead of an Request for Interest (RFI) to facilitate and expedite the leasing process in keeping with the goals and objectives of the Secretary of the Interior's ''Smart from the Start'' initiative. If an RFI were issued and the responses to it indicated competitive interest, the applicable regulations would require BOEMRE to issue a Call, which BOEMRE believes would be duplicative of the RFI process and, therefore, unnecessary and inefficient. Issuance of this Call, without a RFI, is designed to enable BOEMRE to analyze information needed to support appropriate commercial leasing, while ensuring ample opportunity for input from interested and affected parties.

The responses to this Call could lead to the initiation of a competitive leasing process in some areas of the AMI (i.e., where competition exists for certain tracts), and a noncompetitive process in other areas of the AMI (i.e., where no competitive interest exists in certain tracts). The leasing process is described more completely under the ''Determination of Competitive Interest'' and ''Noncompetitive Leasing Process,'' sections of this notice. If BOEMRE determines that there is no competitive interest in some or all of this area offshore Rhode Island and Massachusetts, BOEMRE may proceed with the noncompetitive lease process pursuant to 30 CFR 285.232 for any area(s) where no competitive interest exists. If BOEMRE determines that there is competitive interest in some or all of this area offshore Rhode Island and Massachusetts, BOEMRE may proceed with Area Identification, as set forth in 30 CFR 285.211(b), and the competitive leasing process set forth under 30 CFR 285.211 through 285.225. Whether the leasing process would be competitive or noncompetitive, it would (1) include additional opportunities for the public to provide input; (2) be reviewed thoroughly for potential environmental and multiple use impacts; and (3) be conducted in conformance with all applicable laws and regulations. The area that may be offered for lease, if any, has not yet been determined, and may be reduced in size from the area identified in this Call.

Background

Energy Policy Act of 2005 (EPAct)

The EPAct amended the OCS Lands Act by adding subsection 8(p)(1)(C), which authorizes the Secretary of the Interior to grant leases, easements, or rights-of-way (ROWs) on the OCS for activities that are not otherwise authorized by law and that produce or support production, transportation, or transmission of energy from sources other than oil or gas. The EPAct also required the issuance of regulations to carry out the new authority pertaining to renewable energy on the OCS. The Secretary delegated this authority to issue leases, easements, and ROWs, and to promulgate regulations, to the Director of BOEMRE. On April 29, 2009, BOEMRE published the Renewable Energy and Alternate Uses (REAU) rule, at 30 CFR Part 285, which can be found at: *http://www.boemre.gov/offshore/RenewableEnergy/PDF/FinalRenewableEnergyRule.pdf.*

Executive Order 13547: Stewardship of the Ocean, Our Coasts, and the Great Lakes

On July 19, 2010, the President signed Executive Order 13547 establishing a national ocean policy and the National Ocean Council (75 FR 43023).

The Order establishes a comprehensive, integrated national policy for the stewardship of the ocean, our coasts, and the Great Lakes. Where BOEMRE actions affect the ocean, the Order requires BOEMRE to take such action as necessary to implement this policy, the stewardship principles, and national priority objectives adopted by the Order, and guidance from the National Ocean Council.

BOEMRE appreciates the importance of coordinating its planning endeavors with other OCS users and regulators and intends to follow principles of coastal and marine spatial planning, and coordinate with the regional planning bodies as established by the National Ocean Council to inform its leasing processes. BOEMRE anticipates that continued coordination with the state Renewable Energy Task Forces will help inform comprehensive coastal and marine spatial planning efforts.

Department of the Interior ''Smart From the Start'' Atlantic Wind Initiative

Secretary Ken Salazar announced the ''Smart from the Start'' OCS renewable energy initiative on November 23, 2010. This initiative includes three key elements: (1) Streamlined processes for commercial wind lease issuance; (2) the identification of Wind Energy Areas (WEA) followed by concrete information gathering; and (3) processing OCS energy transmission line proposals on a parallel but separate track from generation projects.

A WEA is an OCS area identified as having high wind resource potential along with relatively low potential use conflict, making it suitable for the consideration of wind energy leasing. Some of the area delineated for this Call may be identified as a WEA during the Area Identification stage of the leasing and planning process.

BOEMRE/State Renewable Energy Task Forces

BOEMRE established the Rhode Island Task Force in November 2009, at the request of Governor Donald Carcieri, to facilitate coordination among affected Federal agencies and state, local, and tribal governments throughout the entire leasing process. The first meeting was held on November 17, 2009, to introduce the intergovernmental members, discuss the purpose of the task force, explain the BOEMRE renewable energy leasing and environmental review process, and discuss a draft charter. BOEMRE began working on a RFI with the BOEMRE/Rhode Island Renewable Energy Task Force, and originally intended to issue a RFI for an area offshore Rhode Island. Rhode Island and Massachusetts then developed a partnership that resulted in an MOU signed by the Governors of both States in July of 2010. This MOU created the AMI and set a framework for the two states to collaborate on issues concerning offshore wind development on the OCS. In October and November of 2010, two developers submitted separate unsolicited requests pursuant to 30 CFR 285.230 for commercial leases within the AMI that partially overlap geographically. BOEMRE convened joint meetings of the BOEMRE/Rhode Island and BOEMRE/Massachusetts Renewable Energy Task Forces to coordinate on offshore renewable energy leasing within this area. The BOEMRE/Rhode Island Renewable Energy Task Force meeting materials and information related to the joint Task Force efforts are

available on the BOEMRE web site at: *http://www.boemre.gov/offshore/RenewableEnergy/StateActivities-RhodeIsland.htm.*

In light of these partially overlapping unsolicited requests, as well as the high level of interest that has been expressed for potential commercial wind leasing in other areas of the OCS (e.g. Maryland and New Jersey), we anticipate that there will be competitive interest within the Call Area. Issuance of this Call is designed to enable BOEMRE to proceed with the competitive process in an efficient manner while ensuring ample opportunity for input from interested and affected parties.

Environmental Review Process

BOEMRE intends to prepare an environmental assessment (EA), which will consider the environmental consequences associated with issuing commercial wind leases and approving site assessment activities on those leases within all or some of this Call area. BOEMRE is seeking public input in identifying the environmental issues and alternatives to be considered through the publication of a Notice of Intent (NOI) to prepare an EA, concurrently with this Call.

The EA will consider the environmental consequences associated with reasonably foreseeable leasing and site characterization scenarios within the Call Area (including geophysical, geotechnical, archaeological, and biological surveys), and reasonably foreseeable site assessment scenarios (including the installation and operation of meteorological towers and buoys) on the potential leaseholds. At a minimum, the alternatives that will be considered are: no action, (i.e. no issuance of leases or approval of site assessment activities); and the issuance of leases and approval of site assessment activities within the areas described in this Call. The NOI solicits input on the environmental effects associated with the activities described above. The EA will not, however, be used to support any future decision regarding the approval of the construction or operation of any wind energy facility on leases that may be issued within this Call Area. Instead, any proposed project will go through a thorough environmental review process at a future date.

Several consultations will be conducted concurrently with and integrated into the National Environmental Policy Act (NEPA) process. These consultations include, but are not limited to, those required by the Coastal Zone Management Act (CZMA), the Endangered Species Act (ESA), the Magnuson-Stevens Fishery Conservation and Management Act, the National Historic Preservation Act (NHPA), and Executive Order 13175—''Consultation and Coordination With Tribal Governments.'' The results of these consultations will assist BOEMRE in deciding whether and where leases may be issued. These consultations would take place prior to the issuance of any leases. BOEMRE has initiated government-to-government tribal consultation pursuant to Executive Order 13175 with three federally recognized tribes that have expressed interest in wind energy development in the New England area. After evaluating the responses to the Call, but before publishing the Proposed Sale Notice (PSN) for a competitive lease sale or issuing a lease noncompetitively, BOEMRE will conduct consultations pursuant to Section 106 of the NHPA. When possible, BOEMRE will conduct consultations concurrently with the NEPA process (30 CFR 800.8(3)(c)).

Actions Taken by the States of Rhode Island and Massachusetts in Support of Offshore Renewable Energy Development

BOEMRE recognizes the importance of the steps that the State of Rhode Island and the Commonwealth of Massachusetts have taken to encourage environmentally sound offshore wind energy development. While a state may promote such development through initiatives such as the creation of screening tools that inform the BOEMRE planning process, BOEMRE retains the exclusive authority to issue leases, easements, and rights-of-way on the OCS for renewable energy purposes. Below is a summary of the initiatives and actions undertaken by the State of Rhode Island and the Commonwealth of Massachusetts that promote the development of wind energy on the OCS.

The State of Rhode Island has devised a process for identifying areas it believes are suitable for renewable energy development, by considering wind development's compatibility with existing uses and the character of the natural resources in those areas. This effort tiered off two previous initiatives: (1) The Rhode Island Winds Report of 2005, which made a preliminary assessment of the feasibility of wind energy projects offshore Rhode Island; and (2) the Baird's Sea Grant Science Symposium, Sound Connections: The Science of Rhode Island and Block Island Sounds, October 2008; findings of which can be found at *http://seagrantadm.gso.uri.edu/Baird_08/default.htm.* The Baird Symposium provided a forum for researchers, resource managers, and stakeholders to discuss the state of the science in various areas important to Rhode Island coastal communities, including ecosystems and fisheries.

The State of Rhode Island has completed and adopted a Marine Spatial Planning Plan called the Ocean Special Area Management Plan (SAMP) for the areas offshore Rhode Island that support siting activities for offshore renewable energy and reflects extensive stakeholder input. This document, adopted by the National Oceanic and Atmospheric Administration (NOAA) on July 22, 2011, will become the basis for the State of Rhode Island's Federal consistency process for the AMI and is recognized in the July 2010 MOU between Rhode Island and Massachusetts as the guiding document for the AMI area.

The State of Rhode Island continues to gather data for a number of areas on the OCS, including data on avian species, fish habitat, marine mammals, physical oceanographic measurements, acoustics, geophysical and other data. BOEMRE appreciates the importance of this information and will use the data and information gathered by the state in its evaluation of potential lease issuance in the AMI.

The July 2010 MOU between Rhode Island and Massachusetts recognizes the benefits of collaborating in the evaluation and potential development of the AMI. Rhode Island and Massachusetts officials held a series of public meetings in Massachusetts to discuss SAMP data and the process involved. Rhode Island and Massachusetts officials expect that similar stakeholder discussions will continue, such as through the convening of a Fisheries Advisory Board consisting of fishing representatives from both States. In the development of the Call Area, input from both the BOEMRE/Rhode Island and BOEMRE/Massachusetts Task Forces has provided a regional perspective on the physical, biological, and socioeconomic resources of the AMI.

BOEMRE's Planning and Leasing Process

BOEMRE has been involved in a planning process for the AMI area since the establishment of the BOEMRE/Rhode Island Renewable Energy Task Force in 2009. The planning process has involved coordination with the joint BOEMRE/Rhode Island and BOEMRE/Massachusetts Renewable Energy Task Forces on the development of this Call. In addition, at the request of the State of Rhode Island and the Commonwealth

of Massachusetts, BOEMRE has participated in ten public information sessions with stakeholders from both states to provide information regarding BOEMRE's planning process. Additional information, including presentations and materials from the public information sessions and the joint Task Force meetings can be found at: *http://www.boemre.gov/offshore/RenewableEnergy/StateActivities-RhodeIsland.htm.*

Determination of Competitive Interest

The first step in the leasing process is to determine whether or not there is interest in acquiring a lease and whether there is competitive interest in acquiring a lease in any particular area. At the conclusion of the comment period for this Call, BOEMRE will review the nominations received, undertake a completeness review and qualifications review, and make a determination as to whether competitive interest exists in any specific location within the Call Area.

If two areas of interest fully or partially overlap, BOEMRE may proceed with the competitive leasing process as described below. For areas where BOEMRE determines that there is no competitive interest, BOEMRE may proceed with the noncompetitive leasing process also described below. While BOEMRE anticipates that this Call will result in multiple nominations for the area that indicate competitive interest exists, it is nonetheless possible that the responses to the Call could lead to following a competitive process, noncompetitive process, or both. BOEMRE may consult with the BOEMRE/Rhode Island and BOEMRE/Massachusetts Task Forces throughout these processes.

Situations may arise in which several parties nominate project areas that do not overlap. Under these circumstances, BOEMRE could choose to employ an allocation system of leases that involves the creation of competition across tracts. This system is referred to as intertract competition and would also be implemented under the competitive process outlined in the regulations. BOEMRE may consult with the BOEMRE/Rhode Island and BOEMRE/Massachusetts Task Forces in determining intertract competition.

Respondents to this Call and members of the public should be aware that no lease will be issued, either competitively or noncompetitively, until the necessary consultations and environmental analysis have been completed and the public has been given ample opportunity to comment. As a result, it is possible that certain areas nominated may not be leased, or that the areas nominated may be modified from their original, proposed form before being offered for lease.

Competitive Leasing Process

If, after receiving responses to this Call, BOEMRE proceeds with the competitive leasing process for certain areas, it would follow the steps required by 30 CFR 285.211 through 285.225:

(1) *Area Identification:* Based on the information submitted in response to this Call, BOEMRE would identify an area in which interest exists, and which will be subject to environmental analysis, in consultation with appropriate Federal agencies, states, local governments, tribes and other interested parties. The area identified will constitute a WEA under the ''Smart from the Start'' initiative, which will be the area analyzed in the EA. The NOI to prepare the EA is being published concurrently with this Call.

(2) *Proposed Sale Notice:* If BOEMRE decides to proceed with lease issuance in the area, then BOEMRE would publish the PSN in the **Federal Register** and send the PSN to any affected tribes, the State Historic Preservation Office, the Governor of any affected state, and the executive of any affected local government. The PSN would describe the areas to be offered for leasing and the proposed conditions of a lease sale, including the proposed auction format, lease form, and lease provisions/stipulations. Additionally, the PSN would describe the criteria and process for evaluating bids. The PSN would be issued after completion of any final NEPA documentation, preparation of the Consistency Determination as required by the CZMA and its implementing regulations, and preparation of various analyses of proposed lease sale economic terms and conditions. The comment period following issuance of a PSN would be 60 days.

(3) *Final Sale Notice:* If BOEMRE decides to proceed with lease issuance after considering comments on the PSN, it would then publish the Final Sale Notice (FSN) in the **Federal Register** at least 30 days before the date of the sale. BOEMRE may use one of the following four auction formats to select the winning bidder(s) as required by 30 CFR 285.220: Multiple-factor bidding; sealed bidding; ascending bidding; or two-stage bidding (a combination of ascending bidding and sealed bidding). BOEMRE would publish the criteria for winning bid determinations in the FSN.

(4) *Bid Submission and Evaluation:* Following publication of the FSN in the **Federal Register**, qualified bidders would be able to submit their bids to BOEMRE in accordance with procedures in the FSN. The bids, including the bid deposits if applicable, would be reviewed for technical and legal adequacy. BOEMRE would evaluate the bids to determine if the bidder has complied with all applicable regulations. BOEMRE reserves the right to reject any or all bids and the right to withdraw an offer to lease an area from the sale.

As stated above, BOEMRE may consider using the multiple-factor auction format in addition to the three other auction formats described at 30 CFR 285.220. If BOEMRE were to use a multiple-factor auction format, the evaluation of bids would be made by a panel composed of members selected by BOEMRE, and factors that BOEMRE may choose to include in the auction could be selected from a wide array of options. Factors that BOEMRE may consider for inclusion in this auction process are: Compatibility with existing state and local needs; or public benefits. These factors would be identified in the FSN.

If BOEMRE were to use a multiple-factor auction format, it is possible that a negotiation stage may be included in the bid assessment criteria, to be used if it becomes necessary to modify a proposed lease prior to acceptance. BOEMRE would coordinate with the state and other stakeholders, as appropriate, to establish procedures designed to assure the selection of the most worthy proposal that would provide a fair return to the United States pursuant to subsection 8(p)(2)(A) of the OCS Lands Act (43 U.S.C. 1337(p)(2)(A)).

(5) *Issuance of a Lease:* Following the selection of a winning bid(s) by BOEMRE, the submitter(s) would be notified of the decision and provided a set of official lease documents for execution. The successful bidder would be required to execute the lease, pay the remainder of the bonus bid, if applicable, and file the required financial assurance within 10 days of receiving the lease copies. Upon receipt of the required payments, financial assurance, and properly executed lease forms, BOEMRE would issue a lease to the successful bidder.

Noncompetitive Leasing Process

If, after evaluating the responses to this notice, BOEMRE determines that there is no competitive interest in a proposed lease area, it may proceed with the noncompetitive lease issuance process pursuant to 30 CFR 285.232, as amended by a rulemaking, which took effect on June 15, 2011 (76 FR 28178).

Should BOEMRE decide to proceed with the noncompetitive leasing process, it would ask if the respondent wants to proceed with acquiring the lease, and if so, the respondent must submit an acquisition fee as specified by 30 CFR 285.502(a). After receiving the acquisition fee, BOEMRE would follow the process outlined in 30 CFR 285.231. After determining that no competitive interest exists, BOEMRE would publish a notice in the **Federal Register** announcing this determination. Within 60 days of the date of that notice, the respondent would be required to submit a Site Assessment Plan (SAP), as described in 30 CFR 285.231(d)(2)(i).

BOEMRE will comply with the requirements of NEPA, CZMA, ESA, NHPA, and other applicable Federal statutes before issuing a lease noncompetitively. BOEMRE would coordinate and consult, as appropriate, with relevant Federal agencies, affected tribes, affected state and local governments, and provide opportunity for public comment prior to issuing a noncompetitive lease and in formulating lease terms, conditions, and stipulations.

It is possible that responses to this notice may result in a determination that there is competitive interest in acquiring leases in some areas but not in others. BOEMRE will announce publicly its determinations before proceeding with any leasing process.

Description of the Area

The Call Area is located on the OCS off the coast of Rhode Island and Massachusetts. The Call Area is divided into two areas separated by an existing TSS. The first section of the Call Area is northwest of the TSS beginning approximately 9 nmi southeast of Point Judith, Rhode Island and extending approximately 2 nmi seaward (Northwest section). This section of the Call Area is approximately 1.25 square nmi and contains 1 partial OCS lease block. The second section of the Call Area is southeast of the TSS beginning approximately 10 nmi south of the Newport, Rhode Island coast and extending approximately 20 nmi seaward (Southeast section). This section of the Call area is approximately 246 square nmi and contains 31 whole OCS lease blocks as well as 10 partial OCS lease blocks.

The following partial OCS lease block is included within the Northwest section of the Call Area, in Providence NK19–07:

Block No.	Sub block
6764	A,B,E

The following whole OCS lease blocks, are included within the Southeast section of the Call Area in Providence NK19–07: 6817, 6866, 6915, 6916, 6919, 6965, 6966, 6967, 6968, 6969, 6970, 6971, 7015, 7016, 7017, 7018, 7019, 7020, 7021, 7064, 7065, 7066, 7067, 7068, 7069, 7070, 7071, 7114, 7115, 7116, and 7117. The following partial OCS lease blocks, are included within the Southeast section of the Call Area in Providence NK19–07:

Block No.	Sub block
6766	L,O,P
6815	P
6816	B,C,D,F,G,H,I,J,K,L,M,N,O,P
6865	C,D,F,G,H,J,K,L,M,N,O,P
6867	A,B,C,D,E,I,M
6914	D,G,H,K,L,O,P
6917	A,E,F,G,H,I,J,K,L,M,N,O,P
6918	B,C,D,E,F,G,H,I,J,K,L,M,N,O,P
6964	C,D,G,H,K,L,O,P
7014	C,D,G,H,J,K,L,N,O,P

The boundary of the Call Area follows the points listed in the tables below for both the Northwest and Southeast sections of the Call Area in clockwise order. Point numbers 1 and 7 are the same in table 1 (Northwest section boundary) and point numbers 1 and 39 are the same in table 2 (Southeast section boundary). Coordinates are provided in X, Y (eastings, northings) UTM Zone 19N, NAD 83 and geographic (longitude, latitude), NAD83.

RHODE ISLAND CALL AREA—NORTHWEST SECTION BOUNDARY (TABLE 1)

Point No.	X (Easting)	Y (Northing)	Longitude	Latitude
1	308000	4574400	−71.293243	41.298222
2	310400	4574400	−71.264599	41.298789
3	310400	4573200	−71.264225	41.287989
4	309200	4573200	−71.278545	41.287706
5	309200	4572000	−71.278169	41.276905
6	308000	4572000	−71.292486	41.276621
7	308000	4574400	−71.293243	41.298222

RHODE ISLAND CALL AREA—SOUTHEAST SECTION BOUNDARY (TABLE 2)

Point No.	X (Easting)	Y (Northing)	Longitude	Latitude
1	321200	4572000	−71.134986	41.279651
2	322400	4572000	−71.120667	41.279915
3	322400	4569600	−71.119968	41.258312
4	327200	4569600	−71.062707	41.259352
5	327200	4563600	−71.061010	41.205340
6	323600	4563600	−71.103920	41.204564
7	323600	4558800	−71.102537	41.161355
8	328400	4558800	−71.045360	41.162385
9	328400	4560000	−71.045696	41.173187
10	336800	4560000	−70.945614	41.174922
11	336800	4555200	−70.944336	41.131709
12	346400	4555200	−70.830021	41.133582
13	346400	4540800	−70.826429	41.003931
14	327200	4540800	−71.054600	41.000088
15	327200	4536000	−71.053259	40.956877
16	308000	4536000	−71.281235	40.952589
17	308000	4545600	−71.284217	41.039000
18	309200	4545600	−71.269952	41.039282

RHODE ISLAND CALL AREA—SOUTHEAST SECTION BOUNDARY (TABLE 2)—Continued

Point No.	X (Easting)	Y (Northing)	Longitude	Latitude
19	309200	4548000	−71.270695	41.060884
20	310400	4548000	−71.256424	41.061165
21	310400	4558800	−71.259756	41.158376
22	311600	4558800	−71.245465	41.158656
23	311600	4560000	−71.245834	41.169457
24	312800	4560000	−71.231539	41.169735
25	312800	4561200	−71.231906	41.180536
26	314000	4561200	−71.217609	41.180813
27	314000	4563600	−71.218339	41.202416
28	315200	4563600	−71.204037	41.202690
29	315200	4564800	−71.204400	41.213492
30	316400	4564800	−71.190096	41.213765
31	316400	4566000	−71.190456	41.224566
32	317600	4566000	−71.176149	41.224838
33	317600	4567200	−71.176508	41.235639
34	318800	4567200	−71.162198	41.235909
35	318800	4569600	−71.162911	41.257512
36	320000	4569600	−71.148597	41.257781
37	320000	4570800	−71.148951	41.268582
38	321200	4570800	−71.134634	41.268849
39	321200	4572000	−71.134986	41.279651

Map of the Call Area

A map of the area can be found at the following URL: *http://www.boemre.gov/offshore/RenewableEnergy/StateActivities-RhodeIsland.htm.*

A large-scale map of the Call Area showing boundaries of the area with numbered blocks is available from BOEMRE at the following address: Bureau of Ocean Energy Management, Regulation and Enforcement, Office of Offshore Alternative Energy Programs, 381 Elden Street, Mail Stop 4090, Herndon, Virginia 20170, *Phone:* (703) 787–1320.

Development of the Call Area

The Call Area was identified by BOEMRE in consultation with the State of Rhode Island and the Commonwealth of Massachusetts, and further delineated through consultation with the BOEMRE/Rhode Island Renewable Energy Task Force and the BOEMRE/Massachusetts Renewable Energy Task Force. Specific mitigation, stipulations, or exclusion areas may be developed as a result of comments and information received in response to this Call, continued coordination with the BOEMRE/Rhode Island Renewable Energy Task Force and the BOEMRE/Massachusetts Renewable Energy Task Force, and the EA for which BOEMRE is concurrently issuing a NOI in the **Federal Register**, and consultations. Issues discussed through consultation with the BOEMRE/Rhode Island Task Force and the BOEMRE/Massachusetts Renewable Energy Task Force and areas where site-specific stipulations may be required are described below.

Unsolicited Requests

In October and November 2010, BOEMRE received two separate unsolicited requests, pursuant to 30 CFR 285.230, for commercial leases for areas within the AMI that partially overlap geographically. Because the unsolicited lease requests identified areas within the AMI, BOEMRE organized a joint meeting with both the BOEMRE/Rhode Island and BOEMRE/Massachusetts Renewable Energy Task Forces to discuss the proposals on December 10, 2010.

The following whole OCS lease blocks were requested in an unsolicited commercial lease request by Deepwater Wind New England, LLC: In Providence NK19–07, blocks, 6815, 6816, 6817, 6864, 6865, 6866, 6867, 6914, 6915, 6970, 6971, 7014, 7015, 7016, 7017, 7019, 7020, 7021, 7064, 7065, 7066, 7067, 7068, 7069, 7070, 7071, 7114, 7115, 7116, and 7117.

The following whole OCS lease blocks were requested in an unsolicited commercial lease request by Neptune Wind, LLC: In Providence NK19–07, blocks, 6970, 6971, 7018, 7019, 7020, and 7021.

Portions of the following OCS blocks submitted in Deepwater Wind New England, LLC's unsolicited request have not been included within the Call Area: In Providence NK19–07:

Block No.	Sub block
6815	A,B,C,D,E,F,G,H,I,J,K,L,M,N,O
6816	A,E
6864	All sub blocks
6865	A,B,E,I
6914	A,B,C,E,F,I,J,M,N
7014	A,B,E,F,I,M

Should Deepwater Wind New England, LLC wish to modify its proposal, it may do so pursuant to the section of this Call entitled ''Required Nomination Information.''

Charted Unexploded Ordnance

BOEMRE is aware of unexploded ordnance, as indicated on the NOAA nautical chart, and has excluded the following OCS lease blocks that overlap:

In Providence NK19–07:

Block No.	Sub block
6867	F,G,H,J,K,L,N,O,P
6917	B,C,D
6918	A

Marine Fisheries and Habitats Within the Call Area

The SAMP has identified portions of the Call Area as important for commercial and recreational fishing activities, as well as important marine fish habitat. Specifically, the area in the vicinity of Cox Ledge is identified in the SAMP as important for a range of commercial fishing activities, including scallop dredging, gillnetting, lobster trapping, bottom trawling and recreational activities. The area also contains complex marine habitats. Specific information on fishery resources, fishing activities and important marine habitats can be found in the Ocean SAMP Fisheries Chapter at: *http://www.crmc.ri.gov/samp_ocean.html.*

Data suggest that future development in and around Cox Ledge would potentially conflict with fishing activities and marine habitats. The National Marine Fisheries Service (NMFS) has expressed concern regarding impacts to these fishery resources that may result from potential future development. BOEMRE may exclude additional areas from further consideration for potential commercial wind energy leasing based on the information acquired in response to this Call and the results of the environmental review process conducted pursuant to NEPA, as described earlier in this notice.

BOEMRE received several comments, in consultation with the joint BOEMRE Rhode Island and Massachusetts Renewable Energy Task Forces, on the development of this Call on commercial and recreational fishing activities and fish habitat within the Call Area. BOEMRE has included a summary of these comments for consideration by respondents preparing to submit an expression of interest in response to this Call. The following associations forwarded comments for consideration through consultation with the joint Rhode Island and Massachusetts Renewable Energy Task Forces: Atlantic Offshore Lobstermen's Association, Eastern New England Scallop Association, Martha's Vineyard/Dukes County Fishermen's Association, Rhode Island Lobsterman's Association, Rhode Island Party and Charter Boat Association, and Sakonnet Point Fishermen's Association. BOEMRE has aggregated these comments and provided the following summary:

The entire area included in this Call was identified as being important for commercial and recreational fishing and marine habitat for several species, including Atlantic blue fin tuna, black sea bass, cod, dogfish, groundfish species, lobster, monkfish, scup, sea scallops, large pelagic sharks, winter flounder, and yellowtail flounder. The following OCS blocks were requested to be removed from further consideration from the Call area, in Providence NK19–07: 6764, 6815, 6816, 6865, 6866, 6914, 6915, 6916, 6964, 6966, 6967, 6968, 6969, 6970, 6971, 7014, 7015, 7016, 7017, 7018, 7019, 7020, 7021, 7064, 7065, 7066, 7067, 7068, 7069, 7070, and 7071. BOEMRE has identified these areas for consideration by respondents preparing to submit an expression of interest in response to this Call.

Navigational Issues

The U.S. Coast Guard (USCG) has provided the following information for consideration by respondents and other interested parties to this Call. The USCG has a responsibility to ensure the safety of navigation under the Ports and Waterways Safety Act (PWSA). The PWSA requires the USCG to provide safe access routes for the movement of vessel traffic proceeding to or from ports or places subject to the jurisdiction of the United States. This is accomplished through designation of necessary fairways and TSS for vessels operating in the territorial sea of the United States and in high sea approaches, outside the territorial sea. The USCG may also determine that establishment of other ships' routing measures would enhance navigational safety, and it works with its Federal interagency and International Maritime Organization partners to establish these voluntary measures as necessary.

The potential for navigational safety risk posed by building structures in the proximity of shipping is affected by numerous factors, including but not limited to: vessel size, vessel type, density of traffic, prevailing conditions, cumulative impacts of multiple obstructions (for example, wind assessment or development facilities), existence of multiple shipping routes (for example, crossing or meeting situations), radar/automatic radar plotting aid (ARPA) interference, and existence of mitigating factors such as navigational aids, vessel traffic services, or pilotage.

Currently, there is no standard recommended separation distance between offshore renewable energy facilities and shipping routes. The USCG has reviewed guidance published by other countries such as the United Kingdom's Maritime Guidance Note MGN–371 and consulted with its own waterways subject matter experts. Currently, the USCG considers that the placement of offshore wind assessment and generation facilities in any areas less than 1 nmi from traditional shipping routes poses a high risk to navigational safety and therefore does not recommend placement of offshore renewable energy facilities in such areas. The USCG considers placement of such wind facilities in areas greater than 5 nmi from existing shipping routes to pose minimal risk to navigational safety. Areas considered for placement of wind facilities between 1 nmi and 5 nmi would require additional USCG analysis to determine if mitigation factors could be applied to bring navigational safety risk to within acceptable levels. Respondents to this Call should note that impacts to radar and ARPA still occur outside of 1 nmi and will have to be evaluated along with other potential impacts. The above are only planning guidelines and may be changed based on the completion of the Atlantic Coast Port Access Route Study (ACPARS) which is described below. In addition, these guidelines maybe further modified upon completion of a Navigational Safety Risk Assessment (NSRA) that may be required before BOEMRE approves construction of any offshore renewable energy facilities.

The USCG is conducting an ACPARS to determine how best to route traffic on the Atlantic coast. (See **Federal Register** 76 FR 27288; May 11, 2011). This study will better inform the USCG about the navigational safety risks, if any, associated with construction of offshore renewable energy facilities. The data gathered during this ACPARS may result in the establishment of new vessel routing measures, modification of existing routing measures, or removal of some existing routing measures off the Atlantic Coast from Maine to Florida.

As a member of the BOEMRE Rhode Island and Massachusetts Renewable Energy Task Forces, the USCG conducted an evaluation, using the best available information, of the Rhode Island and Massachusetts Call Area. The USCG recommended OCS blocks (including sub-blocks) that, if developed, may have an unacceptable effect on navigational safety, and other OCS blocks (including sub-blocks) that would require further study to determine the potential effect that the installation of wind facilities in these blocks would have on navigation safety. In evaluating the practical effect of the OCS blocks that are the subject of this Call Area, the USCG applied the criteria described above and also conducted a review of other available information including: existing AIS data and user input; existing traffic patterns; and a literature review of material relevant to historical and current coastwise and international uses in the Call Area. In addition, the USCG considered the opinions and advice of USCG Subject Matter Experts (SMEs) and the ACPARS workgroup concerning waterways management, and the potential for modifications to existing routing measures and the creation of new routing measures in the area.

The USCG has advised BOEMRE that, at this time, all blocks included in the Call may be considered for possible leasing and potential development. However, the USCG advises that all blocks included in the Call require further study and analysis related to existing traffic usage and patterns, as well as projected future traffic increases based on the development of adjacent and adjoining blocks, which will be accomplished during the development

of the ACPARS. Such an evaluation will help the USCG determine what, if any, risks exist, and whether USCG should recommend that BOEMRE remove any blocks included in the Call Area from consideration for leasing and potential development at a later stage in the leasing or plan approval process. This process will also allow the USCG to consider potential mitigation measures for blocks that are made available for leasing and potential development.

Department of Defense (DOD) Activities

The DOD conducts offshore testing, training, and operations on the OCS. BOEMRE will consult with the DOD on all areas nominated for leasing to ensure that any future development can be compatible with defense activities on the OCS.

Telecommunications Cable

BOEMRE received a request from Verizon to eliminate OCS blocks 7014, 7064, 7065, 7115, and 6017 from consideration for potential future leasing due to the presence of the CB–1 (formerly Gemini) underwater telecommunications cable. BOEMRE has included this information for consideration by potential respondents to this Call.

BOEMRE Approach to Exclusion Requests

Several task force reviewers of the Rhode Island/Massachusetts Call have recommended areas to be excluded from consideration of potential leasing. As explained in the section of the Call entitled, ''Purpose of the Call for Information and Nominations,'' the inclusion of an area in the Call is not a decision to lease that area. It is a decision to solicit information from all interested and affected parties that BOEMRE can use in arriving at an ultimate decision on whether to offer the area for lease. The information the Call seeks relates to both renewable energy development interest and to other resources and uses. After considering the information it receives in response to the Call, BOEMRE may decide to exclude certain areas at the next step in the planning process—the Area Identification—or to include those areas for further consideration and analysis in the NEPA review. Please refer to the NOI that is concurrently published with this notice. Generally, BOEMRE's approach is to analyze areas thoroughly with the goal of eliminating or reducing to an acceptable level any potential resource and use conflicts. However, if BOEMRE concludes that such conflicts cannot be properly mitigated, exclusions may be necessary. BOEMRE intends to make fully informed decisions on exclusions at the appropriate time in the lease planning process.

The Rhode Island/Massachusetts Call includes areas in which competing uses have been identified by task force members. BOEMRE has highlighted in the Call two such uses: (1) Vessel traffic and (2) commercial fishing, for which we are requesting specific data and information to inform subsequent decisions. We will consider the information we receive from interested developers, maritime interests, commercial fishers, and others concerning these areas and uses in reaching an Area Identification and in planning the ensuing NEPA analysis. It is possible that certain geographic areas and associated mitigation measures could be framed as alternatives in the NEPA analysis to enable thorough and conclusive consideration by BOEMRE in its decisionmaking.

Required Nomination Information

If you intend to submit a nomination for a commercial wind energy lease within the Call Area to BOEMRE, you must provide the following:

(1) The BOEMRE Protraction name, number, and specific whole or partial OCS blocks or sub-blocks within the Call Area that are of interest for commercial wind leasing, including any required buffer area. This information should be submitted as a spatial file compatible with ArcGIS 9.3 in a geographic coordinate system (NAD 83) in addition to your hard copy submittal. If your proposed lease area includes one or more partial blocks please describe those partial blocks in terms of a sixteenth (*i.e.,* sub-block) of an OCS block. Note that any nomination identifying areas greater than what would be reasonably necessary to develop a commercial wind facility may not be considered as a valid nomination. BOEMRE will not consider any areas outside of the Call Area in this process;

(2) A description of your objectives and the facilities that you would use to achieve those objectives including: A general description of devices and infrastructure you intend to use; anticipated power production and likely purchasers; a statement that the proposed activity conforms with state and local energy planning requirements, initiatives or guidance, as appropriate;

(3) A preliminary schedule of proposed activities, including those leading to commercial operations;

(4) Available and pertinent data and information concerning renewable energy resources and environmental conditions in the area you wish to lease, including energy and resource data and information used to evaluate the Call Area. Where applicable, spatial information should be submitted in a format compatible with ArcGIS 9.3 in a geographic coordinate system (NAD 83);

(5) If available, identification of potential cable landfall sites, staging areas and any other support sites that may be necessary for your project;

(6) If available, information regarding proposed land-side and near-shore project elements and their potential effects on historic and cultural resources;

(7) Description of the compatibility of your project with commercial fishing activity (*e.g.,* spacing between individual turbines, array configurations, cable burial depths, routing measures, inspections, cable configurations or consolidations, etc.) in this area;

(8) Documentation demonstrating that you are legally qualified to hold a lease as set forth in 30 CFR 285.106 and 107. Examples of documentation appropriate for demonstrating your legal qualifications can be found in Chapter 2 and Appendix B of the BOMRE Renewable Energy Framework Guide Book available at *http://www.boemre.gov/offshore/RenewableEnergy/PDFs/REnGuidebook_03August2009_3_.pdf.* Legal qualification documents will be placed in an official file that may be made available for public review. If you wish that any part of your legal qualification documentation be kept confidential, clearly identify what should be kept confidential, and submit it under separate cover (see Protection of Privileged or Confidential Information Section, below).

(9) You must also include documentation demonstrating that you are technically and financially capable of constructing, operating, maintaining and decommissioning the facilities described in (2) above. Guidance regarding documentation appropriate for demonstrating your technical and financial qualifications can be found at: *http://www.boemre.gov/offshore/RenewableEnergy/RegulatoryInformation.htm.* Documentation you submit to demonstrate your legal, technical, and financial qualifications must be provided to BOEMRE in both paper and electronic formats. BOEMRE considers an Adobe PDF file stored on a compact disc (CD) to be an acceptable format for submitting an electronic copy; and

(10) Information submitted previously in an unsolicited request need not be re-submitted in response to this Call unless

the applicant wishes to modify its nomination.

It is critical that you submit a complete nomination so that BOEMRE may evaluate your submission in a timely manner. If BOEMRE reviews your nomination and determines that it is incomplete, BOEMRE will inform you of this determination in writing. This letter will describe the information that BOEMRE determined to be missing from your nomination, and indicate the information that you must submit in order for BOEMRE to deem your submission complete. You will be given 15 business days from the date of the letter to submit the information that BOEMRE found to be missing from your original submission. If you do not meet this deadline, or if BOEMRE determines this second submission to be insufficient, then BOEMRE may deem your nomination invalid. In such a case, BOEMRE would not move forward with your nomination submitted in response to this Call.

Requested Information From Interested or Affected Parties

BOEMRE is requesting from the public and other interested or affected parties specific and detailed comments regarding the following conditions in the area identified:

(1) Geological and geophysical conditions (including bottom and shallow hazards);

(2) Known archaeological and/or cultural resource sites on the seabed or nearshore and methodologies used to acquire that data;

(3) Historic properties potentially affected by the construction of meteorological towers, the installation of meteorological buoys, or commercial wind development in the area identified in this Call;

(4) Multiple uses of the area, including navigation (in particular, commercial and recreational vessel use), recreation, and fisheries (commercial and recreational); and

(5) Other relevant socioeconomic, biological, and environmental information.

Protection of Privileged or Confidential Information

Freedom of Information Act

BOEMRE will protect privileged or confidential information that you submit as required by the Freedom of Information Act (FOIA). Exemption 4 of FOIA applies to trade secrets and commercial or financial information that you submit that is privileged or confidential. If you wish to protect the confidentiality of such information, clearly mark it and request that BOEMRE treat it as confidential. BOEMRE will not disclose such information, subject to the requirements of FOIA. Please label privileged or confidential information ''Contains Confidential Information'' and consider submitting such information as a separate attachment.

However, BOEMRE will not treat as confidential any aggregate summaries of such information or comments not containing such information. Additionally, BOEMRE will not treat as confidential (1) the legal title of the nominating entity (for example, the name of your company), or (2) the list of whole or partial blocks that you are nominating. Information that is not labeled as privileged or confidential will be regarded by BOEMRE as suitable for public release.

Section 304 of the National Historic Preservation Act (16 U.S.C. 470w–3(a))

BOEMRE is required, after consultation with the Secretary, to withhold the location, character, or ownership of historic resources if it determines that disclosure may, among other things, risk harm to the historic resources or impede the use of a traditional religious site by practitioners. Tribal entities should designate information that falls under Section 304 of NHPA as ''Confidential''.

Dated: August 1, 2011.

Michael R. Bromwich,

Director, Bureau of Ocean Energy Management, Regulation and Enforcement.

[FR Doc. 2011–21136 Filed 8–17–11; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management, Regulation and Enforcement

[Docket No. BOEM–2011–0063]

Commercial Wind Lease Issuance and Site Characterization Activities on the Atlantic Outer Continental Shelf (OCS) Offshore Rhode Island and Massachusetts

AGENCY: Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE), Interior.

ACTION: Notice of Intent to Prepare an Environmental Assessment.

SUMMARY: This notice is being published as an initial step for the purpose of involving Federal agencies, states, tribes, local government, offshore wind energy developers, and the public in the Department of the Interior's (DOI) ''Smart from the Start'' wind energy initiative. The purpose of the ''Smart from the Start'' wind energy initiative is to identify areas that may be most suitable for wind energy leasing on the OCS, and to obtain public and expert input that will inform the Department's decisionmaking with regard to issuing leases and approving site assessment activities in these areas, in accordance with the DOI and the Council on Environmental Quality (CEQ) regulations implementing the provisions of the National Environmental Policy Act (NEPA) of 1969 as amended (42 U.S.C. 4321 *et seq.*). On November 23, 2010, Secretary of the Interior Ken Salazar announced the ''Smart from the Start'' renewable energy initiative to accelerate the responsible development of renewable energy resources on the Atlantic OCS. The initiative focuses on the identification and refinement of areas on the OCS that are most suitable for renewable energy development (Wind Energy Areas (WEAs)), and utilizes coordinated environmental studies, large-scale planning processes, and expedited review processes within these areas to achieve an efficient and responsible renewable energy leasing process.

In consultation with other Federal agencies and the Rhode Island and Massachusetts Renewable Energy Task Forces, BOEMRE has identified an area for consideration for potential future wind energy leasing. This area, offshore Rhode Island and Massachusetts, is identified in the *Commercial Leasing for Wind Power on the Outer Continental Shelf (OCS) Offshore Rhode Island and Massachusetts-Call for Information and Nominations (Call)*, which is being published concurrently with this notice. The area identified in the Call and this notice is located within the Area of Mutual Interest (AMI), as described by a Memorandum of Understanding (MOU) between the Governors of Rhode Island and Massachusetts.

More information on the task forces and the ''Smart from the Start'' initiative can be found at: *http://www.boemre.gov/offshore/RenewableEnergy/StateActivitiesProjects.htm* and *http://www.doi.gov/news/pressreleases/Salazar-Launches-Smart-from-the-Start-Initiative-to-Speed-Offshore-Wind-Energy-Development-off-the-Atlantic-Coast.cfm*.

BOEMRE intends to prepare an environmental assessment (EA), which will consider the environmental consequences associated with issuing commercial wind leases and approving site assessment activities on those leases (within all or some of this Call Area). The EA will not analyze or support

development activities. If a successful lessee proposes development activity, the specific proposal will be given full review at that time. BOEMRE is seeking public input regarding the identification of the important environmental and/or socioeconomic issues and alternatives to be considered in the EA.

Authority: This Notice of Intent (NOI) to prepare an environmental assessment is published pursuant to 43 CFR 46.305.

FOR FURTHER INFORMATION CONTACT: Michelle Morin, BOEMRE Office of Offshore Alternative Energy Programs, 381 Elden Street, MS 4090, Herndon, Virginia 20170–4817, (703) 787–1340 or *michelle.morin@boemre.gov*.

SUPPLEMENTARY INFORMATION:

1. The OCS Wind Energy Leasing and Development Process

There are three key phases of the wind energy leasing and development process on the OCS: (1) Lease issuance; (2) approval of a site assessment plan (SAP); and (3) approval of a construction and operation plan (COP). The first phase, issuance of a commercial renewable energy lease, gives the lessee an exclusive right to apply for approval of subsequent plans, the approval of which is necessary for a lessee to advance to the next stage of the renewable energy development process. The second phase is the applicant's submission, and BOEMRE's subsequent review and approval of a SAP. Approval of a SAP would allow the lessee to construct and install a meteorological tower and/or buoys on the leasehold. *See* 30 CFR 285.600–285.601; 285.605–285.618. After the lessee has collected sufficient site characterization and assessment data, the lessee may submit a COP, the review of which could authorize the actual construction and operation of a renewable energy facility on the lease. *See* 30 CFR 285.620–285.629. Although BOEMRE does not authorize site characterization activities (i.e., geological and geophysical surveys and core samples), a lessee must submit the results of such surveys before BOEMRE can consider its COP. *See* 30 CFR 285.626.

2. Proposed Action and Scope of Analysis

The proposed action that will be the subject of the EA is the issuance of renewable energy leases within all or some of the Call Area described in this Notice, and the approval of site assessment activities on those leases (*i.e.,* Phases 1 and 2 of the wind energy leasing and development process). BOEMRE will also consider in the EA the environmental impacts associated with the site characterization activities that it anticipates lessees might eventually undertake to fulfill the COP information requirements at 30 CFR 285.626.

The EA will not, however, be used to support any future decision regarding the approval of the construction or operation of any wind energy facility on leases that may be issued within all or some of this Call Area. BOEMRE is not currently considering any such plan, nor has any plan been submitted. If and when a lessee is ready to begin this third phase of renewable energy development, it will submit a COP. If a COP is submitted for a particular project on a lease, a separate site- and project-specific NEPA analysis would be prepared. This would take the form of an Environmental Impact Statement (EIS) and would provide additional opportunities for public involvement pursuant to NEPA and the CEQ regulations at 40 CFR parts 1500–1508. Such an EIS process would provide the public and Federal officials with comprehensive site- and project-specific information, and the EIS would consider the reasonably foreseeable environmental impacts of the specific project that the lessee is proposing. These potential impacts will be taken into account when deciding whether to approve, approve with modification, or deny the COP pursuant to 30 CFR 285.628.

The EA, which is the subject of this notice, will consider the environmental consequences associated with reasonably foreseeable leasing scenarios (not development itself), reasonably foreseeable site characterization scenarios within these lease areas (including geophysical, geotechnical, archeological, and biological surveys), and reasonably foreseeable site assessment scenarios (including the installation and operation of meteorological towers and buoys) on the leases that may be issued within all or some of the Call Area. At a minimum, the alternatives that will be considered are: no action (*i.e.,* no issuance of leases or approval of site assessment activities); and the issuance of leases and approval of site assessment activities within the areas described in Section 4 of this Notice. BOEMRE is therefore soliciting input on the environmental issues and alternatives to be considered in the EA related to the potential environmental effects of the activities described above.

Federal, state, and local government agencies, tribal governments, and other interested parties may assist BOEMRE in determining the issues and any additional alternatives to be analyzed in the EA. Input is also requested on measures (*e.g.,* limitations on activities based on technology, distance from shore, or timing) that would mitigate impacts to environmental resources and socioeconomic conditions that could result from leasing, site characterization, and site assessment in and around the Call Area described below. Consultation with other Federal agencies, tribal governments, and affected states will be carried out during the EA process and will be completed before a final decision is made on whether any particular lease will be issued or site assessment activities on those leases approved.

If BOEMRE determines during the EA process that issuing leases and conducting site characterization and assessment activities offshore within the Call Area would result in significant environmental impacts, then BOEMRE would publish a NOI to prepare an EIS for the issuance of renewable energy leases and approval of site assessment activities within all or some of this Call Area. If BOEMRE determines during the EA process that issuing leases and conducting site characterization and assessment activities within all or some of this Call Area would not result in significant environmental impacts, then BOEMRE would issue a Finding of No Significant Impact (FONSI). After either a FONSI is issued or the EIS process is completed, BOEMRE may issue one or more renewable energy leases within all or some of this Call Area. In the event that a particular lease is issued, and the lessee submits a SAP, BOEMRE will determine whether the EA adequately considers the environmental consequences of the activities proposed in the lessee's SAP. If the analysis in the EA adequately addresses these consequences, then no further NEPA analysis would be required before the SAP is approved. If that analysis is inadequate, additional NEPA analysis would be conducted before the SAP could be approved.

3. Information That Will Be Incorporated Into the EA

On November 6, 2007, BOEMRE published a Notice of Availability in the **Federal Register** (72 FR 62,672) of the Programmatic EIS for Alternative Energy Development and Production and Alternate Use of Facilities on the Outer Continental Shelf, Final EIS (OCS Report MMS 2007–046) (Programmatic EIS). On June 26, 2009, BOEMRE published a Notice of Availability in the **Federal Register** (74 FR 30,616) of the EA for Issuance of Leases for Wind Resource Data Collection on the Outer

Continental Shelf Offshore Delaware and New Jersey (OCS EIS/EA MMS 2009–025) (Interim Policy EA), which addressed similar activities.

BOEMRE will incorporate the environmental and socioeconomic analyses of site characterization and assessment activities from the Programmatic EIS, Interim Policy EA, and other public information to inform its analysis in the EA. The EA will be developed using many of the principles of coastal and marine spatial planning, such as comprehensive interagency coordination, to identify information needs for COP submittals necessary for future decisionmaking regarding wind energy development.

4. Description of the Call Area

BOEMRE has identified an area for consideration for potential future wind energy leasing in consultation with other Federal agencies and the Rhode Island and Massachusetts Renewable Energy Task Forces. The area identified in the Call and this notice is located within the AMI, as described by a MOU between the Governors of Rhode Island and Massachusetts. The Call Area is divided into two areas separated by an existing traffic separation scheme. A detailed description of the area can be found in the Call that is published concurrently with this notice.

Map of the Call Area

A map of the area can be found at the following URL: *http://www.boemre.gov/offshore/RenewableEnergy/StateActivities-RhodeIsland.htm.*

A large-scale map of the Call Area showing boundaries of the area with numbered blocks is available from BOEMRE at the following address: Bureau of Ocean Energy Management, Regulation and Enforcement, Office of Offshore Alternative Energy Programs, 381 Elden Street, Mail Stop 4090, Herndon, Virginia 20170, *Phone:* (703) 787–1320.

Based on the information submitted in response to this notice and the aforementioned Call, BOEMRE would identify an area in which interest exists, and which will be subject to environmental analysis, in consultation with appropriate Federal agencies, states, local governments, tribes and other interested parties. The area identified will constitute a WEA under the ''Smart from the Start'' initiative, which will be the area analyzed in the EA.

5. Cooperating Agencies

BOEMRE invites other Federal agencies and state, tribal, and local governments to consider becoming cooperating agencies in the preparation of this EA. CEQ regulations implementing the procedural provisions of NEPA define cooperating agencies as those with ''jurisdiction by law or special expertise'' (40 CFR 1508.5). Potential cooperating agencies should consider their authority and capacity to assume the responsibilities of a cooperating agency and to remember that an agency's role in the environmental analysis neither enlarges nor diminishes the final decisionmaking authority of any other agency involved in the NEPA process.

Upon request, BOEMRE will provide potential cooperating agencies with a draft Memorandum of Agreement that includes a schedule with critical action dates and milestones, mutual responsibilities, designated points of contact, and expectations for handling predecisional information. 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 *http://ceq.hss.doe.gov/nepa/regs/cooperating/cooperatingagencymemofactors.html.*

BOEMRE, as the lead agency, will not provide financial assistance to cooperating agencies. Even if an organization is not a cooperating agency, opportunities will exist to provide information and comments to BOEMRE during the normal public input phases of the NEPA/EA process.

6. Comments

Federal, state, local government agencies, tribal governments, and other interested parties are requested to send their written comments regarding environmental issues and the identification of reasonable alternatives related to the proposed actions described in this notice in one of the following ways:

1. *Electronically: http://www.regulations.gov.* In the entry titled ''Enter Keyword or ID,'' enter BOEM–2011–0063, then click ''search.'' Follow the instructions to submit public comments and view supporting and related materials available for this document.

2. In written form, delivered by hand or by mail, enclosed in an envelope labeled ''Comments on Rhode Island and Massachusetts EA'' to Program Manager, Office of Offshore Alternative Energy Programs (MS 4090), Bureau of Ocean Energy Management, Regulation and Enforcement, 381 Elden Street, Herndon, Virginia 20170. Comments should be submitted no later than October 3, 2011.

Dated: July 27, 2011.

Robert P. LaBelle,

Acting Associate Director for Offshore Energy and Minerals Management.

[FR Doc. 2011–21142 Filed 8–17–11; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWYP00000–L51100000–GA0000–LVEMK09CK370; WYW176095]

Notice of Availability of the Record of Decision for the Wright Area South Porcupine Coal Lease-by-Application and Environmental Impact Statement, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, the Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) for the South Porcupine Coal Lease-by-Application (LBA) included in the Wright Area Coal Lease Applications Environmental Impact Statement (EIS).

ADDRESSES: The document is available electronically on the following Web site: *http://www.blm.gov/wy/st/en/info/NEPA/HighPlains/Wright-Coal.html.* Paper copies of the ROD are also available at the following BLM office locations:

- Bureau of Land Management, Wyoming State Office, 5353 Yellowstone Road, Cheyenne, Wyoming 82009; and
- Bureau of Land Management, Wyoming High Plains District Office, 2987 Prospector Drive, Casper, Wyoming 82604.

FOR FURTHER INFORMATION CONTACT: Mr. Tyson Sackett, Acting Wyoming Coal Coordinator, at (307) 775–6487, or Ms. Sarah Bucklin, EIS Project Manager, at (307) 261–7541. Mr. Sackett's office is located at the BLM Wyoming State Office, 5353 Yellowstone Road, Cheyenne, Wyoming 82009. Ms. Bucklin's office is located at the BLM High Plains District Office, 2987 Prospector Drive, Casper, Wyoming 82604. Persons who use a telecommunications device for the deaf

(TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The ROD covered by this Notice of Availability is for the South Porcupine Coal Tract and addresses leasing Federal coal in Campbell County, Wyoming, administered by the BLM Wyoming High Plains District Office. The BLM approves Alternative 2, which is the preferred alternative for this LBA in the Wright Area Coal Final EIS. Under Alternative 2, the South Porcupine Coal LBA area, as modified by the BLM, includes approximately 3,243 acres. The BLM estimates that it contains approximately 401,830,508 tons of mineable Federal coal reserves under the selected configuration.

The BLM will announce a competitive coal lease sale in the **Federal Register** at a later date. The Environmental Protection Agency published a **Federal Register** notice announcing that the Final EIS was publicly available on July 30, 2010 (75 FR 44951).

This decision is subject to appeal to the Interior Board of Land Appeals (IBLA), as provided in 43 CFR part 4, within thirty (30) days from the date of publication of this Notice of Availability in the **Federal Register.** The ROD contains instructions for filing an appeal with the IBLA.

Donald A. Simpson,

State Director.

[FR Doc. 2011–20936 Filed 8–17–11; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2031–A047–409]

DRAFT General Management Plan and Draft Environmental Impact Statement, Biscayne National Park, FL

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability of the Draft General Management Plan and Environmental Impact Statement.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), the National Park Service (NPS) announces the availability of a Draft Environmental Impact Statement (EIS) for the General Management Plan (GMP) for Biscayne National Park (Park), Florida.

Consistent with NPS laws, regulations, and policies and the purpose of the Park, the Draft EIS/GMP describes the NPS preferred alternative—Alternative 4—to guide the management of the Park over the next 20 to 30 years. The preferred alternative incorporates various management prescriptions to ensure protection, access and enjoyment of the park's resources.

An up-to-date GMP is needed to address how visitors access and use the park and the facilities needed to support those uses, how resources are managed, and how the NPS manages its operations. Recent studies have enhanced the NPS's understanding of resources, resource threats, and visitor use in the park.

DATES: The NPS will accept comments from the public on the Draft EIS/GMP for at least 60 days, starting from the date the Environmental Protection Agency publishes this Notice of Availability. The date, time, and location of the public meetings on the Draft EIS/GMP will be announced through the NPS Planning, Environment, and Public Comment (PEPC) *Web site: http://parkplanning.nps.gov/BISC* and media outlets.

ADDRESSES: Electronic copies of the Draft EIS/GMP will be available online at *http://parkplanning.nps.gov/BISC.* To request a copy, contact Biscayne National Park Superintendent Mark Lewis, 9700 SW 328 Street, Homestead, FL 33033–5634.

Comments may be submitted by several methods. The preferred method is commenting via the internet on the PEPC Web site above. An electronic public comment form is provided on this Web site. You may also mail comments to Superintendent, Biscayne National Park, 9700 SW 328 Street, Homestead, FL 33033–5634. Finally, you may hand-deliver comments to the park. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, please be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. We will always make submissions from organizations or businesses, and from individuals identifying themselves as representatives of or officials of organizations or businesses, available for public inspection in their entirety. A limited number of compact disks and printed copies of the Draft GMP/EIS will be made available at Biscayne National Park headquarters, 9700 SW 328 Street, Homestead, FL.

SUPPLEMENTARY INFORMATION: Public meetings, newsletters, and internet updates have kept the public informed and involved throughout the planning process. The draft GMP provides a framework for management, use, and development of the national park for the next 20 or more years. It presents and analyzes five alternatives: Alternative 1 (no action) provides a baseline for evaluating changes and impacts of the four action alternatives. Alternative 2 provides the highest level of visitor services in the form of increased facilities and access to areas of the park. Alternative 3 adds a visitor permit system and marine reserve zone. Alternative 4 is the NPS Preferred Alternative. It was crafted to emphasize strong natural and cultural resource protection while providing a diversity of visitor experiences. Visitor opportunities in this alternative would range from the challenges of exploring the natural environment alone to the conveniences of built surroundings. A limited amount of moderate resource impacts would be tolerated in high-use areas of the park. While the majority of the park would be open for public enjoyment and appreciation, some areas would be closed to visitors to protect sensitive resources and allow wildlife a respite from people. Alternative 5 provides the highest protection of natural and cultural resources on the park, including a larger marine reserve zone.

The five alternatives are described in detail in chapter 2 of the draft plan. The key impacts of implementing the five alternatives are detailed in chapter 4 and summarized in chapter 2.

FOR FURTHER INFORMATION CONTACT: Biscayne National Park Superintendent Mark Lewis, 9700 SW 328 Street, Homestead, FL 33033–5634 or telephone at (305) 230–1144. The authority for publishing this notice is contained in 40 CFR 1506.6

The responsible official for this Draft EIS is the Regional Director, NPS Southeast Region, 100 Alabama Street SW., 1924 Building, Atlanta, Georgia 30303.

Dated: August 8, 2011.

Gordon Wissinger,

Acting Regional Director, Southeast Region.

[FR Doc. 2011–21084 Filed 8–17–11; 8:45 am]

BILLING CODE 4310–ML–P

DEPARTMENT OF THE INTERIOR

National Park Service

[5017–7152–409]

Draft Environmental Impact Statement for the General Management Plan (DEIS/GMP), Canaveral National Seashore, FL

AGENCY: National Park Service, Interior.

ACTION: Notice of availability of a Draft Environmental Impact Statement for the General Management Plan (DEIS/GMP), Canaveral National Seashore (Seashore).

SUMMARY: Pursuant to 42 U.S.C. 4332(2)(C) of the National Environmental Policy Act of 1969 the NPS announces the availability of a DEIS/GMP for Canaveral National Seashore, Florida.

The document provides a framework for management, use, and development options for the Seashore by the NPS for the next 15 to 20 years. It describes four management alternatives for consideration, including a No-Action Alternative that continues current management policies and the NPS's preferred alternative. The document analyzes the environmental impacts of the alternatives.

DATES: There will be a 60-day comment period beginning with the Environmental Protection Agency's publication of this notice of availability in the **Federal Register**.

ADDRESSES: Copies of the DEIS/GMP are available by contacting the Park Superintendent at Canaveral National Seashore, 212 S. Washington Avenue, Titusville, Florida 32796–3553; telephone: 321–267–1110. An electronic copy of the DEIS/GMP is available on the Internet at *http://parkplanning.nps.gov.*

SUPPLEMENTARY INFORMATION: There will be a 60-day comment period beginning with the Environmental Protection Agency's publication of this notice of availability in the **Federal Register**. If you wish to comment on the DEIS/GMP, you may submit your comments by any one of several methods. You may mail comments to the Superintendent at the address shown above. You may also submit a comment via the Internet at *http://parkplanning.nps.gov.* Finally, you may present your comments in person at the public meetings to be held during the public review period in and around the Seashore.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, please 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.

The DEIS/GMP presents three management alternatives for the Seashore in addition to the no-action alternative. The four alternatives are as follows:

Alternative A (No-action Alternative): The continuation of current management practices and trends, as set forth general in the 1982 GMP and 1998 GMP amendment.

Alternative B (The NPS Preferred Alternative): Would provide the highest protection of natural and cultural resources associated with the Seashores barrier island system.

Alternative C: Would provide the highest level of visitor services in the form of increased facilities and access to areas of the park.

Alternative D: Would provide a limited level of facility development and would enhance visitor and educational opportunities through partnerships.

FOR FURTHER INFORMATION CONTACT: The Superintendent, Canaveral National Seashore, at the address and telephone number shown above. An electronic copy of the DEIS/GMP is available on the Internet at *http://parkplanning.nps.gov.* The authority for publishing this notice is 40 CFR 1506.6.

The responsible official for this DEIS/GMP is the Regional Director, Southeast Region, NPS, 100 Alabama Street SW., 1924 Building, Atlanta, Georgia 30303.

Dated: August 8, 2011.

Gordon Wissinger,

Acting, Regional Director, Southeast Region.

[FR Doc. 2011–21088 Filed 8–17–11; 8:45 am]

BILLING CODE 4310–5X–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *In Re Certain Digital Televisions Containing Integrated Circuit Devices and Components Thereof,* DN 2840; the Commission is soliciting comments on any public interest issues raised by the complaint.

FOR FURTHER INFORMATION CONTACT: James R. Holbein, Secretary to the Commission, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint filed on behalf of Renesas Electronics Corporation and 511 Technologies, Inc. on August 12, 2011. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital televisions containing integrated circuit devices and components thereof. The complaint names as respondent Vizio, Inc. of CA.

The complainant, proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five pages in length, on any public interest issues raised by the complaint. Comments should address whether issuance of an exclusion order and/or a cease and desist order in this investigation would negatively affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the potential orders;

(iii) indicate the extent to which like or directly competitive articles are

produced in the United States or are otherwise available in the United States, with respect to the articles potentially subject to the orders; and

(iv) indicate whether Complainant, Complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to an exclusion order and a cease and desist order within a commercially reasonable time.

Written submissions must be filed no later than by close of business, five business days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Submissions should refer to the docket number (''Docket No. 2840'') in a prominent place on the cover page and/or the first page. The Commission's rules authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf*). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50(a)(4) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50(a)(4)).

By order of the Commission.

Issued: August 15, 2011.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–21115 Filed 8–17–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–798]

Certain Light-Emitting Diodes and Products Containing Same; Notice of Institution of Investigation

Institution of investigation pursuant to 19 U.S.C. 1337.

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on July 15, 2011, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Samsung LED Co., Ltd. of Korea and Samsung LED America, Inc. of Atlanta, Georgia. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain light-emitting diodes and products containing same by reason of infringement of certain claims of U.S. Patent No. 6,551,848 (''the '848 patent''); U.S. Patent No. 7,268,372 (''the '372 patent''); U.S. Patent No. 7,282,741 (''the '741 patent''); U.S. Patent No. 7,771,081 (''the '081 patent''); U.S. Patent No. 7,893,443 (''the '443 patent''); U.S. Patent No. 7,838,315 (''the '315 patent''); U.S. Patent No. 7,959,312 (''the '312 patent''); and U.S. Patent No. 7,964,881 (''the '881 patent''). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue an exclusion order and a cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2011).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on August 12, 2011, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain light-emitting diodes and products containing same that infringe one or more of claims 1, 3, 5–10, and 13–16 of the '848 patent; claims 1–9 of the '372 patent; claims 1 and 5–9 of the '741 patent; claims 1, 2, 4, 6–8, 10, and 11 of the '081 patent; claims 1, 4, 5, and 7–14 of the '443 patent; claims 1–4, 6, and 9–13 of the '312 patent; claims 1–5 of the '315 patent; and claims 1–12 of the '881 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Samsung LED Co., Ltd., 314, Maetan 3-Dong, Yeongtong-gu, Suwon City, Gyeonggi-Do 443–743, Korea.

Samsung LED America, Inc., 6 Concourse Parkway NE., Atlanta, GA 30328.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

OSRAM GmbH, Hellabrunner Strasse 1, 81543 Munich, Germany.

OSRAM Opto Semiconductors GmbH, Leibnizstr 4, 93055 Regensburg, Germany.

OSRAM Opto Semiconductors Inc., 1150 Kifer Road Suite 100, Sunnyvale, CA 94086.

OSRAM Sylvania Inc., 100 Endicott Street, Danvers, MA 01923.

(c) The Office of Unfair Import Investigations, U.S. International Trade

Commission, 500 E Street, SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d)–(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: August 12, 2011.

William R. Bishop,

Acting Secretary to the Commission.

[FR Doc. 2011–21046 Filed 8–17–11; 8:45 am]

BILLING CODE P

INTERNATIONAL TRADE COMMISSION

[USITC SE–11–022]

Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: August 26, 2011 at 11 a.m.

PLACE: Room 101, 500 E Street, SW., Washington, DC 20436. Telephone: (202) 205–2000.

STATUS: Open to the public.

Matters To Be Considered

1. Agendas for future meetings: none.
2. Minutes.
3. Ratification List.
4. Vote in Inv. No. 731–TA–1189 (Preliminary) (Large Power Transformers from Korea). The Commission is currently scheduled to transmit its determination to the Secretary of Commerce on or before August 29, 2011; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before September 6, 2011.
5. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: August 16, 2011.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. 2011–21189 Filed 8–16–11; 11:15 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Settlement Agreement Under the Resource Conservation and Recovery Act and the Emergency Planning and Community Right-to-Know Act

Notice is hereby given that on August 12, 2011, a proposed Consent Decree in *United States* v. *Clean Harbors of Braintree, Inc.,* No. 11–11440, was lodged with the United States District Court of the District of Massachusetts. The United States filed this action, on the same day that the Consent Decree was lodged with the Court, under the Resource Conservation and Recovery Act (''RCRA''), 42 U.S.C. 6901, *et seq.,* and the Emergency Planning and Community Right-to-Know Act (''EPCRA''), 42 U.S.C. 11001, *et seq.* The Complaint alleges that Clean Harbors of Braintree, Inc. (''Clean Harbors'') violated various provisions of RCRA and EPCRA, as well as their implementing permits and regulations, at the hazardous waste treatment, storage, and disposal facility operated by Clean Harbors at 1 Hill Avenue in Braintree, Massachusetts (''Facility'').

Under the Consent Decree, Clean Harbors has agreed to certain injunctive relief, to pay a penalty in the amount of $650,000, and to implement a Supplemental Environmental Project, at a cost of at least $1,062,500, involving the planting of approximately 1,400 trees in low-income or minority areas located in the City of Boston. The Consent Decree resolves the civil claims of the United States for the violations alleged in the Complaint through the date of lodging of the Consent Decree.

For a period of thirty days from the date of this publication, the Department of Justice will receive and consider comments relating to the Consent Decree. All comments must be received by the Department of Justice within this thirty-day period. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044, and should refer to *United States* v. *Clean Harbors of Braintree, Inc.,* No. XX (D. Mass.) and D.J. Ref. No. 90–7–1–09439. A copy of any comments should be sent to Donald G. Frankel, Senior Counsel, Department of Justice, Environmental Enforcement Section, One Gateway Center, Suite 616, Newton, MA 02458, or e-mailed to *donald.frankel@usdoj.gov.*

The Agreement may be examined at the Office of the United States Attorney, District of Massachusetts, United States Federal Courthouse, 1 Courthouse Way, Boston, MA 02210 (contact George B. Henderson, II at 617–748–3100). During the public comment period, the Agreement may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Agreement may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy of the Agreement from the Consent Decree Library, please enclose a check in the amount of $9.50 (25 cents per page reproduction cost) payable to the U.S. Treasury (if the request is by fax or e-mail, forward a check to the Consent Decree library at the address stated above).

Ronald G. Gluck,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–21008 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Clean Water Act

Notice is hereby given that on August 11, 2011, a proposed Consent Decree in *Environment Rhode Island et al. and the*

United States and Rhode Island v. *City of Newport, Rhode Island,* Civil Action No. 08–265S, was filed with the United States District Court for Rhode Island.

In this action, the United States and the other plaintiffs sought penalties and injunctive relief for the Defendant's violations of the Clean Water Act, 33 U.S.C. 1251 *et seq.,* at its sewer system and water pollution control plant. To resolve the United States' claims, the Defendants will pay a penalty of $170,000, and will undertake extensive work to its sewer system and water pollution control plant to eliminate violations of the Clean Water Act.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to either: *Environment Rhode Island et al. and the United States and Rhode Island* v. *City of Newport, Rhode Island,* Civil Action No. 08–265S, or D.J. Ref. 90–5–1–1–09855. The Consent Decree may be examined at the Office of the United States Attorney, District of Rhode Island, Fleet Center, 50 Kennedy Plaza, 8th Floor, Providence, Rhode Island 02903, and at the United States Environmental Protection Agency, 5 Post Office Square, Suite 100, Boston, Massachusetts 02109. During the public comment period, the Consent Decree may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check, payable to the U.S. Treasury, in the amount of $21.50 (25 cents per page reproduction cost), or, if by e-mail or fax, forward a check in the applicable amount to the Consent Decree Library at the stated address.

Ronald Gluck,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–20996 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Proposed Partial Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act and the Clean Air Act

Notice is hereby given that on August 12, 2011, a proposed Partial Consent Decree in *United States* v. *C.A.I., Inc., et al.,* Civil Action No. 1:10–cv–10390–GAO, was lodged with the United States District Court for the District of Massachusetts.

The proposed Partial Consent Decree will settle the United States' claims on behalf of the U.S. Environmental Protection Agency (''EPA'') against Defendants C.A.I., Inc. (''CAI''), Sartorelli Realty, LLC (''SRLLC''), and Roy A. Nelson as Trustee of Nelson Danvers Realty Trust (''NDRT''), pursuant to Section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9607, and Sections 112(r) and 114(a) of the Clean Air Act (''CAA''), 42 U.S.C. 7412(r), 7414(a), with respect to the Danversport Superfund Site, a former inks and paint products manufacturing facility, in Danvers, Massachusetts (''Site''). Pursuant to the Partial Consent Decree, based on demonstrations of limited financial resources: CAI will pay $400,000, including $300,000 in response costs under CERCLA and $100,000 as a civil penalty under the CAA; SRLLC will pay $150,000 in response costs; NDRT will pay $140,000 in response costs; and the settling defendants will transfer to the United States funds from an escrow account totaling approximately $27,000 as of March 2011. In addition, SRLLC and NDRT will make best efforts to sell the Site property and will transfer all net sales proceeds to the United States. Finally, the settling defendants will pay the United States 90% of any net proceeds from the resolution of other Site-related proceedings, up to the total amount of the United States' unreimbursed response costs. The proposed Partial Consent Decree, together with a Partial Consent Decree between the United States and Defendant Arnel Company, Inc. entered on July 1, 2011, will resolve this action in its entirety.

The Department of Justice will receive comments relating to the proposed Partial Consent Decree for a period of 30 days from the date of this publication. Comments on the Partial Consent Decree should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *C.A.I., Inc., et al.,* Civil Action No. 1:10–cv–10390–GAO, D.J. Ref. 90–11–2–09184 & 90–11–2–09184/1.

During the public comment period, the proposed Partial Consent Decree may be examined at the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed Partial Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax number (202) 514–0097, phone confirmation number (202) 514–1547. If requesting a copy by mail from the Consent Decree Library, please enclose a check in the amount of $15.75 ($0.25 per page reproduction cost) payable to the U.S. Treasury or, if requesting by e-mail or fax, forward a check in that amount to the Consent Decree Library at the above-referenced address.

Ronald G. Gluck,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–21002 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on May 4, 2011, Cambrex Charles City, Inc., 1205 11th Street, Charles City, Iowa 50616–3466, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Phenylacetone (8501)	II
Opium, raw (9600)	II
Poppy Straw Concentrate (9670)	II

The company plans to import the listed controlled substances to manufacture a bulk intermediate for sale to its customers. With regards to the phenylacetone, the company plans to use it as a base material in the bulk manufacture of another controlled substance.

No comments, objections, or requests for any hearings will be accepted on any application for registration or re-registration to import crude opium, poppy straw, concentrate of poppy straw, and coca leaves. As explained in the Correction to Notice of Application pertaining to Rhodes Technologies, 72 FR 3417 (2007), comments and requests for hearings on applications to import narcotic raw material are not appropriate.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule I or II, which fall under the authority of section 1002(a)(2)(B) of the Act 21 U.S.C. 952(a)(2)(B) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than September 19, 2011.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745, all applicants for registration to import a basic class of any controlled substance in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: August 11, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21117 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under 21 U.S.C. 952(a)(2) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on May 4, 2011, Cambrex Charles City, 1205 11th Street, Charles City, Iowa 50616–3466, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Noroxymorphone (9668), a basic class of controlled substance listed in schedule II.

The company plans to import the basic class of controlled substance in bulk for sale to its customers.

Any bulk manufacturers who are presently, or are applying to be, registered with DEA to manufacture such basic class of controlled substance may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than September 19, 2011.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745, all applicants for registration to import a basic class of any controlled substance in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: August 10, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21121 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to Title 21, of the CFR 1301.34(a), this is notice that on June 8, 2011, Aptuit, 10245 Hickman Mills Drive, Kansas City, Missouri 64137, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Marihuana (7360)	I
Poppy Straw Concentrate (9670)	II

The company plans to import a finished pharmaceutical product containing cannabis extracts in dosage form for packaging for a clinical trial study. In addition, the company also plans to import an ointment for the treatment of wounds which contain trace amounts of the controlled substances normally found in poppy straw concentrate for packaging and labeling for clinical trials.

No comments, objections, or requests for any hearings will be accepted on any application for registration or re-registration to import crude opium, poppy straw, concentrate of poppy straw or coca leaves. As explained in the Correction to Notice of Application pertaining to Rhodes Technologies, 72 FR 3417(2007), comments and requests for hearings on applications to import narcotic raw material are not appropriate.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than September 19, 2011.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745, all applicants for registration to import a basic class of any controlled substance in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: August 9, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21068 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated May 13, 2011, and published in the **Federal Register** on May 27, 2011, 76 FR 30968, Almac Clinical Services Inc., (ACSI), 25 Fretz Road, Souderton, Pennsylvania 18964, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Oxycodone (9143)	II
Hydromorphone (9150)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to import small quantities of the listed controlled substances in dosage form to conduct clinical trials.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of Almac Clinical Services Inc. (ACSI) to import the basic classes of controlled substances is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Almac Clinical Services Inc. (ACSI) to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: August 11, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21077 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By a Notice dated April 28, 2011, and published in the **Federal Register** on May 4, 2011 76 FR 25374, Rhodes Technologies, 498 Washington Street, Coventry, Rhode Island 02816, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Raw Opium (9600)	II
Concentrate of Poppy Straw (9670)	II

The company plans to import the listed controlled substances in order to bulk manufacture controlled substances in Active Pharmaceutical Ingredient (API) form. The company distributes the manufactured API's in bulk form only to its customers.

As explained in the Correction to Notice of Application pertaining to Rhodes Technologies, 72 FR 3417 (2007), comments and requests for hearings on applications to import narcotic raw material are not appropriate.

DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of Rhodes Technologies to import the basic classes of controlled substances is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Rhodes Technologies to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: August 11, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21076 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on June 17, 2011, Cambridge Isotope Lab, 50 Frontage Road, Andover, Massachusetts 01810, made application by renewal to the

Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Morphine (9300), a basic class of controlled substance listed in schedule II.

The company plans to utilize small quantities of the listed controlled substance in the preparation of analytical standards.

Any other such applicant, and any person who is presently registered with DEA to manufacture such a substance, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than October 17, 2011.

Dated: August 10, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21120 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on June 13, 2011, AMRI Rensselaer, Inc., 33 Riverside Avenue, Rensselaer, New York 12144, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
Meperidine (9230)	II
4-Anilino-N-Phenethyl-4-Piperidine (8333).	II
Fentanyl (9801)	II

The company plans to manufacture bulk controlled substances for use in product development and for distribution to its customers.

In reference to drug code 7360 (Marihuana), the company plans to bulk manufacture cannabidiol as a synthetic intermediate. This controlled substance will be further synthesized to bulk manufacture a synthetic THC (7370). No other activity for this drug code is authorized for this registration.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substance, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than October 17, 2011.

Dated: August 10, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21118 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on July 7, 2011, Chemica, 316 West 130th Street, Los Angeles, California 90061, made application by renewal to the Drug Enforcement Administration (DEA) as a bulk manufacturer of Methamphetamine (1105), a basic class of controlled substance listed in schedule II.

The above listed controlled substance is an intermediate in the manufacture of Benzphetamine, a schedule III non-narcotic controlled substance. The methamphetamine will not be sold as a commercial product. The company plans to utilize a bulk active pharmaceutical ingredient (API), as an intermediate for the development of another controlled substance, and further distribution to its customers. The methamphetamine will not be sold.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substance, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than October 17, 2011.

Dated: August 10, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21074 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 27, 2011, Austin Pharma LLC., 811 Paloma Drive, Suite C, Round Rock, Texas 78665–2402, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

The company plans to manufacture bulk active pharmaceutical ingredients (APIs) for distribution to its customers.

In reference to drug code 7360 (Marihuana), the company plans to bulk manufacture cannabidiol as a synthetic intermediate. This controlled substance will be further synthesized to bulk manufacture a synthetic THC (7370). No other activity for this drug code is authorized for this registration.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substance, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than October 17, 2011.

Dated: August 9, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21071 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 16, 2011, Lin Zhi International Inc., 670 Almanor Avenue, Sunnyvale, California 94085, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
3,4-Methylenedioxymethamphetamine (7405).	I
Cocaine (9041)	II
Oxycodone (9143)	II
Hydrocodone (9193)	II
Methadone (9250)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II

The company plans to manufacture the listed controlled substances as bulk reagents for use in drug abuse testing.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than October 17, 2011.

Dated: August 8, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21070 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 25, 2011, and published in the **Federal Register** on May 4, 2011, 76 FR 25375, Siemens Healthcare Diagnostics Inc., *Attn:* RA, 100 GBC Drive, Mail Stop 514, Newark, Delaware 19702, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Ecgonine (9180)	II
Morphine (9300)	II

The company plans to produce the listed controlled substances in bulk to be used in the manufacture of reagents and drug calibrator/controls which are DEA exempt products.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Siemens Healthcare Diagnostics Inc., to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Siemens Healthcare Diagnostics Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 9, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21058 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 28, 2011, and published in the **Federal Register** on May 4, 2011, 76 FR 25376, Johnson Matthey Pharma Services, 70 Flagship Drive, North Andover, Massachusetts 01845, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Amphetamine (1100)	II
Methylphenidate (1724)	II
Hydrocodone (9193)	II

The company plans to utilize this facility to manufacture small quantities of the listed controlled substances in bulk and to conduct analytical testing in support of the company's primary manufacturing facility in West Deptford, New Jersey. The controlled substances manufactured in bulk at this facility will be distributed to the company's customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Johnson Matthey Pharma Services to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Johnson Matthey Pharma Services to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 10, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21079 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 11, 2011, and published in the **Federal Register** on April 19, 2011, 76 FR 21916, Norac Inc., 405 S. Motor Avenue, P.O. Box 577, Azusa, California 91702–3232, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Gamma Hydroxybutyric Acid (2010).	I

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Methamphetamine (1105)	II
Pentobarbital (2270)	II
Nabilone (7379)	II

With regard to Gamma Hydroxybutyric Acid (2010), Tetrahydrocannabinols (7370), and Methamphetamine (1105) only, the company manufactures these controlled substances in bulk solely for domestic distribution within the United States to customers engaged in dosage-form manufacturing.

With regard to Nabilone (7379) only, the company presently manufactures a small amount of this controlled substance in bulk solely to conduct manufacturing process development within the company. It is the company's intention that, when the manufacturing process is refined to the point that its Nabilone bulk product is available for commercial use, the company will export the controlled substance in bulk solely to customers engaged in dosage-form manufacturing outside the United States. The company is aware of the requirement to obtain a DEA registration as an exporter to conduct this activity.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Norac, Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Norac, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 9, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21073 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 13, 2011, and published in the **Federal Register** on April 20, 2011, 76 FR 22146, Stepan Company, Natural Products Dept., 100 W. Hunter Avenue, Maywood, New Jersey 07607, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Cocaine (9041)	II
Ecgonine (9180)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a), and determined that the registration of Stepan Company to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Stepan Company to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 10, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21081 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 25, 2011, and published in the **Federal Register** on May 4, 2011, 76 FR 25375, Rhodes Technologies, 498 Washington Street, Coventry, Rhode Island 02816, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Methylphenidate (1724)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Oripavine (9330)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for conversion and sale to dosage form manufacturers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Rhodes Technologies to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Rhodes Technologies to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 10, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21080 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05–16]

Lyle E. Craker, PhD; Order Regarding Officially Noticed Evidence and Motion for Reconsideration

Lyle E. Craker, PhD (Respondent) has requested that I reconsider the Final Order I issued on January 7, 2009 (74 FR 2101), which denied his application to

become registered as a bulk manufacturer of marijuana. For the reasons provided below, Respondent has failed to demonstrate that the Final Order contains any erroneous material findings of fact or conclusions of law. Accordingly, Respondent's motion for reconsideration does not provide a basis for altering the decision in the Final Order to deny his application.

I. Post-Final-Order Proceedings

Following the issuance of the January 7, 2009, Final Order, Respondent submitted a letter to me dated January 21, 2009, noting that, in several places in the Final Order, I indicated I was taking official notice of certain documents that were not submitted during the administrative hearing. With respect to such documents, the Final Order states: ''To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of the order.'' Thus, Respondent had until January 23, 2009, to file a motion for reconsideration of the facts of which I took official notice. In his January 21, 2009, letter, Respondent requested an extension of this filing deadline until January 30, 2009. I granted this request for an extension by letter dated January 22, 2009.

On January 30, 2009, Respondent submitted to me a document entitled ''Request for Opportunity Under 5 U.S.C. 556(e) To Respond to New Officially Noticed Evidence and Motion for Reconsideration.'' In this document, Respondent provided a preliminary response to those documents of which I took official notice. However, Respondent asked for additional time to supplement his preliminary response, given the length of the Final Order as well as that of the documents of which I took official notice. I granted this request, allowing Respondent until March 11, 2009, to supplement his response and motion. I further instructed that counsel for the Government would have to submit its response no later than 15 days after being served with Respondent's submission.

On March 11, 2009, Respondent submitted ''Respondent's Supplemental Brief in Support of Request Under 5 U.S.C. 556(e) To Respond to New Officially Noticed Evidence and Motion for Reconsideration.'' In this document, Respondent provided the legal and factual bases for his motion for reconsideration of the Final Order. Also in the document, Respondent requested that the administrative hearing be reopened so that he may call additional witnesses in view of certain documents of which I took official notice in the final order. The Government submitted its response on April 13, 2009. In view of these submissions, and to clarify Respondent's request, I issued an interim order on May 18, 2009, directing Respondent to submit a list of all witnesses he would call if his request to reopen the administrative hearing were granted and to provide a summary of the proposed testimony for each witness. This interim order further instructed Respondent to indicate precisely which documents he sought to introduce for purposes of his motion for reconsideration and, for each document, whether he wanted me to take official notice of it, or whether he wished to introduce it through witnesses if his request to reopen the hearing were granted.

On June 5, 2009, Respondent submitted his ''Witness List and Document List in Support of Motion for Reconsideration.'' On December 2, 2010, I issued an order granting in part, and denying in part, Respondent's request that I take official notice of certain documents. The order denied Respondent's request that I reopen the hearing to allow him to call additional witnesses. Having ruled on which new documents would be considered part of the record (through my taking official notice thereof), the order then gave Respondent an additional opportunity to file a final brief in support his motion for reconsideration. The order stated that Respondent was required to submit such brief on or before March 7, 2011, and that the Government's responsive brief was due no later than 30 days after receipt of Respondent's brief. Respondent submitted his brief on March 7, 2011 (hereafter, ''Respondent's latest submission''), and the Government submitted its responsive brief on April 1, 2011.

II. Respondent's Additional Proposed Documentary Exhibits

Respondent's request to introduce additional documents for purposes of his motion for reconsideration was addressed at length in my December 2, 2010, Order. For each such document Respondent sought to introduce, the December 2, 2010, Order stated (pages 23–27) whether I would take official notice of the document, and the reasons therefor. Only *one* category of documents that Respondent sought to introduce was left unresolved by the December 2, 2010, Order. As to this category, the order stated (page 26):

> If Respondent submits all of the correspondence between Chemic and HHS (or any of its components) relating to this application [Chemic's application to HHS to receive marijuana for research] that he has in his possession or can reasonably access (including, but not limited to, any such correspondence on the MAPS website, such as the January 23, 2009, letter from HHS to Chemic), I will take official notice of all such correspondence.

Thus, the only additional documents that might be considered at this juncture for inclusion in the record (by my taking official notice thereof) are the ''correspondence between Chemic and HHS'' described in the above-quoted sentence. Respondent's latest brief seeks to introduce 11 new documents (which Respondent labels Exhibits A–K). However, only four of these documents (Exhibits C, I, J, and K) appear to be correspondence between Chemic and HHS. The remaining seven documents (A, B, D, E, F, G, and H) do not appear to be correspondence between Chemic and HHS, and Respondent makes no assertion in his brief that they are such. The Government asserts in its responsive brief that these Exhibits A, B, E, F, G, and H are not ''correspondence'' and further that ''Respondent has not laid any foundation to demonstrate that these exhibits were provided to HHS by Chemic.'' For this reason, among others, the Government objects to including these documents in the record.

Accordingly, I rule as follows with respect to these latest proposed exhibits:

(1) I will take official notice of Exhibits C, I, J, and K; and

(2) As Exhibits A, B, D, E, F, G, and H do not comport with the instructions contained in the December 2, 2010, Order, I will not take official notice of these documents, and they will not be considered part of the administrative record considered by the agency in this adjudication.

III. Respondent's Motion for Reconsideration

Given the number of written submissions made by Respondent following the issuance of the January 7, 2009, Final Order, along with the Government's responses thereto and the interim orders I issued regarding these submissions, it is important to reiterate here the purpose for which Respondent was given an opportunity to file a motion for reconsideration. That purpose was stated in the January 7, 2009, Final Order: ''To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall

commence with the mailing of the order.'' 74 FR at 2108 n.24. This was restated in the interim orders I issued following the Final Order. As explained in the Final Order and the December 2, 2010, Order, this opportunity to seek reconsideration of facts of which the agency takes official notice is derived from the Administrative Procedure Act (5 U.S.C. 556(e)) and the DEA regulations (21 CFR 1316.59(e)).

Respondent's post-Final-Order submissions have, in many respects, gone beyond seeking reconsideration of facts of which I took official notice. Respondent has essentially sought broad reconsideration of the factual and legal bases for the Final Order—generally without predicating such arguments on the taking of official notice of any fact. Neither the Controlled Substances Act (CSA) nor the DEA regulations provide for such a broad-based motion for reconsideration of a Final Order.[1] Nonetheless, in the exercise of my discretion, taking into account the complex and sometimes novel issues involved in this matter, I have considered all of the arguments Respondent has submitted in his post-Final-Order submissions—including those that go beyond the scope of what is permitted by 5 U.S.C. 556(e) and 21 CFR 1316.59(e).

The arguments contained in Respondent's post-Final-Order submissions are, for the most part, reiterations of the same arguments that were addressed at length and rejected in the Final Order. In a few instances, as noted below, Respondent does present some slightly different assertions than he previously offered. However, even in these instances, Respondent's core contentions remain those that I previously rejected. Furthermore, Respondent fails in these latest submissions to rebut the fundamental reasons that were provided in the Final Order for denying his application.

A. Respondent's Arguments Relating to the Review of Research Protocols by the Department of Health and Human Services

In his post-Final-Order submissions, Respondent continues to focus on what was his primary theme throughout the adjudication proceedings leading up to the Final Order: his desire to have the Public Health Service and the National Institute on Drug Abuse (NIDA) removed from the process by which the Department of Health and Human Services (HHS) carries out its statutory duty to review proposed research involving marijuana. For purposes of context, it is repeated here, as explained in the Final Order, that under the CSA (21 U.S.C. 823(f)), the Secretary of HHS is responsible for reviewing all proposed research involving schedule I controlled substances. Specifically, section 823(f) provides that, with respect to applications for registration by practitioners wishing to conduct research with schedule I controlled substances, ''the Secretary * * * shall determine the qualifications and competency of each practitioner requesting registration, *as well as the merits of the research protocol.''* (Emphasis added.) Thus, under section 823(f), a research proposal involving marijuana may only go forward where the Secretary both (1) Deems the practitioner qualified and competent and (2) determines the research protocol to be meritorious. Or, as stated by HHS in its 1999 announcement of its policies for providing marijuana to researchers: ''To receive such a registration [under § 823(f)], a researcher must first be determined *by HHS* to be qualified and competent, and the proposed research must be determined *by HHS* to have merit.'' 74 FR at 2120 n.70 (emphasis added in Final Order).

Respondent does not dispute that the statute assigns the foregoing functions to the Secretary of HHS. However, Respondent objects to the manner in which these functions are carried out within HHS. In particular, Respondent seeks to have the Public Health Service and NIDA stripped of any role in this process.[2]

For purposes of addressing this issue, it is useful to repeat the following parts of the Final Order, which discussed the scientific review process that has been utilized by HHS since 1999 to evaluate marijuana research proposals:

[I]n 1999, due in part to an increased interest in marijuana research and taking into account the IOM report, HHS decided to change the procedures by which it would supply marijuana to researchers. The new procedures were announced in a document released by NIH on May 21, 1999. In the announcement, ''HHS recognize[d] the need for objective evaluations of the potential merits of cannabinoids for medical uses[,]'' and that ''[i]f a positive benefit is found, * * * the need to stimulate development of alternative, safer dosage forms.'' Toward this end, NIH explained that the new procedures were designed to increase the availability of marijuana for research purposes by, among other things, making such marijuana ''available on a cost-reimbursable basis.'' This new procedure allowed researchers who were privately funded to obtain marijuana from HHS by reimbursing the NIDA contractor for the cost of the marijuana. This was a departure from the prior practice (pre-1999), whereby HHS only made marijuana available to persons who received NIH funding. The new procedures implemented by HHS in 1999 remain in effect today.

* * * * *

At the administrative hearing in this case, Steven Gust, PhD, Special Assistant to the Director of NIDA, explained that, in addition to seeking to facilitate research into the possible medical utility of marijuana, the new procedures implemented by HHS in 1999 were intended ''to make the process more standardized, and to * * * provide some expertise that did not really exist at NIDA in terms of reviewing applications that involved * * * the use of marijuana * * * for treatment of diseases.'' Accordingly, HHS ''established a separate peer review process that * * * moved the review into the Public Health Service [a component of HHS] * * * where additional expertise from other NIH Institutes and other Federal agencies'' could be utilized in reviewing the scientific merit of the applications. Dr. Gust further explained that the members of the review committee are drawn from the various specialty institutes of NIH, and the Substance Abuse and Mental Health Services Administration (SAMHSA). Dr. Gust also testified that the ''scientific bar has been set very low, [so] that any project that has scientific merit is approved,'' and that ''anything that gets approved gets NIDA marijuana.'' As of April 2004, HHS had approved at least seventeen pre-clinical or clinical studies of marijuana, which were sponsored by the California Center for Medical Cannabis Research (CMCR). According to one witness who testified on behalf of Respondent, all of the CMCR-sponsored researchers who applied to NIDA for marijuana did in fact receive marijuana from NIDA.

* * * * *

In his testimony, Dr. Gust explained the term ''peer review'' as follows: ''Peer review is a process that has been used, certainly by NIH, and I think in other agencies in the Department of Health and Human Services, and probably the Federal Government, where outside expertise is acquired and outside opinions on the scientific merit of specific research proposals.'' Dr. Gust added that the NIH peer review committees ''review

[1] The CSA appeal provision, 21 U.S.C. 877, states: ''All final determinations, findings, and conclusions of the [Administrator of DEA] under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the [Administrator] may obtain review of the decision in the United States Court of Appeals * * *.'' This provision suggests that—outside of the scenario provided by the DEA regulations and APA in which a party, on timely request, seeks the opportunity to controvert facts of which the agency took official notice—DEA is not obligated to allow parties to seek reconsideration of final orders regarding applications for registration. DEA also adheres to the Supreme Court's decision in *Interstate Commerce Comm'n* v. *Bhd. of Locomotive Eng'rs,* 482 U.S. 270 (1987), regarding the reopening of proceedings where it is alleged that new evidence or changed circumstances render the agency's original order inappropriate. *See also Fry* v. *DEA,* 353 F.3d 1041, 1044 (9th Cir. 2003).

[2] *See, e.g.,* 74 FR at 2106 (noting testimony of Rick Doblin, the Director of MAPS, that ''what we're trying to do is get the Public Health Service and NIDA out of the picture'').

proposals three times a year for the NIH, and there are—occasionally a Federal employee participates in one of those reviews, but probably 90 percent or more of the participants are researchers who are in the private sector, for the most part in academic institutions.''

74 FR at 2015, 2119 n.67 (footnotes and citations omitted).

Again, it is Respondent's contention that the involvement of the Public Health Service and NIDA in reviewing proposed marijuana research protocols has the effect of blocking legitimate research into marijuana. Indeed, the primary argument Respondent puts forth in support of his proposed registration is that the current system by which the United States Government makes marijuana available to researchers fails to provide an adequate supply of marijuana within the meaning of 21 U.S.C. 823(a)(1)—precisely because, in Respondent's opinion, the Public Health Service and NIDA have ''institutional biases'' against certain types of marijuana research.

This argument was carefully examined in the Final Order. *See* 74 FR at 2107–08, 2119–20. Respondent's post-Final-Order submissions as to this issue are not materially different from the claims that were rejected in the Final Order. In fact, the new documents that Respondent has submitted following the Final Order, and of which I have taken official notice, provide further confirmation of certain determinations made in the Final Order. Respondent's latest submission contains no citations to actual *evidence* in the record that supports his claims of ''institutional biases'' or ''political'' motivation on the part of the Public Health Service and NIDA.

As to this issue, the Final Order stated, among other things:

Respondent also introduced into evidence a letter from the President of Chemic to HHS responding to several points raised by the PHS Committee in denying Chemic's application. Respondent's letter does not, however, establish that HHS impermissibly denied Chemic's application for marijuana. To the contrary, *the evidence supports the conclusion that HHS (acting through the PHS Committee) made its determination not to supply marijuana on this occasion based on scientific considerations, finding that Chemic's then-latest proposed study was duplicative of prior and ongoing research and not likely to provide useful data.*

74 FR at 2109 (emphasis added; footnote and citation omitted). As noted, I granted Respondent's post-Final-Order request to introduce additional correspondence between Chemic and HHS relating to Chemic's proposed research protocol involving marijuana. Respondent produced six additional pieces of correspondence between Chemic and HHS relating to this matter that were not produced in the administrative hearing. As indicated above and in the December 2, 2010, Order, I have taken official notice of all six of these documents. Each of these documents further confirms that HHS's rejection of the Chemic protocol was—as the Final Order found—based purely on scientific merit.

It is difficult to understand why Respondent would seek to introduce at this juncture six letters between Chemic and HHS that reaffirm what was found in the Final Order—and how Respondent construes these letters as ''rebuttal'' evidence. The statements by HHS in these letters are, without question, focused entirely on the scientific inadequacies of various iterations of Chemic's research proposal. The letters demonstrate that the HHS scientists have actively engaged in a dialogue with Chemic for many years, and have gone to great lengths to explain to Chemic each of the areas in which Chemic needs to revise its protocol so that it can be deemed scientifically meritorious. The letters thereby reaffirm that HHS (including, but not limited to, the Public Health Service and NIDA) has never indicated any opposition (political, philosophical, or otherwise) to any *category* of marijuana research. To the contrary, the letters—particularly the most recent one submitted by Respondent, dated January 23, 2009—actually show that HHS is interested in Chemic's proposal and willing to supply Chemic with marijuana, provided that Chemic provides validation data that is necessary to support Chemic's scientific measurements. In short, the evidence continues to point squarely to the conclusion that HHS is doing precisely what it is required to do under 21 U.S.C. 823(f): Allow only those schedule I research proposals that it determines to be scientifically meritorious to go forward. As the Final Order stated: ''That Respondent finds this process to be scientifically rigorous—and thereby not automatically accepting of any proposed study sponsored by MAPS—provides no basis for any valid objection or any contention that the HHS supply of marijuana is inadequate.'' 74 FR at 2120 (footnotes omitted).[3]

Moreover, Respondent's ''institutional bias'' theory is belied by the following crucial fact. As stated in the Final Order: ''The record reflects that since HHS changed its policies in 1999 to make marijuana more readily available to researchers (by, among other things, allowing privately funded researchers to obtain marijuana), every one of the 17 CMCR [California Center for Medical Cannabis Research]-sponsored pre-clinical or clinical studies that requested marijuana from NIDA was provided with marijuana.'' 74 FR at 2119. Despite the enormity of this fact in relation to Respondent's ''institutional bias'' claim, Respondent makes only the following vague reference to it in his latest submission (page 9): ''Though the DEA points to other marijuana research that NIDA has allowed, none of these studies aimed to develop marijuana into a legal prescription medicine.'' What Respondent downplays as ''other marijuana research that NIDA has allowed'' is, in fact, *seventeen* different clinical trials involving marijuana proposed by CMCR—*all* of which were approved by the Public Health Service and NIDA. As stated in the Final Order:

Any suggestion that the HHS scientific review process is unduly rigorous is belied by the testimony of Dr. Gust that the ''scientific bar has been set very low, [so] that any project that has scientific merit is approved,'' and that ''anything that gets approved gets NIDA marijuana'' (Tr. at 1700–01) as well as the uncontroverted evidence that every one of the 17 CMCR-sponsored research protocols submitted to HHS was deemed scientifically meritorious by HHS and was supplied with marijuana (GX 31, at 3; Tr. 694–95).

74 FR at 2120 n.71.

As for Respondent's contention that ''none of these studies aimed to develop marijuana into a legal prescription medicine,'' this too is contradicted by the record. As stated in the Final Order:

The California research studies were conducted pursuant to a law enacted by California in 1999 known as the Marijuana Research Act of 1999. Cal. Health & Safety Code § 11362.9. This state law established the ''California Marijuana Research Program'' to develop and conduct studies on the potential medical utility of marijuana. *Id.* (The program is also referred to as the ''Center for Medicinal Cannabis Research'' (CMCR). Tr. 396.) The state legislature

[3] It is unclear whether Respondent is suggesting that I should refuse to accept at face value what HHS stated in its correspondence with Chemic and instead conclude—without any evidentiary basis for doing so—that the HHS scientists who are responsible for reviewing proposed marijuana research have conspired for years to carry out an elaborate ruse aimed at thwarting marijuana research. If this is Respondent's mind-set, adopting it would be the antithesis of the principle inherent to the Administrative Procedure Act (APA) that agency action must be presumed to be valid where a reasonable basis exists for its decision. *See, e.g., Kern County Farm Bureau* v. *Allen,* 450 F.3d 1072, 1076 (9th Cir. 2006). It is also at odds with the APA concept that bars a reviewing court—much less a member of the public—from substituting its judgment for that of the agency. *Id.*

appropriated a total of $9 million for the marijuana research studies. Tr. 397.

74 FR at 2105–06 n.16. It is thus beyond question that the CMCR studies were aimed at what Respondent characterizes as ''develop[ing] marijuana into a legal prescription medicine.''[4]

For the same reasons, the record contradicts Respondent's related claim that the involvement of the Public Health Service and NIDA in determining the scientific merit of proposed marijuana research ''renders the supply [of marijuana] inadequate because entire categories of legitimate medical research are effectively foreclosed.'' Respondent fails to explain what ''categories of legitimate medical research'' are supposedly being foreclosed. Again, it seems (but is unclear) that Respondent is suggesting that the Chemic research proposal, and/or Dr. Russo's proposal (see below), were more geared toward ''develop[ing] marijuana into a legal prescription medicine'' than were the 17 CMCR studies. In other words, Respondent appears to be suggesting that the Public Health Service and NIDA went into their alleged ''institutional bias'' mode when reviewing the Chemic and Russo proposals, but turned off that mode when reviewing the 17 CMCR proposals because the latter were less geared toward developing marijuana into an FDA-approved medicine. If this is what Respondent is suggesting, there is no evidentiary foundation for such a claim as neither Chemic's proposal nor Dr. Russo's could be characterized as closer than the CMCR studies to the goal of obtaining FDA approval of marijuana as a drug.[5]

To address further the portion of Respondent's latest submission pertaining to Dr. Russo, the following part of the Final Order is recited:

> [Dr. Ethan Russo] sought funding from NIDA to study the use of marijuana to treat migraine headaches beginning around 1996. The precise dates of the events related to Dr. Russo are somewhat unclear as Respondent presented these events through the testimony of Mr. Doblin. (Dr. Russo did not testify.) Based on Mr. Doblin's testimony, it appears that during 1996–97, NIDA twice rejected Dr. Russo's protocol for reasons which are not clearly established by the record. However, according to Mr. Doblin, Dr. Russo conceded that, on both of these two occasions when NIDA rejected his protocol, NIDA's bases for doing so did include ''some valid critiques.'' Mr. Doblin testified that Dr. Russo subsequently attempted for a third time to obtain marijuana from NIDA, but on this third occasion he decided not to seek government funding but to seek private funding to purchase the marijuana from NIDA. According to Mr. Doblin, this third protocol submitted by Dr. Russo was approved by both the FDA and Dr. Russo's institutional review board, but NIDA again refused to supply marijuana. When asked when this last denial by NIDA occurred, Mr. Doblin testified: ''I think it was 1999.''
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> As noted above, NIH announced on May 21, 1999, HHS's new procedures for making marijuana available to researchers. Bearing in mind that Respondent had the burden of proving any proposition of fact that he asserted in the hearing, 21 CFR 1301.44(a), nothing in Mr. Doblin's testimony, or any other evidence presented by Respondent, established that HHS denied Dr. Russo's request for marijuana under the new procedures implemented by the agency in 1999. Indeed, Respondent produced no evidence showing that HHS has denied marijuana to any clinical researcher with an FDA-approved protocol subsequent to the adoption of the 1999 guidelines.

74 FR at 2108 (citations omitted).

In his post-Final-Order submissions, Respondent submitted a letter dated February 1, 2000, from the Public Health Service and NIDA to Dr. Russo (Exhibit C to Respondent's March 11, 2009, Supplemental Brief). In the December 2, 2010, Order, I granted Respondent's request to take official notice of this document. As Respondent indicates, this letter was issued after HHS announced in 1999 its new procedures for providing marijuana to researchers. Even assuming, arguendo, that this letter demonstrates that the third protocol submitted by Dr. Russo was evaluated by HHS under the new procedures established in 1999,[6] this does not materially alter the conclusions in the Final Order. This is because the Final Order stated, in essence, that even if Dr. Russo's proposal had been evaluated by HHS under the post-1999 procedures, ''the evidence indicates that the denials involving * * * Dr. Russo were based on HHS finding [his] protocols to be lacking in scientific merit.'' *See* 74 FR at 2119 n.68.

The most recent document submitted by Respondent regarding Dr. Russo (the February 1, 2000, letter from Public Health Service to Dr. Russo) confirms yet again that the Public Health Service and NIDA focus on *scientific merit* in reviewing proposed marijuana research. The February 1, 2000, letter advised Dr. Russo that a scientific review of his protocol had been conducted by the Center for Scientific Review (CSR) of the National Institutes of Health on behalf of the Public Health Service, and that the CSR recommended certain changes to the protocol. If, the letter continued, such changes were incorporated into a new protocol and submitted by Dr. Russo, the Public Health Service would reconsider his request. Among the specific changes that Dr. Russo was advised to make were the following: Including a placebo arm; taking steps to account for possible attrition of research subjects; and ensuring that research subjects received equivalent doses of THC. These are quintessentially scientific refinements that the researcher was being asked to make—not, as Respondent alleges, a refusal to allow a category of research to take place.

Thus, even when viewing Respondent's newly submitted evidence regarding Dr. Russo as an example of a denial by HHS of marijuana under the post-1999 HHS procedures, it is in the same category as the Chemic protocols: A denial based on scientific merit under the post-1999 procedures. This would bring the total figures under the post-1999 procedures to the following: 17 studies approved and supplied with marijuana; two studies denied until the researcher makes certain changes in the protocol to render the proposal scientifically meritorious. Stated alternatively, under the post-1999 procedures, HHS's approval rate for marijuana studies is at least 89.5 percent, with the possibility of that figure rising to 100 percent if two of the researchers were willing to make adjustments to their protocols to make them scientifically meritorious.

Respondent's latest submission also refers to certain documentary and testimonial statements by NIDA officials, which Respondent contends support his claim of ''institutional bias.'' As these statements were part of the record that the parties addressed in their pre-Final-Order submissions, and since the Final Order already addressed this type of argument by Respondent, it is not necessary to reexamine this issue at length here. Moreover, the *actions* by HHS in response to actual research proposals are by far the best evidence of the agency's true willingness to supply marijuana to researchers, and these actions render inconsequential any attempt by Respondent to surmise ''institutional bias'' from abstract statements isolated from the documents

[4] The process by which FDA approves new drugs for marketing is summarized in the Final Order. 74 FR at 2106 n.21.

[5] As stated in the Final Order, no clinical trials involving marijuana—not even the 17 CMCR studies—have advanced beyond Phase 1 of the three phases required for FDA approval of a new drug. 74 FR at 2107 n.23. The proposed Chemic study does not even appear to be a clinical trial, let alone a study more advanced in the phases of FDA approval than the CMCR studies.

[6] While the letter itself is dated February 1, 2000, Respondent failed to present evidence indicating when Dr. Russo submitted his third protocol, or when HHS began its review of that protocol. Thus, it remains uncertain whether this third protocol was evaluated under the pre-1999 or post-1999 HHS procedures.

and testimony. The same considerations apply with respect to Respondent's argument that NIDA's mission stands as an obstacle to allowing legitimate marijuana research to take place. This argument was addressed in the Final Order and is overwhelmingly refuted by the evidence of HHS's actual track record in supplying marijuana to researchers.[7]

Respondent also asserts that two provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) and an FDA regulation mandate that the FDA—and not NIDA—must carry out the Secretary of HHS's responsibility under 21 U.S.C. 823(f) to determine the scientific merit of proposed marijuana research. Specifically, Respondent cites 21 U.S.C. 393(b) (FDA's mission statement), 21 U.S.C. 355 (new drug approval process), and 21 CFR 312.22(a) (general principles of submission of an investigational new drug application (IND)), in support of this assertion.

This assertion is mistaken in a number of respects, including, but not limited to, the following. First, the fact that the FDA's statutory mission statement lists certain functions by no means precludes other agencies within HHS from having overlapping functions.[8] Second, while FDA is indeed the agency within HHS that is chiefly responsible for administering the new drug approval process under 21 U.S.C. 355, this is a distinctly different function than the determination under 21 U.S.C. 823(f) of the scientific merit of proposed research involving schedule I controlled substances. There is certainly no basis for Respondent (or any other member of the public) to dictate to the Secretary that the same agency within HHS that carries out the former function must also carry out the latter.[9] Third, although the review by FDA of an IND may (depending on the phase of the investigation) be similar in certain respects to the review under § 823(f) of a schedule I research proposal, the two types of reviews are distinct administrative functions carried out within HHS. This is evident from the first sentence of the very regulation that Respondent cites, 21 CFR 312.22(a), which states: ''FDA's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and in Phase 2 and 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety.'' Thus, in reviewing an IND for a Phase 1 investigation, FDA's primary objective is to assure the *safety and rights of subjects*—not to assess the scientific quality of the clinical investigation. This is especially notable since, as stated above, none of the clinical trials involving marijuana that have been proposed to HHS has advanced beyond Phase 1.

The foregoing discussion also sheds light on another assertion made by Respondent in his latest submission: That ''several research projects have been blocked by NIDA in spite of FDA-approved protocols.''[10] Preliminarily, it should be noted that Respondent fails to specify exactly what he means here by ''several research projects.'' The record reveals only *two* clinical research proposals submitted to HHS involving marijuana that did not receive marijuana: Dr. Abrams's proposal (in the pre-1999 era) and Dr. Russo's proposal.[11] In addition, it is important at this juncture to correct an error in terminology. *FDA does not ''approve'' INDs.* Rather, the IND process works as follows. An investigator seeking to use an investigational new drug in a clinical trial must submit an IND for the drug to the FDA. 21 CFR 312.40. The IND automatically goes into effect 30 days after the FDA receives the IND,[12] unless the FDA notifies the sponsor that the investigation is subject to a clinical hold. *Id.*

Thus, it is incorrect for Respondent to state that the FDA ''approved'' any ''protocols'' for proposed marijuana research.[13] More accurately stated, the most that can be inferred from the evidence is that the FDA *reviewed INDs* submitted by Dr. Abrams and Dr. Russo, and that the FDA did not place a clinical hold on either proposed investigation.[14] However, as just explained, the FDA regulations indicate that, for Phase 1 investigations, FDA's review of an IND focuses primarily on the safety and rights of subjects—not the scientific quality of the clinical investigation. Thus, while the FDA appears to have concluded that allowing Dr. Russo's and Dr. Abrams's Phase 1 studies to proceed would not have presented an unacceptable risk of harm to the human research subjects,[15] there is no evidentiary basis to conclude that FDA evaluated the scientific quality of either proposal—and particularly no basis to conclude that FDA determined that the studies were scientifically meritorious within the meaning of 21 U.S.C. 823(f).

As stated in the Final Order, under the procedures implemented by HHS in 1999 for reviewing proposed marijuana research, the review by FDA on an IND is *one part* of that process.[16] Yet, Respondent seems to want FDA's

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[7] Although HHS's actual record in supplying marijuana to researchers is the best evidence of its willingness to do so, the following testimony of Dr. Gust at the hearing explains how HHS took steps in 1999 to ensure the availability of marijuana to researchers—including those interested in pursuing medical uses of marijuana—irrespective of NIDA's mission:

It was about this time [1999] when there was some increased interest in research, in pursuing the medical use of marijuana, and in an effort to make the process more standardized, and to basically provide some expertise that did not really exist at NIDA in terms of reviewing applications that involved primarily the use of marijuana or any other substance for that matter for treatment of diseases, which did not really fall within NIDA's mission, the department [HHS] established a separate peer review process that made the review—that moved the review into the Public Health Service at the time where additional expertise from other NIH Institutes and other Federal agencies could be brought to bear to help—and help provide reviews, appropriate reviews, of the scientific merit of these applications.

Tr. 1632–33. Thus, Respondent's attempt to focus on NIDA's particular mission, without regard to the mission of other components of HHS involved in review of marijuana research proposals, and without regard to the overall aims of the procedures established by HHS in 1999 for providing marijuana to researchers, is misplaced.

[8] Moreover, not even those functions expressly listed in FDA's statutory mission statement are carried out solely by the FDA. As stated in the very next subsection after the one cited by Respondent, 21 U.S.C. 393(c), which is entitled ''Interagency collaboration'': ''The Secretary [of HHS] shall implement programs and policies that will foster collaboration between the [FDA], the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies. * * *''

[9] Under 21 U.S.C. 823(f), Congress assigned to the Secretary of HHS sole discretion to determine how HHS carries out its responsibility to review the scientific merit of schedule I research proposals.

[10] Respondent uses this particular wording on page 9 of his latest submission, and he reiterates the assertion numerous times in the document.

[11] As Respondent seems to concede, Chemic's proposed research involving marijuana is *not* a clinical trial. Accordingly, Respondent does not appear to be suggesting that Chemic submitted an IND to the FDA for its research proposal. Thus, it does not appear that Respondent is including the Chemic situation in his category of ''research projects [that] have been blocked by NIDA in spite of FDA-approved protocols.''

[12] The FDA may also notify the investigator that the clinical investigation may begin earlier than 30 days after the FDA receives the IND. 21 CFR 312.40(b)(2).

[13] The word ''approve'' (or ''approval'') is a term of art in the FDCA. The FDA ''approves'' new drug applications upon an adequate showing of safety and efficacy for the uses in the proposed labeling, which allows a drug to be legally marketed. 21 U.S.C. 355; 21 CFR 314. An effective IND is considered ''accepted,'' not ''approved,'' by FDA.

[14] I am assuming, for the sake of discussion, that Dr. Russo and Dr. Abrams submitted INDs and that the FDA did not issue clinical holds, even though Respondent did not introduce such INDs or call Dr. Russo or Dr. Abrams to testify.

[15] *See* 21 CFR 312.42(b) (grounds for imposition of a clinical hold of a Phase 1 study under an IND).

[16] *See* 74 FR at 2105.

review of an IND for Phase 1 investigations—which focuses on the safety and rights of subjects, rather than the scientific quality of the clinical investigation—to serve as the entire review process, *i.e.,* to supplant the full-fledged evaluation of the scientific merit required by 21 U.S.C. 823(f). Had Congress intended such a result, it could have easily stated in 21 U.S.C. 823(f) that the only scientific prerequisite to conducting research with a schedule I controlled substance is that an IND be in effect with respect to such research.[17] But it is evident from the language of § 823(f) that Congress intended HHS to conduct a different type of evaluation of the scientific merit of research proposals than that which will suffice for purposes of an IND. It is unclear whether Respondent fails to understand this distinction between the review by FDA of a Phase 1 IND and the review of the scientific merit of a research proposal under § 823(f), or if Respondent does understand this distinction and simply wishes that the less rigorous review (the Phase 1 IND review) would suffice so that even those marijuana research proposals that lack scientific merit could be carried out.[18] For the reasons noted above, neither of the foregoing is a legally valid position.

In sum, Respondent's motion for reconsideration provides no basis for deviating from the conclusions in the Final Order relating to the process by which HHS determines the scientific merit of proposed marijuana research pursuant to 21 U.S.C. 823(f). Congress assigned to the Secretary of HHS responsibility for deciding how to carry out that function within HHS, and the evidence demonstrates that the procedures established by HHS in 1999, including the Public Health Service interdisciplinary review process, properly focus on the scientific merit of research proposals. As the Final Order indicated, that process makes marijuana available to all researchers who meet the criteria of § 823(f), and Respondent's post-Final-Order submissions provide no evidence suggesting otherwise. Respondent's desire to substitute his opinion for that of the Secretary as to what type of scientific review should be carried out under § 823(f), and who within HHS should carry it out, is legally untenable.

Respondent's claim that the supply of marijuana is inadequate is dependent on his supposition that the current HHS process for supplying marijuana to researchers improperly denies marijuana to researchers. That supposition was found in the Final Order to be without merit, and his latest submission warrants no departure from that finding, as explained above. Accordingly, Respondent has provided no basis to change the conclusion in the Final Order that he failed to meet his burden of proving that the supply of marijuana is inadequate within the meaning of 21 U.S.C. 823(a)(1).

B. Respondent's Arguments Relating to the Single Convention on Narcotic Drugs, 1961

Respondent seeks reconsideration of the determinations in the Final Order relating to the Single Convention on Narcotic Drugs, 1961 (Single Convention). Respondent's post-Final-Order arguments relating to the Single Convention are not predicated on the taking of official notice of any fact. Nonetheless, as indicated, I have considered these arguments. Respondent's core contentions regarding the Single Convention were addressed in the Final Order and, therefore, it is unnecessary to repeat all of that discussion here. However, in view of his latest submissions, a few points warrant reiteration and/or clarification.

Under 21 U.S.C. 823(a), DEA must deny an application by a person seeking to become registered as a bulk manufacturer of a schedule I controlled substance if the agency determines that such registration would be inconsistent with United States obligations under applicable international drug control treaties—*i.e.,* the Single Convention. When it comes to marijuana (referred to under the treaty as ''cannabis''), one of the key principles of the Single Convention is that the federal government maintain a monopoly over the wholesale distribution of the drug. As to this point, the Final Order recited the following statement from the Official Commentary to the Single Convention:

> Countries * * * which produce * * * cannabis * * *, [i]n so far as they permit private farmers to cultivate the plants * * *, cannot establish with sufficient exactitude the quantities harvested by individual producers. If they allowed the sale of the crops to private traders, they would not be in a position to ascertain with reasonable exactitude the amounts which enter their controlled trade. The effectiveness of their control régime would thus be considerably weakened. In fact, experience has shown that permitting licensed private traders to purchase the crops results in diversion of large quantities of drugs into illicit channels. * * * [T]he acquisition of the crops and the wholesale and international trade in these agricultural products cannot be entrusted to private traders, but must be undertaken by governmental authorities in the producing countries. Article 23 * * * and article 28 * * * therefore require a government monopoly of the wholesale and international trade in the agricultural product in question in the country which authorizes its production.

74 FR at 2115 (citing Commentary at 278).

As indicated in the Final Order, the United States has, since 1968, implemented this aspect of the treaty through the following system carried out within HHS. NIDA enters into a contract with a private grower, with the grower being obligated under the contract to produce the amount and quantity of marijuana specified by NIDA and to produce marijuana cigarettes to supply researchers as directed by NIDA.[19] Throughout the 44 years since the United States ratified the Single Convention in 1967, the entire United States supply of marijuana for researchers has been distributed through this system. In this manner, the United States Government has always monopolized the wholesale trade in marijuana, consistent with its obligations under the treaty.

It is true, as Respondent points out in his post-Final-Order submissions, that the Single Convention (article 23, paragraph 3) calls upon parties to carry out the functions of article 23 by a single government agency. It is also true, as Respondent indicates, that the United States fails to adhere strictly to this provision of the treaty as both DEA and HHS carry out certain functions set forth in article 23, paragraph 2.[20] Specifically, DEA carries out those functions of article 23 paragraph 2 that are encompassed by the DEA registration system, and HHS (through NIDA) carries out those functions relating to purchasing the marijuana and maintaining a monopoly over the wholesale distribution. That these

[17] Several provisions of the CSA reference the IND provision of the FDCA. For example, 21 U.S.C. 827(c)(2)(A) expressly excludes ''research conducted in conformity with an exemption granted under [21 U.S.C. 355(i)]'' from the CSA's recordkeeping requirements.

[18] Illustrative of this point is Respondent's statement in his latest submission (page 14) that ''if a research protocol is good enough for the FDA, it should be good enough to be carried out.''

[19] Prior to 1999, NIDA entered into two contracts: one with the grower and one with the entity that produced the cigarettes. In 1999, NIDA decided that a single contract should be awarded for both activities, which resulted in the contractor (a division of the University of Mississippi) continuing to grow the marijuana, but subcontracting to Research Triangle Institute the responsibility of producing the cigarettes. 74 FR at 2122 n.79.

[20] Respondent is incorrect, however, in asserting that the Final Order stated that NIDA carries out all the functions under article 23, paragraph 2. No such statement appears in the Final Order.

functions are divided among the two agencies—rather than being carried out by a single agency—is a result of the existing statutes, regulations, and Congressional appropriations.[21] Nonetheless, when evaluating an application for registration under 21 U.S.C. 823(a), DEA must attempt to conform with the provisions of the Single Convention to the fullest extent possible under the existing statutory and regulatory framework. Accordingly, even in the absence of a single government agency carrying out all the functions referred to in article 23, paragraph 2, DEA must seek to adhere to the other provisions of this article that are attainable within the existing statutory and regulatory framework, including that which calls upon the United States Government to monopolize the wholesale distribution of marijuana.[22]

Therefore, for the reasons detailed in the Final Order, Respondent's stated goal of becoming registered for the purpose of ending the Government monopoly on the wholesale distribution of marijuana to researchers is directly at odds with the Single Convention, which independently warrants denial of his application. Respondent seems to continue to either ignore and/or misunderstand this fundamental aspect of the treaty. In his latest submission, Respondent states (pages 20–21): ''It is certainly true Dr. Craker seeks to cultivate marijuana outside *NIDA's* monopoly, but it does not follow that Dr. Craker seeks to cultivate marijuana outside the structures of *any government regulation.* * * * Dr. Craker and [Mr. Doblin] are in no way opposed to the regulation of marijuana by [DEA].'' (Emphasis in original.) This statement suggests that Respondent believes incongruously that as long as he agrees to comply with the DEA regulations relating to registration and security, his proposed registration should be deemed consistent with the Single Convention. Based on this flawed assumption, Respondent is effectively arguing that the provision of the Single Convention requiring a Government monopoly over the wholesale distribution of marijuana may be jettisoned whenever an applicant for registration promises to comply with the DEA regulations governing registration and security.

Respondent also continues to argue that the marijuana he seeks to grow is ''exempt'' from the Single Convention requirement of a government monopoly over the wholesale distribution of marijuana. According to Respondent, because he is seeking to supply marijuana to researchers for the purpose of conducting research that he hopes will someday lead to the FDA approval of marijuana as medicine, the marijuana he is seeking to grow should be deemed ''medicinal cannabis'' within the meaning of the Single Convention and thus the government monopoly set forth in article 23, paragraph 2(e) should be considered inapplicable to his proposed activity. The Government correctly suggests in its responsive brief (pages 8–9) that Respondent's interpretation would vitiate the language of article 23, paragraph 2(e). As I stated in the December 2, 2010, Order, it is theoretically possible that a marijuana-derived drug might be approved by the FDA in the future that would constitute ''medicinal cannabis'' within the meaning of the Single Convention. However, no drug product derived from marijuana has been approved by the FDA and, therefore, there is currently no such thing as ''medicinal cannabis'' in the United States. For this reason, the exception in article 23, paragraph 2(e) for ''medicinal cannabis'' has no bearing on this adjudication.

For purposes of the Single Convention, the marijuana that Respondent seeks to produce is clearly ''cannabis'' subject to the government monopoly under article 23, paragraph 2(e). As to this point, the Final Order observed:

> In its 2005 Annual Report, the [International Narcotics Control Board] reiterated: ''Articles 23 and 28 of the [Single] Convention provide for a national cannabis agency to be established in countries where the cannabis plant is cultivated licitly for the production of cannabis, even if the cannabis produced is used for research purposes only.''

74 FR at 2115 (footnote omitted).

Respondent also makes the following statement in his latest submission (pages 15–16): ''Additionally, the conduct of the one currently DEA-licensed manufacturer, who has been permitted by DEA to grow large amounts of marijuana *outside* of the NIDA contract, disproves the theory that marijuana grown for any purpose other than to supply NIDA-approved research would violate the Convention.'' (Emphasis in original.) Respondent is referring here to the cultivation of marijuana by the National Center for Natural Products Research (National Center), a division of the University of Mississippi.[23] As explained in the Final Order, in 1999, DEA and the National Center entered into a Memorandum of Agreement (MOA) under which the National Center was granted an additional registration to manufacture marijuana and THC independent of its contract with NIDA. 74 FR at 2104 n.13. The Final Order further explained:

> As set forth in the MOA, the purpose of the registration was ''to allow the Center to develop a new product formulation for effecting delivery of THC in a pharmaceutically acceptable dosage form suppository * * * and to provide crude THC extract to a DEA-registered manufacturer of THC for further purification.'' The MOA further stated that, under the terms thereof, the Center would ''manufacture marijuana for the purpose of extracting THC therefrom.'' Subsequently, the Center submitted a new application for a registration to bulk manufacture marijuana and THC ''to prepare marihuana extract for further purification into bulk active [THC] for use in launching FDA-approved pharmaceutical products.'' DEA has not yet issued a final order as to this application. (DEA publishes in the Federal Register all final orders on applications for registration to bulk manufacture schedule I and II controlled substances.)
>
> *The MOA further provided that ''[i]n accordance with articles 23 and 28 of the Single Convention on Narcotic Drugs * * * private trade in 'cannabis' is strictly prohibited. Therefore, the Center shall not distribute any quantity of marijuana to any person other than an authorized DEA employee.''* Continuing, the MOA explained that ''[t]he Single Convention does not prohibit private trade in 'cannabis preparations,' '' and noted that this term, ''within the meaning of the Single Convention, is a mixture, solid or liquid containing cannabis, cannabis resin, or extracts or tinctures of cannabis.'' Because ''[t]he THC that the Center will extract from marijuana [is] considered such a 'cannabis preparation[,]' * * * the Center may, in accordance with the Single Convention, distribute the crude THC extract to private entities'' provided the Center otherwise complies with the CSA and DEA regulations. The MOA also set forth a detailed series of controls to maintain accountability of the marijuana from acquisition of the seeds through the extraction of THC from the harvested material.

Id. (emphasis added; citations omitted). The Final Order further stated:

[21] Whether, in the absence of Congressional action, DEA could promulgate regulations that would result in DEA alone carrying out all the functions of article 23 is beyond the scope of this adjudication.

[22] Although Respondent argues that the Government does not take actual physical possession of the marijuana grown by the NIDA contractor (as contemplated by article 23, paragraph 2(d)), one could conclude that the NIDA contract process does fulfill this obligation. For the reasons indicated above, this does not compel DEA to abandon the provision of article 23 requiring a government monopoly on the wholesale distribution of marijuana. *See* 74 FR at 2114 (''taking possession and engaging in wholesale distribution are two separate activities under the Convention'').

[23] For ease of understanding, the National Center is sometimes referred to here and in the Final Order as ''the University of Mississippi.''

In 2005, the University of Mississippi applied for a new registration to manufacture marijuana ''to prepare marihuana extract for further purification into bulk active [THC] for use in launching FDA-approved pharmaceutical products.'' DEA has not yet issued a final order as to this application and the University therefore does not currently have DEA authorization to undertake such activity. As with Respondent's application, DEA may only grant the pending University of Mississippi application if the agency determines that the University has demonstrated that the registration would be consistent with United States treaty obligations and the public interest. In making such determinations, DEA will not simply rely on the prior issuance of registration under the 1999 MOA but will consider the application anew, in view of the current circumstances and consistent with this final order. Among other things that must be considered with respect to the pending University of Mississippi application, I note that the Commentary to the Single Convention states the following with respect to the exemption for ''opium preparations'' under Article 23, paragraph (e): ''Opium-producing countries may thus authorize private manufacture of, and private international and domestic wholesale trade in, medicinal opium and opium preparations. *The opium other than medicinal opium needed for such manufacture must however be procured from the national opium agency.''* Commentary at 284 (emphasis added). Whether the University of Mississippi's proposed registration would be consistent with this aspect of the treaty has not yet been determined by DEA and is not the subject of this adjudication.

74 FR at 2118 n.61 (emphasis in original; citations omitted).

When viewing the foregoing statements from the Final Order in juxtaposition with Respondent's latest assertions regarding the National Center, two points should be considered. First, the above statements reflect that as part of the 1999 MOA with the National Center, DEA insisted—as it has in Respondent's case—on adherence to the principle under the Single Convention of prohibiting private trading in cannabis. The National Center has never been permitted to distribute marijuana to any persons except upon the specific instructions of NIDA through the system described above. Second, contrary to Respondent's assertion, DEA has never taken the position that ''marijuana grown for any purpose other than to supply NIDA-approved research would violate the Convention.'' Rather, as just noted, DEA has consistently taken the position that, in accordance with the Single Convention, the Government must maintain a monopoly on the wholesale distribution of cannabis.

One other argument made by Respondent in his latest submission warrants a brief response. Respondent repeatedly makes erroneous assertions about the legal and factual circumstances surrounding his application, then denounces the situation as a ''catch-22.'' For example, on page 17 of his latest submission, Respondent describes the following as a ''catch-22'': ''Medical marijuana does not exist, according to DEA, unless it is an FDA-approved medicine, but Dr. Craker's license to supply marijuana for the research necessary to test such a medicine and secure FDA approval cannot be granted because medical marijuana does not exist.'' In fact, not only DEA, but also the United States Supreme Court, interpreting the text of the CSA, has stated—*unanimously*—that marijuana is not medicine. In *United States* v. *Oakland Cannabis Buyers' Cooperative,* 532 U.S. 483, 491 (2001), the Court stated: ''[F]or purposes of the [CSA], marijuana has 'no currently accepted medical use' at all.'' Moreover, Respondent, in denouncing the notion that marijuana must gain FDA-approval to be considered medicine, is objecting to what has been a cornerstone of the FDCA for 50 years—that a drug may not be marketed as medicine in this country unless the FDA has determined, based on submissions of scientific evidence established in clinical trials, that the drug is safe and effective for the treatment of a disease or condition. As for Respondent's contention that marijuana research cannot go forward unless he becomes registered to grow marijuana, as explained above in section A., this is flatly refuted by the fact that HHS and DEA authorized 17 of the last 17 marijuana research proposals submitted by CMCR—all of which were aimed at establishing a scientific foundation for the FDA approval of marijuana. Thus, Respondent's use of the term ''catch-22'' is empty rhetoric.

C. Respondent's Arguments Relating to the Involvement of Rick Doblin in Respondent's Proposed Activities

Respondent also seeks reconsideration of my determinations in the Final Order relating the involvement of Rick Doblin in Respondent's application and proposed activities. Again, in the exercise of my discretion, I have considered Respondent's post-hearing submissions as to this issue, even though they do not arise out of the taking of official notice of any fact.

To briefly recap, the Final Order listed the various ways in which Mr. Doblin was involved in Respondent's application process and how Mr. Doblin would have a role in Respondent's activities if the application were granted. 74 FR at 2126. The Final Order then stated:

In short, Mr. Doblin has mapped out and assisted in most acts, if not every act, that Respondent has taken toward applying for a registration to manufacture marijuana and, if the registration were granted, Mr. Doblin would continue to maintain responsibility for managing and monitoring the activities of the registrant. Given this level of involvement by Mr. Doblin—and the passive, if not subservient, nature of Respondent's involvement—it is appropriate under factor six to consider the following conduct by Mr. Doblin relating to controlled substances. First, Mr. Doblin admits that he smokes marijuana for ''recreational use'' on a weekly basis. Thus, Mr. Doblin violates federal and state laws relating to controlled substances on a weekly basis. This demonstrates that Mr. Doblin has disregard for the controlled substances laws. It is simply inconceivable that DEA would—consistent with its obligations under the CSA—grant a registration to engage in certain activities involving controlled substances where it is clear that a person who will have *any* role in the oversight and management of such activities routinely engages in the illegal use of controlled substances. It is still more untenable where that person has the level of oversight and management that Mr. Doblin would have—and where the controlled substance he illegally uses is the very controlled substance the applicant seeks to produce. Indeed, it is remarkable that Mr. Doblin would—given his admitted illegal involvement in controlled substances—ask DEA to effectively grant him permission to take on such a prominent role in the manufacture of the most widely abused illegal controlled substance in the United States.

Id. (emphasis in original; citations and footnotes omitted).

In his latest submission, Respondent points out that in the Final Order, under the fifth public interest factor (21 U.S.C. 823(a)(5)), I concluded that if the registration were granted, Respondent would have in the establishment (*i.e.,* in his growing facility) effective controls against diversion. 74 FR 2125–26. Respondent contends that this conclusion precludes me from concluding under the sixth public interest factor (21 U.S.C. 823(a)(6)) that Mr. Doblin's involvement in Respondent's activity weighs against granting his application.

It is plain when comparing the text of factor five with that of factor six that a favorable finding with respect to factor five does not preclude an unfavorable finding under factor six. As explained in the Final Order, under public interest factor five, ''the existence in the establishment of effective control against diversion'' includes, among other considerations, appropriate physical security and employee screening as required by the DEA

regulations as confirmed through a DEA on-site inspection of the premises. 74 FR at 2128 (citing 21 CFR 1310.71–1301.93). Factor six, in contrast, is a catchall category that is designed to give DEA wide latitude to consider all evidence that might reasonably bear on the suitability of an applicant for registration. In other words, even if a registrant has promised to undertake security procedures sufficient to obtain a favorable finding under factor five, if other evidence (not covered by factors one through five) casts doubt on whether the applicant can be entrusted with the responsibility of a DEA manufacturing registration, such evidence may be considered under factor six.

Consider, for example, if a person were seeking to become registered as a manufacturer of oxycodone, and the applicant promised to install and maintain in the facility all the physical security measures and employee screening procedures required by the regulations. Assume further that evidence came to light that the main investor in the facility, who planned to make the decisions as to how the facility would distribute oxycodone, admitted that he obtains oxycodone illegally and uses it for ''recreational'' purposes on a weekly basis. In such circumstances, it would certainly be appropriate for DEA to draw an adverse inference under factor six based on such person's illicit activity involving oxycodone—regardless of whether the applicant made assurances that it would comply with the security regulations. Thus, I cannot adopt Respondent's suggestion that Mr. Doblin's regular marijuana use should be ignored as a factor relevant to his application.

Nonetheless, it bears repeating that the ultimate decision in this matter did not turn on consideration of Mr. Doblin's marijuana activity. As stated in the Final Order, two other independent grounds existed for denying the application and, therefore, the same result would have been reached had I determined that Mr. Doblin's marijuana activity were irrelevant.

To be clear, if I determined that the proposed registration were consistent with United States obligations under the Single Convention and further that the supply of marijuana available to researchers in the United States were inadequate within the meaning of 21 U.S.C. 823(a)(1), it is conceivable that arrangements could have been made to mitigate the concerns regarding Mr. Doblin's marijuana activity. For example, under a conditional grant of registration or memorandum of agreement, sufficient terms perhaps could have been imposed to ensure that Mr. Doblin would not be allowed to have access to the growing facility and would have no role in any decision making relating to management of the facility or the distribution of marijuana. However, consideration of such an approach was not feasible here given the other grounds for denying the application.

IV. Conclusion

For the foregoing reasons, Respondent's motion for reconsideration is hereby denied. The administrative record is modified as indicated herein and in my December 2, 2010, order. The January 14, 2009, Final Order, as supplemented by this order, is effective on September 7, 2011.

Dated: August 8, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–21064 Filed 8–17–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Joe C. Fermo, M.D.; Revocation of Registration

On September 30, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Joe C. Fermo, M.D. (Registrant), of Tulsa, Oklahoma. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration, BF7430781, as well as the denial of any pending applications to renew or modify his registration, on the ground that his ''continued registration would be inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 823(f) and 824(a)(4)).

The Show Cause Order specifically alleged that on February 23, 1990, Registrant was convicted in the District Court for Oklahoma County, State of Oklahoma, of ten counts of submitting false claims to the Oklahoma Department of Human Services in violation of Oklahoma law, and that on June 20, 1990, the United States Department of Health and Human Services excluded him from participating in federal health care programs under 42 U.S.C. 1320a–7(a). *Id.* at 1–2. The Order further alleged that based on his convictions, on June 21, 1990, the Oklahoma State Board of Medical Licensure placed his medical license on probation and that Registrant materially falsified three separate applications (in 1991, 1994, and 1997) to renew his DEA registration by failing to disclose the state board's action. *Id.* at 2 (citing 21 U.S.C. 824(a)(1)).[1]

Finally, the Show Cause Order alleged that on August 27, September 24, and September 26, 2007, an undercover officer had obtained prescriptions from Registrant for alprazolam (at all three visits) and propoxyphene (at the first two visits), both of which are schedule IV controlled substances. *Id.* The Order further alleged that these prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice in violation of Federal and State laws. *Id.* (citing 21 CFR 1306.04 and Okla. Admin. Code 475.30–1–3(a)).

On or about October 5, 2009, the Show Cause Order, which also notified Registrant of his right to either request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for doing so, and the consequence if he failed to do so, was served on Registrant by certified mail addressed to him at the address of his registered location. *Id.* at 2–3 (citing 21 CFR 1301.43). Since service of the Show Cause Order, more than thirty days have now passed and neither Registrant, nor anyone purporting to represent him, has either requested a hearing or submitted a written statement in lieu of a hearing. *See* 21 CFR 1301.43(b)–(d). Accordingly, I find that Registrant has waived his rights to a hearing or to submit a written statement. *Id.* 1301.43(d). I therefore issue this Decision and Final Order without a hearing based on relevant evidence contained in the investigative record submitted by the Government.

Findings

Registrant is the holder of DEA Certificate of Registration, BF7430781, which authorizes him to dispense controlled substances in schedules II through V as a practitioner at the registered location of 5970 E. 31 St., Suite O, Tulsa, Oklahoma. While his registration was to expire on September 30, 2010, on August 13, 2010, Registrant filed a renewal application. In accordance with the Administrative Procedure Act and DEA regulations, I find that Registrant's registration remains in effect pending the issuance

[1] The Show Cause Order alleged that in March 2001, Registrant and DEA entered into a Memorandum of Agreement (MOA) which settled a Show Cause Proceeding filed in April 2000 based on the allegations described above. Show Cause Order at 2. The Show Cause Order also alleged that under the MOA, Registrant surrendered his registration and was allowed to reapply no earlier than March 2004, and that in October 2004, DEA issued him a new registration. *Id.*

of this Final Order. *See* 5 U.S.C. 558(c); 21 CFR 1301.36(i).

On August 27, 2007, an Agent with the Oklahoma Bureau of Narcotics went to Registrant's office to perform an undercover visit with Merli Fermo, M.D., Registrant's wife, who was also a DEA registrant.[2] Upon meeting the receptionist, to whom she paid $65, the Agent was told that she would have to wait one hour to see Merli Fermo and was asked if she wanted to see Registrant, who was available immediately. The Agent agreed and was taken to his office.

After the Agent and Registrant discussed the former's having spent some time in Minnesota and why she had returned to Oklahoma, who she lived with, how she was supporting herself, and her address, Registrant asked the Agent: ''So what do you want me to put you on?'' The Agent replied: ''I've been on Xanax. Two milligrams.'' Registrant then asked the Agent if she had ''been on it for a while?'' The Agent replied that she had been, that she had ''continued it when'' she had gone to Minnesota, and had gotten it ''from a doctor up there.''

Registrant then asked: ''You're taking Xanax three times a day?''; the Agent replied ''four times a day.'' Registrant responded: ''It says three times a day,'' to which the Agent said, ''I know but it was increased up there.'' Registrant then told the Agent to ''take it two times a day. Two milligrams.'' The Agent asked: ''So I'm only get[ing] it two times a day?'' Registrant replied affirmatively and asked, ''What else are you taking?'' The Agent answered: ''I was taking Darvocet too.''

Registrant then asked ''are you having some pain?'' The Agent replied: ''Oh, every once in a while.'' Registrant told the Agent to ''[t]ake it two times a day and I'll give you a hundred''; the Agent replied: ''Okay. I wish you'd give me the four on this Xanax though.'' After several comments which were unintelligible, Registrant and the Agent discussed how far the latter had lived from Minneapolis, whether the Agent went there much when she lived in Minnesota, and Registrant's having previously lived in the Minneapolis area. Before the visit ended, Registrant gave the Agent prescriptions for 100 Xanax (alprazolam) 2 mg and 100 Darvocet-N (propoxyphene) 100 mg, both of which are schedule IV controlled substances, *see* 21 CFR 1308.14(b), (c), as well as Celera, a non-controlled anti-depressant.

On September 24, 2007, the Agent returned to Registrant's office and paid the receptionist $65. While the Agent was scheduled to see Registrant's wife, when informed that the latter was not available, she agreed to see Registrant, and after a short wait, was taken to his office.

Registrant asked the Agent how she was doing; she replied ''great.'' Registrant then asked ''what's going on with you?'' The Agent answered: ''Not a thing. I wonder if I could get a hundred and twenty of the Xanax instead of a hundred?'' Registrant asked why she wanted one hundred twenty; the Agent answered: ''I ran out.''[3] Registrant then said: ''No, not if you take it down * * * the way it is prescribed for you, you wouldn't run out.'' After the Agent said ''I know,'' Registrant stated—in contrast to his instruction at the previous visit to take the Xanax twice a day—''Just take it three times a day, that's precisely why it's controlled because people have a tendency to (*Inaudible*) take it more than what's prescribed.'' Registrant then apparently warned the Agent that she could have seizures if she took more than what he prescribed ''and then if you don't take it for some reason or another'' and added ''it's not good to be doing that.''

After telling the Agent that she could take the Xanax ''three times a day,'' Registrant asked her: ''Do you still need the Darvocet?''; the Agent answered: ''Yes.'' After a conversation about such subjects as how much social security the Agent was getting, what type of work she had previously done, her shopping habits, and whether she had a boyfriend, Registrant told the Agent to take the Celexa because it is an anti-depressant that works with Xanax and would help her to get going in the morning. After still more conversation about the Agent's social life, Registrant gave her new prescriptions for 100 Xanax 2 mg, 100 Darvocet-N 100 mg, and Celexa. Shortly thereafter, the visit ended.[4]

[2] Merli Fermo has since passed away.

[3] Based on the dosing instruction he gave the Agent at the initial visit, the Xanax should have lasted 50 days; the Agent was thus seeking the drug approximately three weeks early.

[4] The Government also submitted a copy of the Information filed by the State of Oklahoma charging Registrant with ten counts of submitting false claims to the Oklahoma Department of Human Services; a ''Deferred Sentence, Plea of Guilty, Summary of Facts'' filed in the state court proceedings; a June 20, 1990, letter from the Office of Inspector General, U.S. Department of Health & Human Services, which excluded Registrant ''from participation in the Medicare program and any State health program'' for a period of fifteen years based on his state court convictions; and a Final Order of the Oklahoma State Board of Medical Licensure and Supervision (issued on June 21, 1990) which placed him on probation for four years and nine months based on his guilty plea in the state criminal proceeding.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that ''[a] registration pursuant to section 823 of this title to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In making the public interest determination in the case of a practitioner, Congress directed that the following factors be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * 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).

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie,* 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application. *Id.* Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); (citing *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005)).

The Government did not, however, submit either the MOA, which Registrant entered into with DEA, or any of the applications which it alleged he had materially falsified. Instead, it submitted the MOA that DEA entered into with his wife and an affidavit of an Agency Investigator stating that he had ''received information from'' an Investigator in another office that Registrant's MOA ''was identical'' to his wife's. Affidavit of Diversion Investigator, at 1.

Even accepting this would establish that Registrant settled the Show Cause Proceeding on the same terms as his wife did, his wife's MOA merely stated that an April 21, 2000 Order to Show Cause ''further alleged that on August 13, 1991, September 22, 1994, and again on August 28, 1997, the Respondent materially falsified her renewal applications by failing to disclose that the Board placed her medical license on probation in June 1990.'' MOA, at 2. Continuing, the MOA states: ''The above matters, if proven at an administrative hearing, constitute grounds for revocation of the Respondent's DEA Certificate of Registration, and denial of her pending application for renewal of that registration.'' *Id.* Nowhere in the MOA did Registrant's wife admit to the material falsification allegation. Thus, even if Registrant's MOA imposed the same terms, it is clear that the Government has not proved the allegation that he materially falsified his 1991, 1994, and 1997 applications.

In this matter, while I have considered all of the factors, I conclude that it is not necessary to make findings with respect to factors one (the recommendation of the state licensing board), three (registrant's conviction record) and five (such other conduct which may threaten public health and safety). I find that the Government's evidence with respect to Registrant's experience in dispensing controlled substances (factor two) and his compliance with applicable Federal and State laws related to the distribution and dispensing of controlled substances (factor four) makes out a *prima facie* case that Registrant has committed acts which render his registration ''inconsistent with the public interest.'' 21 U.S.C. 823(f), 824(a)(4). I will therefore order that his registration be revoked and that his pending application to renew his registration be denied.

Factors Two and Four—Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Under a longstanding DEA regulation, a prescription for a controlled substance is not ''effective'' unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). This regulation further provides that ''an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.'' *Id.; see also* 21 U.S.C. 802(10) (defining the term ''dispense'' as meaning ''to deliver a controlled substance to an ultimate user by, or pursuant to *the lawful order of, a practitioner,* including the prescribing and administering of a controlled substance'') (emphasis added); Okla. Admin. Code 475:30–1–3(a) (''A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by a registered or otherwise authorized individual practitioner acting in the usual course of his/her professional practice.'').

As the Supreme Court recently explained, ''the [CSA's] 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, 143 (1975)).

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,* 73 FR 43260, 43265 n.22 (2008); *see also Moore,* 423 U.S. at 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 generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. *See Kamir Garces-Mejias,* 72 FR 54931, 54935 (2007); *United Prescription Services, Inc.,* 72 FR 50397, 50407 (2007).[5]

Under the Oklahoma Board of Medical Licensure and Supervision's rule on the ''[u]se of controlled substances for the management of chronic pain,'' ''[a] medical history and physical examination must be obtained, evaluated and documented in the medical record.'' Okla. Admin. Code 435:10–7–11(1). Moreover, ''[t]he medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function and history of substance abuse.'' *Id.* The Oklahoma rule also requires, *inter alia,* that a ''physician should discuss the risk and benefits of the use of controlled substances with the patient.'' *Id.* at 435:10–7–11(3).

As found above, on two occasions, Registrant prescribed Darvocet-N 100 mg., a drug which includes propoxyphene, a schedule IV narcotic controlled substance, as well as Xanax (alprazolam) to an OBN Agent acting in an undercover capacity. Notably, during the first visit, Registrant did not ask the Agent whether she had any medical complaints. Rather, after engaging in small talk and asking for her address, Registrant asked the Agent: ''So what do you want me to put you on?'' While the Agent stated Xanax 2 mg, and told her she had been getting it from another doctor, Registrant did not even ask her if she had anxiety.

Moreover, Registrant then asked the Agent: ''what else are you taking?'' After the Agent replied that she ''was taking Darvocet too,'' Registrant asked: ''I think, are you having some pain?'' While the Agent replied: ''[e]very once in a while,'' Registrant did not ask the Agent any questions regarding ''the nature and intensity of the pain,'' the ''effect of the pain on [the Agent's] physical and psychological function,'' whether the Agent had been previously treated for pain, or whether she had a ''history of substance abuse'' as required under the Oklahoma rule. *See* Okla. Admin. Code 435:10–7–11(1). Moreover, while under the Oklahoma rule a physical examination must ''be obtained,'' the transcript of the undercover visit contains no indication that Registrant performed a physical examination and developed a diagnosis. *See id.* I thus conclude that at the Agent's first visit, Registrant failed to establish a doctor-patient relationship with her. I further conclude that he lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Xanax and Darvocet-N to her and thus violated Federal law. *See* 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1).

The Xanax and Darvocet prescriptions Respondent gave the Agent at her second visit also violated Federal law. While at this visit, Registrant, after being told by the Agent (who was seeking an even larger quantity of the drug and was three weeks early in seeking the refill) that she had run out of Xanax, did discuss with her that she should not take more of the drug than he prescribed and explained that the drug is controlled ''because people have a tendency to'' take more than is prescribed, once again, he did not determine that the Agent had anxiety or another medical condition that might warrant a prescription for the drug.

Likewise, after telling the Agent to only take the Xanax three times per day, he then asked her if she ''still need[ed]

[5] However, on October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law. 110–425, 122 Stat. 4820 (2008). Section 2 of the Act prohibits the dispensing of a prescription controlled substance ''by means of the Internet without a valid prescription,'' and defines, in relevant part, the ''[t]he term 'valid prescription' [to] mean[] a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least 1 in-person medical evaluation of the patient.'' 122 Stat. 4820 (codified at 21 U.S.C. 829(e)(1) & (2)). Section 2 further defines ''[t]he term 'in-person medical evaluation' [to] mean[] a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.'' *Id.* (codified at 21 U.S.C. 829(e)(2)(B)). These provisions do not, however, apply to Respondent's conduct.

the Darvocet?'' The Agent answered ''yes,'' but Registrant did not even ask her if she had pain, let alone ask her any questions regarding the nature and intensity of the pain, whether the Darvocet was helping to alleviate her pain, or how the pain was affecting her physical and psychological function. Accordingly, with respect to the Agent's second visit, I again conclude that Registrant failed to establish a doctor-patient relationship with her. I also conclude that Registrant lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Xanax and Darvocet-N to her and violated Federal law. *See* 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1).

As the forgoing demonstrates, Registrant has committed acts which ''render his registration * * * inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I will therefore order that his registration be revoked and that any pending applications be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as by 28 CFR 0.100(b), I hereby order that DEA Certificate of Registration, BF7430781, issued to Joe C. Fermo, M.D., be, and it hereby is, revoked. I further order that any pending application of Joe C. Fermo, M.D., to renew or modify his registration be, and it hereby is, denied. This Order is effective September 19, 2011.

Dated: August 5, 2011.

Michele M. Leonhart,

Administrator.

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BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Ideal Pharmacy Care, Inc., D/B/A Esplanade Pharmacy; Revocation of Registration

On November 12, 2010, I, the then Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Ideal Pharmacy Care, Inc., d/b/a Esplanade Pharmacy (Registrant), of New Orleans, Louisiana. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration FF1125651, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy, on the ground that it has committed acts which render its registration ''inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 824(a)(4)). The Show Cause Order also proposed the denial of any pending applications to renew or modify Registrant's registration. *Id.*

The Show Cause Order specifically alleged that on October 14, 2010, investigators conducted an accountability audit of Registrant and found that it had ''significant shortages'' of various controlled substances. *Id.* The Order alleged that these included shortages of: (1) 3,891 dosage units of hydrocodone 7.5/650 mg, 78 percent of the accountable total; (2) 27,179 dosage units of hydrocodone 7.5/750 mg, 59 percent of the accountable total; (3) 5,514 dosage units of hydrocodone 10/500 mg, 48 percent of the accountable total; (4) 114,826 dosage units of hydrocodone 10/650 mg, 96 percent of the accountable total; (5) 83,254 dosage units of alprazolam 2 mg, 96 percent of the accountable total; and (6) 1,616,420 ml of promethazine with codeine, 99 percent of the accountable total. *Id.* at 1–2. Based on the audit results, the Order alleged that the Registrant had violated 21 U.S.C. 827(a)(3) and 842(a)(5), as well as 21 CFR 1304.03, 1304.04, and 1304.21. *Id.* at 2.

Next, the Show Cause Order alleged that various distributors make deliveries of controlled substances to Registrant when it ''is closed,'' and that the ''deliveries are received and signed for by'' non-employees who work ''at the grocery store in which [it] is located,'' and that the deliveries are then ''diverted in violation of 21 U.S.C. 843(a)(3).'' *Id.* The Order thus alleged that Registrant ''has failed to provide effective controls'' against theft and diversion of controlled substances. *Id.* (citing 21 CFR 1301.71).

The Show Cause Order also alleged that Registrant had violated a Memorandum of Agreement (MOA) it entered into with DEA. *Id.* The Order alleged that in the MOA, Registrant agreed that it would not employ its former owners ''in any capacity relating to [its] business,'' and that it would not permit its former owners to have ''access to any area of [it] where controlled substances are kept, stored, or maintained.'' *Id.* The Order alleged that Registrant ''has permitted [its former owners] to enter the pharmacy where controlled substances are present in violation of'' the MOA and 21 CFR 1301.72(d). *Id.*

Based on the matters set forth above, I concluded that Registrant's continued registration during the pendency of the proceeding would constitute ''an imminent danger to public health and safety.'' *Id.* (citing 21 U.S.C. 824(d)). I, therefore, ordered the immediate suspension of Registrant's registration. *Id.*

On November 17, 2010, the Order to Show Cause and Immediate Suspension of Registration, which also notified Registrant of its right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for doing either, and the consequences for failing to do either, *id.* at 3 (citing 21 CFR 1301.43(a) & (c)), was personally served on Registrant's Pharmacist-in-Charge. GX 2. Since the date of service of the Order, more than thirty days have now passed, and neither Registrant, nor anyone purporting to represent it, has requested a hearing or submitted a written statement. Accordingly, I find that Registrant has waived its right to a hearing or to submit a written statement in lieu of a hearing. 21 CFR 1301.43(a), (c) & (d). I, therefore, issue this Decision and Final Order based on relevant material contained in the record submitted by the Government. 21 CFR 1301.43(e).

Findings

Registrant is the holder of DEA Certificate of Registration FI1125651, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered address of 1400 Esplanade Ave., New Orleans, Louisiana. Registrant's registration does not expire until November 30, 2011. Registrant is apparently located in a building which also contains a grocery store. Affidavit of DI, at 8 (GX 22).

On October 14, 2010, DEA Investigators conducted an audit of Registrant's handling of controlled substances. *Id.* at 9. The audit covered the period of October 22, 2008, on which date Registrant had no controlled substances on hand, through the beginning of business on October 14, 2010, at which time the closing inventory for the audit was taken. *Id.* According to the DI, she obtained invoices provided by Registrant's suppliers to determine the total amount of the controlled substances it had purchased during the audit period and was accountable for; the DI also obtained Registrant's records (including the prescriptions on file), as well as data from the state's prescription monitoring program showing the pharmacy's dispensings, and added the amount of its dispensings to the closing inventory to determine the total amount of each drug which it could account for. *Id.* Upon comparing the two amounts, the DI found that Registrant had large

shortages of six different drugs. These included:

1. A shortage of 3,891 dosage units of hydrocodone/apap 7.5/650 mg, which was 78 percent of the total amount for which it was accountable;
2. A shortage of 27,179 dosage units of hydrocodone/apap 7.5/750 mg, which was 59 percent of the total amount for which it was accountable;
3. A shortage of 5,514 dosage units of hydrocodone/apap 10/500 mg, which was 48 percent of the total amount for which it was accountable;
4. A shortage of 114,826 dosage units of hydrocodone/apap 10/650 mg. which was 96 percent of the total amount for which it was accountable;
5. A shortage of 83,254 dosage units of alprazolam 2 mg., which was also 96 percent of the total amount for which it was accountable; and
6. A shortage of 1,616,420 ml of promethazine with codeine, a shortage of 99 percent of the total amount for which it was accountable.

Id. at 9.

While pharmacy employees told the DI that they were the only persons who accepted controlled substance deliveries, based on the records obtained from one of Registrant's distributors, the DI determined that many of the shipments had been delivered on Saturdays, a day when the pharmacy was closed, and that a number of the shipments were signed for by non-pharmacy employees who worked in the grocery store. *Id.* at 7–8, 10. Moreover, while Registrant's employees had told the DI that McKesson was the only distributor it purchased controlled substances from, Registrant was also purchasing from ANDA and Smith Drug Company. *Id.* at 7–8.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to ''dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In making the public interest determination, the CSA requires that the following factors be considered:

(1) The recommendation of the appropriate state licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * 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 FR 15227, 15230 (2003). I may rely on any one or a combination of factors, and I may give each factor the weight I deem appropriate in determining whether to revoke an existing registration. *Id.* Moreover, I am ''not required to make findings as to all 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 proof. 21 CFR 1316.56.

Having considered all of the factors, I conclude that the evidence pertinent to Registrant's compliance with applicable laws related to controlled substances (factor four) is dispositive and supports a finding that it has committed acts which render its registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

As found above, DIs conducted an audit of Registrant's handling of various controlled substances and found that it could not account for extraordinary quantities of four different formulations of hydrocodone, a schedule III controlled substance, and alprazolam 2 mg (generic for Xanax), a schedule IV controlled substance; both of these drugs are highly popular with drug abusers. *See* 21 CFR 1308.13(e); 13018.14(c). More specifically, approximately 150,000 dosage units of various hydrocodone drugs and 83,000 dosage units of alprazolam (96% of the amount purchased) were purchased by Registrant and could not be accounted for. In addition, 1.6 million mls of promethazine with codeine (99% of the amount purchased), another highly-abused controlled substance, was purchased by Registrant and could not be accounted for.

Pursuant to DEA regulations, all ''registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.'' 21 CFR 1301.71(a). Among the factors DEA considers in assessing whether a registrant maintains effective controls against theft and diversion, is ''[t]he adequacy of the registrant's * * * system for monitoring the receipt * * * distribution, and disposition of controlled substances in its operations.'' *Id.* 1301.71(b)(14).

Moreover, under Federal law and DEA regulations, ''every registrant under this subchapter * * * distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance * * * received, sold, delivered, or otherwise disposed of by [it].'' 21 U.S.C. 827(a)(3). *See also* 21 CFR 1304.03; 1304.04, 1304.21, 1304.22(c). A registrant is required to maintain these records for at least two years. *Id.* § 827(b) (''every inventory or other record required under this section * * * shall be kept and be available, for at least two years, for inspection and copying''). *See also* 21 CFR 1304.03 (''Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section.''); *id.* § 1304.04 (mandating that records be maintained for at least two years and be available for inspection and copying). *See also Paul H. Volkman,* 73 FR 30630, 30644 (2008) (''Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.'').

Whether the shortages are attributable to outright diversion by either pharmacy or store employees, theft, or the failure to maintain accurate records, does not matter. What is clear is that Registrant purchased several hundred thousand dosage units of highly abused controlled substances which cannot be accounted for and that it has committed acts which render its registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Accordingly, I will order that Registrant's registration be revoked and that any pending application be denied.[1]

[1] On November 17, 2010, the Louisiana Board of Pharmacy issued an Active Suspension Notice to Registrant, which placed its Louisiana Pharmacy Permit in active suspension pending further proceedings. Thus, Registrant also no longer meets the CSA's requirement for holding a registration that it be ''authorized to dispense * * * controlled substances under the laws of the State in which [it] practices.'' 21 U.S.C. 823(f); *see also id.* § 824(a)(3) (authorizing revocation where registrant's ''[s]tate license or registration [has been] suspended * * * by competent State authority and [registrant] is no longer authorized by State law to engage in the * * * dispensing of controlled substances''); *id.* § 802(21) (defining ''[t]he term 'practitioner' [to] mean[] a * * * pharmacy * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which [it] practices * * * to dispense * * * a controlled substance in the course of professional practice'').

Registrant's loss of state authority thus provides an additional ground to revoke its registration. *See Bourne Pharmacy, Inc.,* 72 FR 18273, 18274 (2007). However, the State's suspension was not cited as a basis for Agency action in the Order to Show Cause (as it occurred five days after the latter was issued) and there are no pleadings establishing that the Agency subsequently gave notice of its intent to rely

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FI1125651, issued to Ideal Pharmacy Care, Inc., d/b/a/Esplanade Pharmacy, be, and it hereby is, revoked.

I further order that any pending application to renew or modify this registration, be, and it hereby is, denied.

Dated: August 5, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–21060 Filed 8–17–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–2]

Surinder Dang, M.D.; Revocation of Registration

On August 31, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Surinder Singh Dang, M.D. (''Respondent''), of Fountain Valley, California. The Order proposed the revocation of Respondent's DEA Certificate of Registration, AD6122143, as a practitioner, as well as the denial of any pending applications to renew or modify his registration ''for reason that [Respondent's] continued registration[] would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f) and 824(a)(4).'' ALJ Ex.1, at 1.

The Order specifically alleged that between January 2004 and July 2007, Respondent and his wife, Dr. Satinder Dang, ''who also possesses a DEA registration and shares [Respondent's] registered location,'' ordered ''more than 5,000,000 dosage units of hydrocodone'' and that Respondent ''failed to properly account for, secure, and otherwise handle these controlled substances.'' *Id.* The Order alleged that on January 17, 2006, one of Respondent's ''employees removed 30,000 dosage units of controlled substances'' from his registered location and ''attempted to take them to her residence.'' *Id.* The Order further alleged that on the same day, ''DEA Special Agents seized another 10,000 dosage units of controlled substances from this employee's residence.'' *Id.* at 1–2. Continuing, the Order alleged that on March 16, 2006, ''DEA Special Agents seized 50,000 dosage units more from this employee's residence.'' *Id.* at 2.

Next, the Order alleged that on March 16, 2006, DEA conducted an accountability audit of Respondent's handling of hydrocodone and that Respondent ''could not account for more than 3,500,000 dosage units'' that Respondent and his wife ''had ordered,'' and that Respondent ''failed to keep accurate and complete records of each controlled substance received, sold, delivered, or otherwise disposed of as required by 21 U.S.C. 827(c) and 21 CFR 1304.01 *et seq.*'' *Id.* Finally, the Order alleged that when Respondent ''made dispensing records,'' he ''frequently failed to indicate whether'' he or his wife ''actually dispensed the controlled substances as required by 21 CFR 1304.03(b).'' [1] *Id.*

By letter of October 2, 2009, Respondent, through his counsel, requested a hearing on the allegations. ALJ Ex. 2. The matter was then assigned to an Administrative Law Judge (ALJ), who conducted a hearing on March 3, 2010, in Santa Ana, California.

At the hearing, the Government called one witness to testify and introduced documentary evidence. Respondent did not call any witnesses and introduced a single exhibit, this being a letter from the counsel for Respondent's employee R.K. stating that she intended to assert her Fifth Amendment privilege if called to testify. *See* RX 1. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law and argument.

On May 19, 2010, the ALJ issued her Recommended Decision (also ALJ). Therein, the ALJ considered the five public interest factors, *see* 21 U.S.C. 823(f), and concluded that Respondent's continued registration would be inconsistent with the public interest and recommended that his registration be revoked. ALJ at 26, 30–31.

As to the first factor—the recommendation of the appropriate State licensing board or professional disciplinary authority—the ALJ found that the California Medical Board ''has not taken any formal action to limit Respondent's right to practice medicine nor has it recommended limiting his ability to prescribe controlled substances.'' *Id.* at 23. However, the ALJ recognized that under Agency precedent ''the fact that the Medical Board of California has currently authorized * * * Respondent to practice medicine is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest.'' ALJ at 22–23 (citing *Patrick W. Stodola,* 74 FR 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 FR 459, 461 (2009)). The ALJ thus concluded that ''this factor does not fall in favor of revocation.'' *Id.* at 23. Likewise, with respect to factor three—Respondent's record of convictions for offenses relating to the manufacture, distribution, or dispensing of controlled substances—the ALJ found that Respondent has not been convicted of such an offense and that this factor also did not ''fall in favor of revocation.'' *Id.*

The ALJ then considered factors two and four—Respondent's experience in dispensing controlled substances and his compliance with Federal, State, and local laws relating to controlled substances—together. *Id.* at 23–26. The ALJ specifically found that: (1) ''Respondent authorized'' his employee R.K. ''to purchase large amounts of hydrocodone using his DEA registration and that of his wife''; (2) another physician who practiced at Respondent's clinic had ''stated that the patient load'' at the clinic ''would not justify such large purchases of controlled substances''; (3) R.K. remained in Respondent's employ even after ''drugs were discovered in [her] personal vehicle by the California Highway Patrol''; (4) ''[l]arge bundles of cash, controlled substances, and other * * * evidence, such as receipts and money order stubs were discovered at [her] home''; and (5) ''[a]fter being questioned, [R.K.] stated that she was ordering and transporting controlled substances all at the direction of the Respondent.'' *Id.* at 24. Based on these findings, the ALJ concluded that ''either [Respondent] is personally involved in hydrocodone diversion or he is facilitating such diversion on the part of his employee.'' *Id.*

The ALJ further found that Respondent ''prescribed Vicodin,'' a schedule III controlled substance, to patient B.R. ''on many occasions without a thorough examination.'' *Id.* Based on Cal. Bus. & Prof. Code § 2242(a), which provides that it is ''unprofessional conduct'' to ''[p]rescrib[e], dispens[e] or furnish[ ] dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication,'' the ALJ concluded that Respondent prescribed Vicodin to B.R. without an ''appropriate prior examination.'' *Id.* at 25. The ALJ thus concluded that Respondent ''prescribed controlled substances without establishing a bona-fide patient relationship'' and violated both Federal and state law. *Id.* at 24–25.

Next, the ALJ found that Respondent did not have any inventories for the controlled substances his clinic dispensed, that he ''failed to maintain accurate records of the controlled

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on the State's suspension. *See* 5 U.S.C. 554(b). I therefore do not rely on it.

substances he dispensed,'' and that an audit could not account for ''almost four million dosage units of hydrocodone.'' *Id.* at 26. The ALJ thus concluded that Respondent ''violated federal regulations by not conducting a biennial inventory and maintaining the appropriate records of his controlled substances.'' *Id.* The ALJ further held that the Government's evidence under factors two and four ''established prima facie grounds for revocation of * * * Respondent's DEA Certificate of Registration.'' *Id.*

Turning to factor five—other conduct which may threaten the public health and safety—the ALJ found ''it likely that * * * Respondent is engaged in the illegal diversion of hydrocodone.'' *Id.* As support for her conclusion, the ALJ noted her findings that Respondent ''was involved in the ordering of the hydrocodone,'' that ''[h]is colleagues stated that his practice did not justify such exorbitant purchases,'' his inability ''to account for the whereabouts of the controlled substances,'' and the ''circumstances,'' which she did not further specify, ''surrounding [the DEA Group Supervisor's] investigations.'' *Id.* According to the ALJ, these facts ''suggest[ed] that * * * Respondent is at least recklessly, if not intentionally, contributing to this illegal diversion.'' *Id.*

The ALJ further explained that ''[e]ven if Respondent did not commit the above violations of Federal law and DEA regulations,'' she would still find that he had ''committed acts which constitute 'conduct which may threaten the public health and safety' and which render his registration 'inconsistent with the public interest.'" *Id.* (quoting 21 U.S.C. 823(f)(5) & 824(a)(4)). Noting that ''[u]nder DEA precedent, a registrant who entrusts his registration to another person is strictly liable for the latter's misuse of his registration,'' the ALJ reasoned that ''even if there had been no conspiracy between Respondent and [R.K.] to unlawfully distribute the drugs, he would still be liable for the acts she committed while being allowed to use his registration.'' ALJ at 26–27 (citations omitted). The ALJ concluded that ''Respondent is thus liable for [R.K.'s] acts of unlawful possession and distribution of the controlled substances that she obtained under his registration.'' [2] *Id.* (citations omitted).

The ALJ then addressed whether Respondent had rebutted the Government's *prima facie* case. ALJ at 29–30. The ALJ found that ''Respondent has not admitted any fault whatsoever,'' but rather ''has merely pointed an accusing finger at his employee.'' *Id.* at 30. Noting that Respondent did not testify in the proceeding, the ALJ concluded that ''[t]he fact that the Respondent has chosen not to hold himself accountable for his own indiscretions weighs heavily against his continued registration.'' *Id.* While the ALJ further considered facts she deemed favorable to Respondent, she nonetheless concluded that ''none of these factors outweigh the overwhelming security violations and evidence of diversion,'' which she deemed to be ''egregious.'' *Id.* at 31. The ALJ therefore recommended that I revoke Respondent's registration. *Id.*

Neither party filed exceptions to the ALJ's decision. Thereafter, the record was forwarded to me for Final Agency Action. Having considered the entire record, I adopt the ALJ's findings of fact and conclusions of law except as expressly noted herein. I further adopt the ALJ's ultimate conclusion that Respondent's ''continued registration is not in the public interest,'' *id.* at 30, and her recommendation that his registration be revoked. As ultimate factfinder, I make the following findings:

Findings

Respondent is the holder of DEA Certificate of Registration, AD6122143, which authorizes him to dispense controlled substances in schedules II through V, as a practitioner, at the registered location of 17150 Euclid #200, Fountain Valley, California. GX 1. While Respondent's registration was to expire on June 30, 2009, *Id.,* on May 13, 2009, Respondent filed an application to renew his registration. GX 2. Accordingly, his registration remains in effect pending the issuance of this Decision and Final Order. 5 U.S.C. 558(c); *see also* ALJ Ex. 3, at 2 (Prehearing Order; Stipulations).

Respondent currently holds a license to practice medicine in California and the California Medical Board has not taken any formal action to limit his ability to practice medicine or to prescribe controlled substances. ALJ Ex. 3, at 3. Also, Respondent has not been convicted of an offense related to the manufacture, distribution, or dispensing of controlled substances. *Id.*

Respondent is married to Satinder Dang, M.D.[3] She and Respondent practice medicine at Complete Medical Care, Inc. (''CMC''). Tr. 41; GX 6, at 20. Their son, Sameer Dang, also works in the CMC office. Tr. 51. At all relevant times (including through the date of the hearing) CMC's office manager was Ms. Rani K.[4] (R.K.). *Id.* at 26, 164.

In November 2005, a Diversion Group Supervisor (GS) in DEA's Riverside Diversion Group reviewed ARCOS [5] records and found that Respondent was the largest purchaser of controlled substances from Anda Pharmaceuticals, Inc. (''Anda''). Tr. 21. The GS also determined that Respondent was buying controlled substances ''from other companies too.'' *Id.*

Of particular concern to the GS were Respondent's purchases of hydrocodone, a schedule III controlled substance. Tr. 22; 21 CFR 1308.13(e)(iv). According to ARCOS records, while in 2004, Respondent purchased 190,600 tablets of hydrocodone from all suppliers, in 2005, he purchased 1,353,600 such tablets. Tr. 24; GX 4, at 2–6. ARCOS data further showed that in 2005, Respondent and his wife had ordered a combined total of 3,626,400 tablets of hydrocodone. GX 3, at 13; GX 4, at 6; *see also* Tr. 121, 124 (GS's testimony that between January 1, 2005 and March 16, 2006, Respondent and his wife purchased approximately four million tablets of hydrocodone).

Upon reviewing the ARCOS data, the GS contacted several of the firms that were distributing controlled substances to Respondent. *See, e.g.,* GX 6, at 7. At several points throughout the investigation, these firms provided copies of various documents to the GS including sales records, invoices, statements of account, delivery records, applications for credit, and correspondence.[6] *See generally* GX 5 (records from Moore Medical, L.L.C.), GX 6 (record from Henry Schein, Inc.), GX 9 (records from ParMed Pharmaceuticals, Inc.).

Throughout the investigation, several of the firms also provided the GS with information regarding when various deliveries were to be made to Respondent's clinic. On December 14, 2005, the GS, who had received information from two different distributors (Henderson and Moore Medical) that controlled substances

[2] The ALJ also rejected Respondent's argument that R.K. had stolen the drugs, noting that as of the hearing, she was still an employee. *Id.* at 27 (citations omitted).

[3] Dr. Satinder Dang holds DEA Certificate of Registration, AD9234446; she is registered at the same address as Respondent. ALJ Ex. 3, at 2

[4] R.K.'s first name is spelled as both Rani and Roni in various documents.

[5] Pursuant to 21 CFR 1304.33(c), manufacturers and distributors of various controlled substances including schedule III narcotics are required to report their distributions of controlled substances to DEA through the Automated Records and Consolidated Orders System (ARCOS). *See also* Tr. 21–22.

[6] Some of the documents may have been obtained pursuant to a search warrant.

deliveries were to be made that day, conducted ''surveillance at the [Dangs's] clinic'' from 9 a.m. to 6 p.m. Tr. 39–42. During the surveillance, the GS observed both deliveries and noted that ''no more than ten or fifteen'' people entered the clinic that day. *Id.* at 41–42.

On January 13, 2006, from ''[m]orning till late afternoon,'' the GS conducted a second surveillance. *Id* at 42. During the surveillance, the GS saw Ms. R.K. ''taking boxes out of the clinic and plac[ing] them in her vehicle,'' which was ''a green SUV.'' *Id.* at 42–43.

On January 17, 2006, from 9 a.m. to 6 p.m., the GS, who had received notice of a controlled substance delivery from another distributor (ParMed Pharmaceuticals, Inc.), conducted another surveillance. *Id.* at 43. Once again, Investigators observed R.K. ''tak[e] boxes from the clinic'' and place them in ''her vehicle.'' *Id.* at 44. The GS observed R.K. drive away and notified the California Highway Patrol (CHP). *Id.* at 44–45. After observing R.K., who was driving forty miles per hour, operate her vehicle within five feet of the vehicle in front of her, a CHP officer conducted a traffic stop. *Id.* at 45; GX 10 at 2.

As he approached R.K., the CHP officer observed ''cardboard boxes that were taped shut in the rear cargo area.'' GX 10, at 2. The CHP officer advised R.K. of the reason for the stop and requested her license, registration, and insurance. *Id.* He then asked R.K. ''what the boxes were.'' *Id.* R.K. stated that the boxes held Vicodin, a schedule III controlled substance which contains hydrocodone. *Id.;* ALJ Ex. 3, at 1. When the CHP officer asked R.K. if she was a doctor, she stated that ''she was the president of a medical facility and that she was going to give the Vicodin to the doctor at her facility.'' GX 10, at 2. The CHP Officer asked her a second time if she was a doctor; R.K. again said ''no'' and became ''extremely nervous.'' *Id.*

After the CHP Officer asked R.K. to step out of her car, he asked ''why she had cases of Vicodin.'' *Id.* She responded that she ran a medical office and handed him a business card listing her name as R.K. and her position as ''president.'' *Id.* R.K. further stated that ''she received a delivery of Vicodin from a delivery company at about 1100 hours and that she needed to give it to'' Respondent. *Id.* When the Officer asked R.K. if the Vicodin had been delivered ''to her car or to her office,'' R.K. stated that it had been delivered to the office. *Id.* When the Officer asked if her office had a locker in which to store the Vicodin, R.K. answered ''yes,'' but added that she had to personally give the drugs to Respondent. *Id.*

The CHP Officer then asked how the Vicodin had ended up in her vehicle, R.K. stated that ''she [had] carried the boxes to her vehicle around noon time and left them there,'' and that she had stayed in her office until about 5 p.m., at which point ''she left * * * to get something to eat.'' *Id.* When the Officer told R.K. that he was ''concerned that she was in possession of so much of a controlled substance,'' R.K. said she would return it to the office. *Id.* R.K. then stated that Respondent was ''doing a procedure at an unknown hospital and he would be returning at an unknown time to the office'' and that she would then give him the Vicodin. *Id.*

The CHP Officer then ''asked R.K. to open the boxes'' to confirm that they contained Vicodin. *Id.* R.K. opened six boxes containing a total of 70 bottles of hydrocodone bitartrate/acetaminophen (hereinafter, hydrocodone/apap or hydrocodone). *Id.* at 2–3. Each of the bottles contained between 100 and 500 tablets (for a total of ''approximately 31,000 tablets'') in 7.5/500 mg, 10/500 mg, and 10/325 mg strengths. *Id.* The Officer then seized the Vicodin and gave R.K. a receipt for it. *Id.* After giving R.K. a citation, the officer allowed her to leave. *Id.* at 3.

The CHP Officer then contacted a DEA Task Force Officer (TFO) and arranged to transfer custody of the drugs to DEA; upon the TFO's arrival at the Officer's location, the TFO took possession of the drugs. *Id.* The TFO gave the CHP Officer a receipt which confirms the figures in the latter's report.[7] *Id.* at 6.

R.K. then drove to her residence in Anaheim Hills; Investigators followed her there in order to question her about the drugs that were found in her vehicle. Tr. 47. R.K. told the Investigators that she had taken the hydrocodone with her for safekeeping because Respondent was out of the office; she also maintained that she intended to return them to the office after she ate. *Id.* at 47–48. While R.K. initially claimed that this was the first time she had done this, upon being confronted with the fact that Investigators had on another occasion observed her placing boxes in her vehicle, she admitted that this was the second time she had done so. *Id.* at 48.

R.K. stated that there were about five physicians who worked at Respondent's clinic, that they dispensed the pills in 30 and 60-count bottles, and that the clinic had approximately twenty to twenty-five patients per day. *Id.* R.K. further said that she used her personal credit card to purchase drugs from wholesalers and that Respondent would reimburse her with cash. *Id.* at 49. R.K. would then obtain money orders to pay off her credit card bills. *Id.*

The Investigators then asked R.K. if she would consent to a search of her residence; she agreed. *Id.* at 49–50. According to the GS, the Investigators found approximately $69,500 in cash in an upstairs closet, which was ''wrapped up in paper''; a ''small quantity of drugs,'' which included 2000 lorazepam tablets and 1400 hydrocodone tablets; ''a lot of money order stubs''; ''some bank records''; and ''[s]ome credit card information.'' *Id.* at 50, 113, 117. The GS testified that these records confirmed that R.K. paid her credit card bills with money orders. *Id.* at 50. However, on cross-examination, the GS acknowledged that he had no documentary evidence to substantiate R.K.'s assertion that Respondent reimbursed her in cash. *Id.* at 146. To explain the cash, R.K. claimed the sum was a combination of money she received from the sale of a house in India, a home-based business she had previously run, and a gift from relatives. *Id.* at 51, 142.

On cross-examination, the GS acknowledged that the amount of drugs found at R.K.'s residence could indicate she was stealing drugs from Respondent's clinic. *Id.* at 116. The GS further testified that at the time of the search, the street value of hydrocodone tablets was between three and five dollars per pill. *Id.* at 132.

On February 7, 2006, the GS obtained notice of another delivery of controlled substances and conducted another surveillance. *Id.* at 51–52. While on this date, UPS made a delivery, nothing was moved out of CMC. *Id.* at 52.

On February 24, 2006, Respondent wrote a letter to CHP requesting the return of the hydrocodone which had been seized during the traffic stop of R.K. Tr. 52–53; GX 12. The letter stated that R.K. was Respondent's ''office manager,'' and that she had ''informed CHP that the property was not hers, and instead belonged to her employer, Complete Medical Care Inc.'' GX 12.

On March 16, 2006, DEA executed search warrants at both Respondent's clinic and R.K.'s residence. Tr. 61, 67–68, 70. At the clinic, the Investigators took an inventory of the controlled substances on hand and found 48,000 tablets of hydrocodone, which they seized; the Investigators also seized CMC's controlled substance purchasing records and dispensing log. *Id.* at 94.

[7] More specifically, there were 14 bottles of 500 count of hydrocodone/apap 7.5/500 mg, 10 bottles of 500 count hydrocodone/apap 10/500 mg, 36 bottles of 500 count hydrocodone/apap10/325 mg, and 10 bottles of 100 count hydrocodone/apap 10/500 mg. GX 10, at 6.

During the search of the clinic, Respondent declined to be interviewed.[8] Tr. 68.

The Investigators did, however, interview four of Respondent's employees and a patient who was present. A.N. had been a medical assistant at CMC since 1992; her duties involved taking patients to the examination room. *Id.* at 86–87. A.N. told the Investigators that R.K. inventoried the drugs when they arrived at CMC and also maintained the dispensing log. *Id.* at 89–91. She also stated that the dispensings to patients were noted in the patient records and identified the handwriting in the dispensing log as R.K's. *Id.* at 89, 91–92.

K.G. had been a medical assistant at CMC for seven months; her duties included taking patients' blood pressure, drawing blood, and performing other tests. *Id.* at 92–93. K.G. stated that both R.K and Respondent ordered the drugs for CMC. *Id.* at 94. K.G. further stated that R.K. usually accepted deliveries of drug orders; however, sometimes K.G. would accept delivery of drug orders and she ''would leave them unopened for R.K. to handle.'' *Id.* at 93. K.G. commented that she saw only R.K. write in the dispensing log. *Id.* at 95.

L.Y. had been hired as medical assistant in November 2005; her responsibilities included the scheduling of appointments and flu shots. *Id.* at 95–96. According to L.Y., the clinic saw twenty to twenty-five patients per day. *Id.* at 97. L.Y. also stated that both Respondent and R.K. handled the drugs once they had arrived. *Id.* at 96. When shown the dispensing log, L.Y. identified handwriting belonging to both Respondent and R.K.; she also stated that Respondent's wife primarily prescribed drugs, while Respondent typically dispensed them. *Id.* at 97.

S.B. had worked at CMC for three years and did patient billing. *Id.* at 98. S.B. stated that R.K. would order the drugs and that Sameer Dang (Respondent's son) would check the deliveries. *Id.* at 98–99. She also stated that R.K. handled the dispensing log. *Id.* at 100.

S.B. further stated that CMC had approximately twenty-five patients per day, of which fifteen saw Respondent and ten saw his wife. *Id.* According to S.B., both Sameer Dang and R.K. paid for the drugs.[9] *Id.* She also said that both Respondent and R.K. had access to the controlled substances received at the CMC office. *Id.* at 103.

As found above, on March 16, 2006, DEA Investigators also executed a search warrant at R.K.'s residence. *Id.* at 70. R.K. was present during the search and was interviewed during which she provided ''the same information'' as she had two months earlier. *Id.* at 71. R.K. stated that since January 17, 2006, she had stopped using her personal credit card to order the drugs and only dispensed drugs in the presence of a physician. *Id.* at 72. R.K. also stated that all of the clinic's drug orders were approved by Respondent. *Id.* Finally, R.K. stated that Respondent was the clinic's ''primary dispenser'' of the drugs. *Id.*

In April 2006, the GS interviewed Dr. B., one of the physicians listed as being part of Respondent's clinic. *Id.* at 76. Dr. B. stated that he had worked at CMC for about five years on a part-time basis. *Id.* Dr. B., who also worked at a psychiatric facility for the local county government, saw some of these patients at Respondent's clinic. *Id.* at 77–78.

Dr. B. stated that he rarely prescribed controlled substances to his patients, and that when he did, he did not dispense drugs. *Id.* at 78. He also stated that the patient load at CMC did not justify the quantities of controlled substances that were being purchased by the clinic. *Id.* at 79.

In May 2006, a Diversion Investigator (DI) interviewed one of Respondent's patients, A.A., who said that she saw him for knee pain and ''asthmatic issues.'' Tr. 81. A.A. had worked for twelve years as a patient care representative in ''a couple hospitals''; at one, she was the Quality Care Coordinator with ''duties related to medical, financial counseling and medical billing.'' *Id.* at 81–82.

A.A. stated that on several occasions during her visits to Respondent's clinic, she observed R.K. take persons ''into a back room'' and that ''several minutes later,'' these persons ''would come out with bags in their hands.'' *Id.* at 83. A.A. stated that she did not believe these persons had seen Respondent. *Id.* A.A. further stated (and wrote a letter to DEA to the same effect) that she had told Respondent that R.K. ''was * * * dispensing drugs in some form or fashion, or selling medications without'' the patients ''seeing the doctor.'' *Id.*

The Government also submitted into evidence a portion of a Report of Investigation relating an interview of another of Respondent's patients, B.R. Tr. 167; *see also* GX 17. According to the Report, B.R. told Investigators that she had been Respondent's patient since 2001 and had been treated for leg pain. GX 17, at 1. B.R. stated that Respondent ''did not examine her thoroughly and did not request any tests,'' yet he dispensed Vicodin to her. *Id.* B.R. further stated that she had started seeing another physician who examined her thoroughly and ordered an MRI and X-ray. *Id.* B.R.'s new doctor concluded that her back was the cause of her leg pain and that she was over-medicated; he referred her to a pain clinic. *Id.*

B.R. further said that she was buying bottles of 100 tablets of Vicodin 7.5 mg every two weeks for $20 per bottle and that Respondent had instructed her to take the Vicodin as needed with no further instructions. *Id.* Both R.K. and Respondent had given Vicodin to her, and on occasion she would simply telephone R.K. for a refill and receive it from her without seeing Respondent. *Id.* at 2.

However, the report of B.R.'s interview contains no evidence suggesting that she was not a legitimate patient. Moreover, the Government did not introduce B.R.'s patient record into evidence and offered no evidence (beyond the conclusory assertion that his exam was not thorough) regarding the scope of the physical examination Respondent performed on her. Nor did it offer any evidence from an Expert (whether through testimony or a report) establishing that Respondent failed to perform a medically appropriate prior examination and lacked a medical indication when he prescribed Vicodin to B.R.

Using the records seized during the search of Respondent's clinic and its patient files (which were subsequently obtained with Respondent's consent), ARCOS data, and information provided by several of the distributors,[10] the GS conducted an audit of the hydrocodone ordered under both Respondent's and his wife's registrations between January 1, 2005 and March 16, 2006. Tr. 59–60, 67; GX 15. Because the Dangs did not maintain records of their inventory (notwithstanding Federal law requiring them to do so, *see* 21 U.S.C. 827(a) & (b)), the GS chose January 1, 2005 as the starting date and assumed that no

[8] Later that day, Investigators went to Respondent's residence and sought consent to search his house. Tr. 69. Respondent and his wife declined to provide consent. *Id.*

[9] S.B. also told Investigators that Respondent had changed the clinic's procedures and now required R.K. to get his approval before she dispensed any drugs. Tr. 101–02.

[10] Moore Medical provided DEA with records of its hydrocodone sales under Respondent's registration from late 2005 to early 2006. Tr. 25; GX 5. ANDA provided DEA with a spreadsheet listing all sales under the registrations of Respondent and his wife from May 2000 through mid-October 2005. Tr. 30; GX 8. DEA also acquired sales records and a sales summary from ParMed which show Respondent's purchases of controlled substances between November 28, 2005 and January 4, 2006. GX 9.

controlled substances were then on hand; for the closing inventory, the GS used the inventory taken (48,000 tablets) when the search warrant was issued.[11] Tr. 59–60; GX 15. To this latter figure, the DI added the hydrocodone that was seized during the January 17, 2006 traffic stop of R.K. (31,000 tablets) and the 1,400 tablets found during the search of R.K.'s residence which occurred later that day.[12]

Using both the ARCOS data and distributor invoices, the GS determined that 4,037,900 tablets of hydrocodone had been ordered during the audit period.[13] Tr. 61; GX 15. The clinic's dispensing logs, which did not identify which doctor had authorized the various dispensings, *see* GX 14, showed that only 12,000 tablets had been dispensed;[14] in addition, the GS reviewed the clinic's patient files and determined that another 75,000 tablets had been dispensed.[15] Tr. 61–63, 119, 129; GXs 12, 15. Accordingly, the Dangs could only account for approximately 167,000 tablets of hydrocodone.[16] Tr. 64–65, 119; GX 15. Thus, Respondent (and his wife) could not account for approximately 3,870,500 tablets.[17] Tr. 66, 119; GX 15.

Among the documents the Government entered into evidence is a November 7, 2005 letter from Respondent to J.N., a compliance coordinator at Henry Schein. GX 6, at 20. Therein, Respondent wrote that he was the Medical Director of ''a multiple specialty medical group,'' comprised of five physicians including himself, his wife, the aforementioned Dr. B., as well as Drs. H.L. and D.S. *Id.* Respondent further wrote that the clinic had ''introduced a program of dispensing some medications to our patients'' for their ''convenience * * * and to help them save some money.'' *Id.* Respondent also wrote that his clinic ''provide[s] physical therapy and pain management to our patients,'' that it ''dispense[d] medications to our patients only,'' and that the ''practice has been growing.'' *Id.*

The Government also entered into evidence a credit application submitted on behalf of CMC to ParMed. GX 9, at 4. The application, which is dated November 21, 2005, lists Respondent as the person making the application; his name is printed in the signature block (which is signed), and the application also contains the name of a ParMed Sales Representative.[18] *See id.*

The Government further entered into evidence reports prepared by ParMed on January 5, 2006, which list ParMed's controlled substance distributions to Respondent and his wife. *See id.* at 1–2. The report for Respondent's wife bears a handwritten note, which according to the GS, was written by D.L., an employee of ParMed's regulatory affairs section. Tr. 34–35. The note read: ''pain management—group of Dr's—about 30 Dr's in this medical group & she purchases for all Dr's (as per sales rep).'' GX 9, at 2. The note then listed the names and registration numbers of Respondent and his wife and stated: ''Both new accounts from 11–05.''[19] *Id.*

Respondent did not testify in the proceeding and offered only one exhibit, a letter from R.K.'s attorney stating that she would invoke her Fifth Amendment privilege if called to testify. RX1.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that ''[a] registration pursuant to section 823 of this title to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In making the public interest determination in the case of a practitioner, Congress directed that the following factors be considered:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
> (2) The applicant's experience in dispensing * * * 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).

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie,* 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application. *Id.* Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005) (citing *Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005)).

With respect to a practitioner's registration, the Government bears the burden of proving by a preponderance of the evidence that the continuation of a registration would be inconsistent with the public interest. 21 CFR 1301.44(d). However, where the Government satisfies its *prima facie* burden, as for example, by showing that a registrant has committed acts which are inconsistent with the public interest, the burden then shifts to the registrant to demonstrate why he can be entrusted with a registration. *Medicine Shoppe-Jonesboro,* 73 FR 363, 380 (2008).

In this matter, having considered the entire record and all of the statutory factors, I reject the ALJ's finding that Respondent violated Federal and State law when he prescribed Vicodin to B.R. However, I agree with the ALJ's conclusions that the Government's evidence under factors two, four, and five makes out a *prima facie* case that Respondent has committed acts which render his registration inconsistent with the public interest.[20] ALJ at 26, 30. I

[11] The practical effect of assigning a zero starting inventory is to reduce the size of any shortage.

[12] According to the computation chart prepared by the GS, he used 1200 tablets as the amount seized during the search of R.K.'s residence. GX 15, at 1. As the ALJ noted, given that the audit found that nearly four million tablets could not be accounted for, the error is inconsequential. ALJ at 13 n.5.

[13] Respondent does not contend that the GS double-counted any of the orders that were used in calculating this figure.

[14] The dispensing logs also did not contain the name of the dispensing physician, the initials of the person dispensing the drugs, and the patient's address as required by 21 CFR 1304.22(c). Tr. 58, 147; *see also* GX 14. Moreover, while there were some dispensing logs from 2003, the remaining logs only covered the period from February 28 through March 15, 2006. Tr. 57; *see also* GX 14.

[15] The GS credited CMC with dispensing 87,000 tablets of hydrocodone as he could not determine whether the dispensings recorded in the dispensing logs overlapped with those noted in the patient files. Tr. 129–30.

[16] Neither Respondent nor his wife had reported to DEA any thefts, losses, or destructions of controlled substances. Tr. 65.

[17] According to the GS, the street value of a hydrocodone tablet is between three to five dollars, Tr. 132, and that the value of the drugs, which Respondent could not account for, would be about $15 to 20 million. *Id.* at 133. The GS also acknowledged that although the Government had seized various accounts controlled by R.K., Respondent and his wife, he found no evidence of bank deposits approaching this amount; nor did he find evidence of extravagant purchases. Tr. 134–35.

[18] The application also lists R.K. as the ''accounts payable contact.'' GX 9, at 4.

[19] The GS testified that on or about January 6, 2006, he had spoken with D.L., who told him that R.K. was the contact person for Respondent and his wife, and that R.K. had represented to ParMed that the reason for the quantities of controlled substances that were being ordered was that there were thirty doctors at the clinic. Tr. 36–37.

[20] I acknowledge that Respondent holds a valid medical license from the State of California. Moreover, the State Board has not taken action against him nor made any recommendation in this matter (factor one). ALJ Ex. 3, at 3.

Be that as it may, in enacting the CSA, Congress vested this Agency with ''a separate oversight responsibility [apart from that which exists in state

Continued

further agree with the ALJ's conclusion that Respondent has not accepted responsibility for his misconduct and that he has not rebutted the Government's *prima facie* case.

Factors Two, Four, and Five—Respondent's Experience in Dispensing Controlled Substances, Compliance With Applicable Laws Related to Controlled Substances, and Other Conduct Which May Threaten Public Health and Safety

The Government's case implicates each of these factors. As found above, during an approximately fifteen month period, more than four million tablets of highly abused combination drugs containing hydrocodone, a schedule III controlled substance, were purchased by R.K., Respondent's office manager, using his and his wife's DEA registrations. When DEA Investigators audited Respondent's handling of hydrocodone, they could account for only 167,000 tablets, leaving nearly 3.9 million tablets unaccounted for.[21] In addition, law enforcement authorities found that R.K. had large quantities of hydrocodone in her possession during both a traffic stop and a search of her residence; Investigators also found a large quantity of cash in R.K.'s home.

At a minimum, the evidence clearly shows that Respondent violated the CSA's various recordkeeping provisions. Under Federal law, as soon as Respondent ''first engage[d] in the * * * distribution or dispensing of controlled substances, and every second year thereafter,'' he was required ''*to make a complete and accurate record of all stocks thereof on hand.''* 21 U.S.C. 827(a)(1) (emphasis added); *see also* 21 CFR 1304.03(a)–(b), 1304.04(a) & (g), 1304.11. As found above, during the audit, Respondent could not produce an inventory record for any of the controlled substances that were purchased under his registration.

Under Federal law, Respondent was also required to ''maintain, on a current basis, *a complete and accurate record of each such substance * * * received, sold, delivered, or otherwise disposed of by him.''* 21 U.S.C. 827(a)(3) (emphasis added). With respect to a practitioner who engages in dispensing, DEA regulations require that the record include ''the number of units or volume of such finished form dispensed, * * * the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed and the written or typewritten name or initials of the individual who dispensed * * * the substance on behalf of the dispenser.'' 21 CFR 1304.22(c); *see also id.;* 21 CFR 1304.03(a)–(b), 1304.04(a) & (g), 1304.21, 1304.22(c). However, as found above, while Respondent had purchased large quantities of controlled substances throughout 2004 and 2005, he had no dispensing logs for these years and his 2006 logs covered only from February 28 through March 15. Moreover, the logs that were maintained lacked required information such as the name of the dispensing doctor, the initials/name of the person doing the dispensing, and the address of the patient. GX 14.

Recordkeeping is one of the central features of the CSA's closed system of distribution. *See Paul H. Volkman,* 73 FR 30630, 30644 (2008), *pet. for rev. denied* 567 F.3d 215, 224 (6th Cir. 2009). As I have previously explained, ''a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.'' *Id.* Given that millions of dosage units of a highly abused controlled substance that were ordered under Respondent's registration cannot be accounted for, his failure to comply with the CSA's recordkeeping requirements is egregious. This finding provides reason alone to conclude (with respect to factors two and four) that his continued registration ''is inconsistent with the public interest.'' 21 U.S.C. 823(f); *see also Volkman,* 73 FR at 30644 (holding that recordkeeping violations alone supported denial of practitioner's application).

While in his brief, Respondent, who did not testify, acknowledges that ''he failed * * * to maintain complete records reflecting his dispensing of controlled substances,'' Resp. Br. at 6, he argues that R.K. ''ordered, received and paid for'' the drugs, and that she ''distributed or sold the drugs outside [of] the CMC practice.'' *Id.* at 5. Respondent's brief implies that he was unaware of R.K.'s illegal activities, and his brief is otherwise silent on the issue of whether he bears any responsibility for the missing drugs. *See generally id.* He does.

DEA has long held that a registrant is strictly liable for the misuse of his registration by a person to whom he entrusts his registration. *See Anthony L. Capelli,* 59 FR 42288 (1994); *see also Harrell E. Robinson,* 74 FR 61376, 61377 (2009); *Paul H. Volkman,* 73 FR 30630, 30644 n.42 (2008); *Rosemary Jacinta Lewis,* 72 FR 4035, 4041 (2007) (citing *Capelli); Leonard Merkow,* 60 FR 22075, 22076 (1995). The record clearly supports the conclusion that Respondent entrusted his registration to R.K.

Moreover, several documents in evidence support the conclusion that Respondent was clearly aware that controlled substances were being ordered under his registration. These include Respondent's November 2005 letter to Schein declaring that he had ''decided to order medications through your company,'' GX 7, and the credit application he submitted to ParMed. GX 9, at 4.

The evidence also supports the inference that Respondent authorized R.K. to use his registration to order controlled substances. Several clinic employees told Investigators that R.K. would order the drugs. *See, e.g.,* Tr. 94. Moreover, several invoices prepared by Schein, both before and after Respondent's November 2005 letter, include the notation: ''Roni, Thank you for your order,'' GX 6, at 9, 14–15, 18; and on the ParMed credit application, Respondent listed R.K. as his accounts payable contact. GX 9, at 4. Finally, R.K. stated in her January 2006 interview that, while she paid for the drugs with her personal credit card, Respondent reimbursed her with cash. Tr. 94.

Thus, it is clear that Respondent authorized R.K. to order controlled substances using his registration. And even if it were the case that Respondent was unaware of R.K.'s illegal activities (although it is not), he is still strictly liable for her misuse of his registration and his failure to properly monitor how

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authorities] with respect to the handling of controlled substances.'' *Mortimer B. Levin,* 55 FR 8209, 8210 (1990). DEA has therefore long recognized that it has ''a statutory obligation to make its independent determination as to whether the granting of [a registration] would be in the public interest.'' *Id.* Accordingly, ''a State's failure to take action against a registrant's medical license is not dispositive in determining whether the continuation of a registration is in the public interest.'' *Jayam Krishna-Iyer,* 74 FR 459, 461 (2009); *see also Levin,* 55 FR at 8210 (holding that practitioner's reinstatement by state board ''is not dispositive'' in public interest inquiry). Thus, that the Medical Board of California has taken no action with respect to Respondent's medical license is not dispositive in determining whether his continued registration is consistent with the public interest.

There is also no evidence that Respondent has been convicted of an offense related to the manufacture, distribution, or dispensing of controlled substances under either Federal or state law (factor three). ALJ Ex. 3. However, while a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of (or even prosecuted for) such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry. *Krishna-Iyer,* 74 FR at 461; *Edmund Chein,* 72 FR 6580, 6593 n.22 (2007). Accordingly, that Respondent has not been convicted of an offense related to the distribution or dispensing of controlled substances is not dispositive of whether the continuation of his registration is consistent with the public interest.

[21] During 2005 alone, approximately 1.35 million dosage units were ordered under Respondent's registration. Thus, Respondent could not account for at least 1.1 million tablets.

his registration was being used. *See Jacinta Lewis,* 72 FR at 4041–42; *Robinson,* 74 FR at 61377; *Volkman,* 73 FR at 30644 n.42; *Capelli,* 59 FR at 49288.

As for Respondent's implicit suggestion that he lacked knowledge of R.K.'s activities, the evidence is to the contrary. *See* Resp. Br. at 5. Most significantly, as demonstrated by the letter Respondent sent seeking the return of the hydrocodone seized during the traffic stop of R.K., he knew that she had removed 31,000 tablets from his clinic. GX 12. Yet even after this, Respondent continued to employ R.K. (indeed, the evidence shows that she was still employed by him as of the date of the hearing) and R.K. continued to order controlled substances. *See* GX 6, at 5 (Schein invoice dated March 13, 2006 for hydrocodone and temazepam and stating: ''RONI, Thank You For Your Order''); Tr. 72. This begs the question—which is unanswered because Respondent did not testify—as to what he thought R.K. planned to do with the drugs she had in her possession when she was stopped by the CHP.[22]

It is well established that the Agency may draw an adverse inference from a respondent's failure ''to testify in response to probative evidence offered against'' him. *Baxter* v. *Palmigiano,* 425 U.S. 308, 318 (1976); *see also United States* v. *Solano-Godines,* 120 F.3d 957, 962 (9th Cir. 1997) (''In civil proceedings * * * the Fifth Amendment does not forbid fact finders from drawing adverse inferences against a party who refuses to testify.''); *Dewey C. MacKay,* 75 FR 49956, 49977 (2010). It is appropriate to draw an adverse inference here, where the Government produced evidence showing that Respondent authorized R.K. to use his registration to obtain massive quantities of controlled substances, of which only a small fraction can be accounted for, and Respondent failed to testify and respond to this evidence.

I thus conclude that Respondent knew that R.K. was engaging in illegal activity and did nothing to prevent it. Respondent's misconduct clearly threatened public health and safety, 21 U.S.C. 823(f)(5), and is especially egregious given that nearly four million dosage units of hydrocodone cannot be accounted for and were likely diverted.[23] These findings provide further reason to conclude that Respondent's registration is ''inconsistent with the public interest.''[24] 21 U.S.C. 823(f); 824(a)(4).

Sanction

Under Agency precedent, where the Government has made out a *prima facie* case that a registrant has committed acts which render his ''registration inconsistent with the public interest,'' he must '''present[] sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.''' *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988)). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), this 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-Jonesborough,* 73 FR at 387.

As noted above, Respondent failed to testify in this proceeding. While in his brief, he now acknowledges that he violated Federal law and DEA regulations by failing to maintain proper records, notably, he does not acknowledge his misconduct in failing to properly monitor how R.K. was using his registration.[25] I thus conclude that Respondent has not accepted responsibility for his misconduct and has not rebutted the Government's *prima facie* case.[26]

Given the grievous nature of Respondent's misconduct and his failure to accept responsibility, none of the ''favorable facts'' cited by the ALJ provide any reason to impose a sanction less than revocation. While the record may contain no other evidence of misconduct on Respondent's part, ALJ at 31, as I have previously explained, the fact that a practitioner can point to even an extensive body of compliance with the CSA does not negate a *prima facie* showing that he has committed acts inconsistent with the public interest.[27] *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009). While such evidence is entitled to some weight in assessing whether a practitioner has credibly shown that he has reformed his practices, where, as here, a practitioner commits egregious acts (whether intentional or not) that have likely resulted in diversion, and fails to accept responsibility for his actions, ''such evidence is entitled to no weight.'' *Id.* Indeed, that there is no other evidence of misconduct on his part does nothing to mitigate the harm Respondent has caused to public health and safety. Finally, given Respondent's failure to accept responsibility, and the nature of his misconduct, I conclude that it would be inconsistent with the public interest to grant him even a restricted registration. Accordingly, I will order that Respondent's registration be revoked and that any pending application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as by 28 CFR 0.100(b), I hereby order that DEA Certificate of Registration, AD6122143, issued to Surinder Singh Dang, M.D., be, and it hereby is, revoked. I further order that any pending application of Surinder Singh

[22] The GS also related that a patient (A.A.) had told Respondent that she believed that R.K. was selling drugs to patients who did not see him. Tr. 83.

[23] Respondent elicited testimony from the G.S. that when the Government seized the accounts and/or cash of R.K., Respondent, and his wife, it did not find a money trail consistent with the potential sales value of the illicit market of the unaccounted for hydrocodone. However, Respondent offered no evidence challenging the results of the audit. Nor has he offered any explanation as to the disposition of the unaccounted for drugs. The audit results alone provide enough evidence to support the conclusion that the drugs were diverted; the Government is not obligated to show that it found a money trail consistent with the potential sales value of the drugs in the illicit market.

[24] The ALJ further found that Respondent ''prescribed controlled substances without establishing a bona-fide doctor-patient relationship'' with B.R. ALJ at 24–25 (citing Cal. Bus. & Prof. Code § 2242(a)). The ALJ apparently based her conclusion on B.R.'s statement that Respondent ''did not examine her thoroughly and did not request any tests.'' GX 17, at 1.

The evidence suggests, however, that B.R. had a legitimate medical complaint, and there is absolutely no evidence (such as B.R.'s medical record) other than the conclusory assertion set forth above as to the scope of the examination Respondent performed. Finally, there is no evidence as to the scope of the medical examination necessary to properly diagnose and treat B.R.'s condition. I therefore conclude that the ALJ's finding is not supported by substantial evidence.

[25] Because Respondent has not addressed his misconduct in failing to prevent the misuse of his registration, I need not decide whether the assertion in his brief that he ''recognizes that he failed * * * to maintain complete records,'' Resp. Br. at 6, satisfies the Agency's rule requiring that he accept responsibility for his misconduct. Respondent offered no evidence to support this assertion, and statements of counsel in a brief are not evidence. *See INS* v. *Phinpathya,* 464 U.S. 183, 186 n.6 (1984).

[26] While the ALJ concluded that ''Respondent has not admitted any fault'' and that he was ''either intentionally engaged in diversion or * * * at least facilitating such diversion on the part of his employee,'' she nonetheless concluded that ''the inquiry does not end here'' and proceeded to analyze what she deemed to be favorable facts. ALJ at 30 (citing *Martha Hernandez,* 62 FR 61,145, 147 (1997)).

[27] To similar effect, the ALJ found that Respondent ''warned at least one patient about the dangers surrounding narcotics.'' ALJ at 31. As explained in *Krishna-Iyer,* this finding is too insubstantial to warrant any further discussion. 74 FR at 463.

Dang, M.D., to renew or modify his registration be, and it hereby is, denied. This Order is effective September 19, 2011.

Dated: August 5, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–21062 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–4]

Satinder Dang, M.D.; Revocation of Registration

On August 31, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Satinder K. Dang, M.D. (Respondent), of Fountain Valley, California. The Order proposed the revocation of Respondent's DEA Certificate of Registration, AD9234446, as a practitioner, as well as the denial of any pending applications to renew or modify her registration, ''for reason that [Respondent's] continued registration[] would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f) and 824(a)(4).'' ALJ Ex.1, at 1.

The Order specifically alleged that between January 2004 and July 2007, Respondent and her husband Surinder Dang, ''who also possesses a DEA registration and shares [Respondent's] registered location,'' ordered ''more than 5,000,000 dosage units of hydrocodone'' and that Respondent ''failed to properly account for, secure, and otherwise handle these controlled substances.'' *Id.* The Order alleged that on January 17, 2006, one of Respondent's ''employees removed 30,000 dosage units of controlled substances'' from her registered location and ''attempted to take them to her residence.'' *Id.* The Order further alleged that on the same day, ''DEA Special Agents seized another 10,000 dosage units of controlled substances from this employee's residence.'' *Id.* Continuing, the Order alleged that on March 16, 2006, ''DEA Special Agents seized 50,000 dosage units more from this employee's residence.'' *Id.*

Next, the Order alleged that on March 16, 2006, DEA conducted an accountability audit of Respondent's handling of hydrocodone and that Respondent ''could not account for more than 3,500,000 dosage units'' that Respondent and her husband ''had ordered''; the Order thus also alleged that Respondent ''failed to keep accurate and complete records of each controlled substance received, sold, delivered, or otherwise disposed of as required by 21 U.S.C. 827(c) and 21 CFR 1304.01 *et seq.''* *Id.* at 2. Finally, the Order alleged that, when Respondent ''made dispensing records,'' she ''frequently failed to indicate whether'' she or her husband ''actually dispensed the controlled substances as required by 21 CFR 1304.03(b).'' *Id.*

By letter of October 2, 2009, Respondent, through her counsel, requested a hearing on the allegations. ALJ Ex. 2. The matter was then assigned to an Administrative Law Judge (ALJ), who conducted a hearing on March 2–3, 2010, in Santa Ana, California.

At the hearing, the Government called two witnesses to testify and introduced documentary evidence. Respondent testified on her own behalf. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law and argument.

On June 18, 2010, the ALJ issued her Recommended Decision (also ALJ). Therein, the ALJ considered the five public interest factors, *see* 21 U.S.C. 823(f), and concluded that Respondent's continued registration would be inconsistent with the public interest and recommended that her registration be revoked. ALJ at 29, 37–38.

As to the first factor—the recommendation of the appropriate State licensing board or professional disciplinary authority—the ALJ found ''no evidence that the Medical Board of California has taken any action against the Respondent.'' *Id.* at 27. However, the ALJ recognized that under Agency precedent, ''the fact that the Medical Board of California has currently authorized * * * Respondent to practice medicine is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest.'' *Id.* (citing *Patrick W. Stodola,* 74 FR 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 FR 459, 461 (2009)). The ALJ then concluded that ''this factor does not fall in favor of revocation.'' *Id.* Likewise, with respect to factor three—Respondent's record of convictions for offenses relating to the manufacture, distribution, or dispensing of controlled substances—the ALJ found that Respondent has not been convicted of such an offense and that this factor also did not ''fall in favor of revocation.'' *Id.* at 27–28.

The ALJ then considered factors two and four—Respondent's experience in dispensing controlled substances and her compliance with Federal, State, and local laws relating to controlled substances—together. *Id.* at 28–29. The ALJ found that the record was ''replete with Respondent's lack of oversight concerning the use of her controlled substances registration.'' *Id.* at 28. Specifically, the ALJ found that: (1) Respondent's clinic was unable to provide a biennial inventory (or an inventory of any kind); (2) ''Respondent was unable to account for any of the controlled substances ordered using her DEA registration number''; and (3) Respondent had admitted that ''she did not maintain a key to the controlled substance cabinet'' at her clinic. *Id.* at 28–29. Further, the ALJ found that an ''audit revealed that the approximately 3,870,700 dosage units of hydrocodone were unaccounted for.'' *Id.* at 29. Based on these findings, the ALJ concluded that ''Respondent failed to maintain adequate records.'' *Id.*

The ALJ rejected Respondent's argument that ''the DEA's findings did not distinguish between the controlled substances prescribed or dispensed to Respondent's patients versus the patients of'' her husband. *Id.* The ALJ found that ''the missing controlled substances were ordered under both DEA registration numbers in a haphazard manner and subsequently mixed into an incoherent mélange.'' *Id.* The ALJ reasoned that if ''Respondent maintained some oversight of her controlled substances registration, then DEA would most likely be able to 'distinguish between controlled substances prescribed or dispensed to Respondent's patients versus' those of her husband.'' *Id.* Based on these findings, the ALJ concluded that ''Respondent's circular reasoning does not absolve her [of] culpability.'' *Id.* The ALJ thus held that the Government's evidence under factors two and four ''established prima facie grounds for revocation of * * * Respondent's DEA Certificate of Registration.'' *Id.*

Turning to factor five—such other conduct as may threaten the public health and safety—the ALJ explained that ''[e]ven if Respondent was not directly involved in the illegal diversion of controlled substances * * * she committed acts which constitute 'conduct which may threaten the public health and safety' and which render her registration 'inconsistent with the public interest.' '' *Id.* (quoting 21 U.S.C. 823(f)(5), 824(a)(4)). Noting that ''[u]nder DEA precedent, a registrant who entrusts [her] registration to another person is strictly liable for the latter's misuse of [her] registration,'' the ALJ reasoned that ''even if there had been no conspiracy amongst Respondent, her husband, and [R.K., the

office manager of the clinic where she practiced with her husband] to unlawfully distribute the drugs, [Respondent] would still be liable for the acts [R.K.] committed while being allowed to use [her] registration.'' *Id.* (citations omitted).

The ALJ further found incredible Respondent's testimony that ''she was unaware of [R.K's] actions.'' *Id.* Noting Respondent's ''admitted lack of supervision'' over R.K.—including that Respondent would ''tell [R.K.] which drug she wanted to dispense,'' R.K. ''would retrieve the controlled substances from the steel cabinet and update the logbook,'' and ''only [R.K.] had a key to the controlled substances cabinet''—placed R.K. in a ''position where she could take advantage of the lax security'' of Respondent's controlled substances, the ALJ rejected Respondent's contention that these were ''minor record-keeping violations'' and held that she was ''responsible for enabling [R.K.'s] acts of unlawful possession and distribution of the controlled substances that [R.K.] obtained under Respondent's registration.'' *Id.* (citing *Harrell E. Robinson, M.D.,* 74 FR 61370, 61376–77 (2010)). The ALJ also found that Respondent is ''still engaged in an ongoing working relationship with [R.K.],'' *id.* at 32, and held that ''[a] practitioner's failure to properly supervise patients or staff to prevent them from personally abusing controlled substances or selling them to others constitutes conduct 'inconsistent with the public interest' and can support * * * the revocation of an existing registration.'' *Id.* at 33 (citing *Jeri Hassman, M.D.,* 75 FR 8194, 8227 (2010); *Gonzales v. Oregon,* 546 U.S. 243, 274 (2006)).

Noting that Respondent blamed her husband and R.K. for her misconduct, the ALJ further found that ''Respondent's acceptance of responsibility has been minimal'' and ''weighs heavily against her continuing registration.'' *Id.* at 35. The ALJ further held that Respondent's ''lack of cooperation with the DEA investigation nominally weighs against her continued registration.'' *Id.* at 36–37.

The ALJ also found that ''the fact that [Respondent] still works alongside [R.K.] is an aggravating factor.'' *Id.* at 35. While noting Respondent had offered to file quarterly reports of her prescriptions with the Agency, the ALJ found that ''Respondent's careless use of her DEA Certificate of Registration coupled with her lack of assurances that she will no longer enable others such as [R.K.] and her husband to abuse her controlled substances registration weighs heavily against her continuing registration.'' *Id.* at 37. The ALJ therefore recommended that ''Respondent's DEA Certificate of Registration be revoked.'' *Id.* at 38.

On August 9, 2010, Respondent filed Exceptions to the ALJ's Decision, and on August 18, the ALJ forwarded the record to me for Final Agency Action. On September 10, 2010, the Government filed a motion with my Office to accept its response to Respondent's Exceptions. In its motion, the Government stated that Respondent's counsel had consented to its filing. Accordingly, by this Order I grant the Government's motion.

Having considered the entire record, I adopt the ALJ findings of fact and conclusions of law except as expressly noted herein. I further adopt the ALJ's ultimate conclusion that Respondent's ''continued registration is not in the public interest,'' ALJ at 38, and her recommendation that her registration be revoked. As ultimate factfinder, I make the following findings:

Findings

Respondent is the holder of DEA Certificate of Registration, AD9234446, which authorizes her to dispense controlled substances in schedules II through V, as a practitioner, at the registered location of 17150 Euclid #200, Fountain Valley, California. GX 1. While Respondent's registration was to expire on June 30, 2007, *id.,* on June 4, 2007, Respondent filed an application to renew her registration. GX 2. Accordingly, her registration remains in effect pending the issuance of this Decision and Final Order. 5 U.S.C. 558(c); *see also* ALJ Ex. 3, at 2 (Prehearing Order; Stipulations).

Respondent currently holds a medical license issued by the Medical Board of California. Moreover, the Board has not taken any formal action to limit her ability to practice medicine or to prescribe controlled substances. ALJ Ex. 3, at 3. Also, Respondent has not been convicted of an offense related to the manufacture, distribution, or dispensing of controlled substances. *Id.*

Respondent is married to Surinder Dang, M.D.[1] He and Respondent practice medicine at Complete Medical Care, Inc. (''CMC''). Tr. 188–189; GX 6, at 20. Their son, Sameer Dang, also works in the CMC office. Tr. 58, 188. At all relevant times (including through the date of the hearing), CMC's office manager was Ms. Rani K. (R.K.).[2] *Id.* at 190–91, 194–95, 203–04.

In November 2005, a Diversion Group Supervisor (GS) in DEA's Riverside Diversion Group reviewed ARCOS[3] records which showed that large amounts of controlled substances, including hydrocodone,[4] were being ordered under the DEA registration numbers of both Respondent and her husband.[5] Tr. 30–32; GXs 3 & 4. Upon reviewing the ARCOS data, the GS contacted several of the firms that were distributing controlled substances to Respondent. *See, e.g.,* GX 6, at 7. At several points throughout the investigation, these firms provided the GS with copies of various documents, including sales records, invoices, statements of account, delivery information, applications for credit, and correspondence. *See generally* GX 5 (records from Moore Medical, L.L.C.),[6] GX 6 (record from Henry Schein, Inc.), GX 9 (records from ParMed Pharmaceuticals, Inc.).

The majority of the controlled substances ordered under Respondent's DEA registration were obtained from Anda Pharmaceuticals. GX 3; Tr. 130, 139. The GS obtained purchase records from Anda showing hydrocodone and other controlled substances purchases by both Respondent and her husband between 2000 and 2005. GX 8; Tr. 47–49. However, there is no evidence that Respondent ever personally ordered these controlled substances. Tr. 140.

CMC also ordered controlled substances, primarily hydrocodone, from another drug distributor, Henry Schein, Inc. GX 6; Tr. 44. The Schein records show that the orders were placed under Respondent's husband's name, but a number of the invoices note Respondent's name as well as her husband's. GX 6, at 8–9, 11, 14–15, 17–18, 29. R.K.'s name was also listed as

[1] Dr. Surinder Dang holds DEA Certificate of Registration AD6122143; he is registered at the same address as Respondent. ALJ Ex. 3, at 2, GX 2 at 2.

[2] In various documents R.K.'s first name was spelled as both Rani and Roni. *Compare* GX 5, at 7, *with* GX 6, at 1, 5, 9, 14–15, 18, 29; *see also* GX 10 at 1.

[3] Pursuant to 21 CFR 1304.33(c), manufacturers and distributors of various controlled substances including schedule III narcotics are required to report their distributions of controlled substances to DEA through the Automated Records and Consolidated Orders System (ARCOS). *See also* Tr. 33.

[4] As a combination product, hydrocodone is a schedule III controlled substance. 21 CFR 1308.13(e)(1)(iv).

[5] The ARCOS system reports the registration number used, but not necessarily the person who actually ordered the drugs. Tr. 114–16.

[6] Moore Medical Supply reported to DEA that CMC ordered excessive amounts of hydrocodone. Tr. 32–34; GX 5. The order to Moore was placed under Respondent's husband's DEA registration and R.K.'s name appears on a fax sheet sent to Moore Medical and related to CMC's account number. GX 5, at 7; Tr. 131.

the contact person for the Henry Schein account. Tr. 132–34.

In a letter dated November 7, 2005, Respondent's husband explained to Henry Schein that CMC would begin ordering controlled substances so that CMC's physicians could dispense medications directly to CMC's patients. GX 7; Tr. 46. This letter listed the CMC physicians as Surinder Dang, M.D.; Satinder Dang, M.D.; Robert Belanger, D.O.; Huey Lin, M.D.; and Davinder Singh, M.D. GX 7. The letter also stated: ''We dispense medications to our patients only. Our practice has been growing.'' *Id.* However, none of the records obtained in the investigation show that controlled substances were ordered from Schein under the registrations of any of the doctors besides those of Respondent and her husband. GX 6, at 7; Tr. 176–79.

The DEA registration numbers of both Respondent and her husband were used to order controlled substances from Darby Medical Supply and ParMed Pharmaceuticals. GX 16; GX 9, 11; Tr. 51, 61–62. The Darby records show that Respondent ordered hydrocodone fourteen times. GX 16, at 1, 5, 7, 11. The ParMed records show that between December 29, 2005 and January 4, 2006, 88,800 dosage units of hydrocodone were ordered under Respondent's registration. GX 9, at 2. At one point, D.L., ParMed's Regulatory Affairs officer, reported to the GS that CMC's orders were ''excessive and suspicious''; D.L. also identified R.K. as the point of contact for the clinic and that R.K. had opened the CMC accounts. Tr. 51–53.

According to ARCOS records, while in 2004, Respondent purchased 157,100 dosage units of hydrocodone, in 2005, she purchased 2,272,800 dosage units. GX 3, at 2–13. ARCOS data further showed that in 2005, Respondent and her husband had ordered a combined total of 3,626,400 tablets of hydrocodone. GX 3 at 13; GX 4, at 6; *see also* Tr. 93–94 (GS's testimony that between January 1, 2005 and March 16, 2006, Respondent and her husband purchased approximately 4 million tablets of hydrocodone).[7]

Throughout the investigations, several of the firms also provided the GS with information regarding when various deliveries were to be made to Respondent's clinic. On December 14, 2005, the GS, who had received information from two different distributors (Henry Schein and Moore Medical) that controlled substances deliveries were to be made that day, conducted surveillance at the [Dangs'] clinic from approximately 9:00 a.m. until 6:00 p.m. Tr. 43, 67–68, 75. During the surveillance, the GS observed both deliveries and noted that ''approximately no more than a dozen'' people entered the clinic that day. *Id.* at 75.

On January 13, 2006, the GS conducted a second surveillance from approximately 9:00 a.m. until 3 p.m. *Id.* at 76–77. During the surveillance, the GS saw R.K. ''tak[ing] boxes from the office and plac[ing] them in the trunk of her * * * SUV.'' *Id.* at 77.

On January 17, 2006, the GS, who had received notice of a controlled substance delivery from another distributor (ParMed Pharmaceuticals, Inc.), conducted another full-day surveillance. *Id.* at 77–78. Once again, Investigators observed R.K. ''place numerous boxes in her vehicle that had been delivered to the clinic'' and ''put them in the back of her * * * SUV.'' *Id.* at 78. The GS observed R.K. drive away and notified the California Highway Patrol (CHP). *Id.* at 78, 80, 147–48. After observing R.K., who was driving forty miles per hour, operate her vehicle within five feet of the vehicle in front of her, the CHP officer conducted a traffic stop. *Id.* at 78; GX 10, at 2.

As he approached R.K., the CHP officer observed ''cardboard boxes that were taped shut in the rear cargo area.'' GX 10, at 2. The CHP officer advised R.K. of the reason for the stop and requested her license, registration, and insurance. *Id.* He then asked R.K. ''what the boxes were.'' *Id.* R.K. stated that the boxes held Vicodin, a schedule III controlled substance which contains hydrocodone. *Id.;* ALJ Ex. 3, at 1; 21 CFR 1308.13(e)(iv). When the CHP officer asked R.K. if she was a doctor, she stated that ''she was the president of a medical facility and that she was going to give the Vicodin to the doctor at her facility.'' GX 10, at 2. The CHP Officer asked R.K. a second time if she was a doctor; R.K. again said ''no'' and became ''extremely nervous.'' *Id.*

After the CHP Officer asked R.K. to step out of her car, he asked ''why she had cases of Vicodin.'' *Id.* R.K. answered that she ran a medical office and handed him a business card listing her name and her position as ''president.'' *Id.* R.K. further stated that ''she received a delivery of Vicodin from a delivery company at about 1100 hours and that she needed to give it to'' Respondent. *Id.* When the Officer asked R.K. if the Vicodin had been delivered ''to her car or to her office,'' R.K. stated that it had been delivered to the office. *Id.* When the Officer asked if her office had a locker in which to store the Vicodin, R.K. answered ''yes,'' but that she had to personally give the drugs to Respondent. *Id.*

The CHP Officer then asked how the Vicodin had ended up in her vehicle; R.K. stated that ''she [had] carried the boxes to her vehicle around noon time and left them there,'' and that she had stayed in her office until about 5 p.m., at which point ''she left * * * to get something to eat.'' *Id.* When the Officer told R.K. that he was ''concerned that she was in possession of so much of a controlled substance,'' she said she would return it to the office. *Id.* R.K. then stated that Respondent was ''doing a procedure at an unknown hospital and he would be returning at an unknown time to the office'' and that she would then give him the Vicodin. *Id.*

The CHP Officer then ''asked R.K. to open the boxes'' to confirm that they contained Vicodin. *Id.* R.K. opened six boxes containing a total of 70 bottles of hydrocodone bitartrate/acetaminophen (hereinafter, hydrocodone/apap or hydrocodone). *Id.* at 2–3. Each of the bottles contained between 100 and 500 tablets (for a total of ''approximately 31,000 tablets'') in 7.5/500 mg, 10/500 mg, and 10/325 mg strengths. *Id.* The Officer then seized the Vicodin and gave R.K. a receipt for it. *Id.* at 3. After giving R.K. a citation, the officer allowed her to leave. *Id.*

The CHP Officer then contacted a DEA Task Force Officer (TFO) and arranged to transfer custody of the drugs to DEA; upon the TFO's arrival at the Officer's location, the drugs were transferred to the TFO. *Id.* The TFO gave the CHP Officer a receipt which confirms the figures in the latter's report.[8] *Id.* at 6.

R.K. then drove to her residence in Anaheim Hills; Investigators followed her there in order to question her about the drugs that were found in her vehicle. Tr. 82. R.K. told the Investigators that she had taken the hydrocodone with her for safekeeping because Respondent was out of the office; she also maintained that she intended to return them to the office after she ate. *Id.* at 83. While R.K. initially claimed that this was the first time she had done this, upon being confronted with the fact that Investigators had on another occasion observed her placing boxes in her vehicle, R.K. admitted that this was the second time she had done so. *Id.*

[7] The GS stated that he analyzed ARCOS data, distributors' sales records, audit inventories, patient files and dispensing logs when creating GX 15. Tr. 92–97.

[8] More specifically, there were 14 bottles of 500 count of hydrocodone/apap 7.5/500 mg; 10 bottles of 500 count hydrocodone/apap 10/500 mg; 36 bottles of 500 count hydrocodone/apap 10/325 mg; and 10 bottles of 100 count hydrocodone/apap 10/500 mg. GX 10, at 6.

R.K. stated that there were about five physicians who worked at Respondent's clinic, that they dispensed the pills in 30- and 60-count bottles, and that the clinic had approximately twenty to twenty-five patients per day. *Id.* at 84. R.K. further said that she used her personal credit card to purchase drugs from wholesalers and that Respondent would reimburse her. *Id.*

The Investigators then asked R.K. if she would consent to a search of her residence; she agreed. *Id.* According to the GS, the Investigators found approximately $69,500 in cash in an upstairs closet, a ''quantity of hydrocodone and lorazepam in the house'' (2000 lorazepam tablets and 1400 hydrocodone tablets), ''money order receipts,'' and receipts of ''payments made to the credit card companies by [R.K.].'' *Id.* To explain the cash found at her residence, R.K. claimed the sum was a combination of money received from the sale of a house in India and a home-based business she had previously run. *Id.* at 85–86.

On February 24, 2006, Respondent's husband wrote a letter to CHP requesting the return of the hydrocodone which had been seized during the traffic stop of R.K. Tr. 88–89; GX 12. The letter asserted that R.K. was the clinic's ''office manager,'' and had ''informed CHP that the property was not hers, and instead belonged to her employer, Complete Medical Care Inc.'' GX 12.

On March 16, 2006, DEA executed search warrants at both Respondent's clinic and R.K.'s residence. Tr. 90, 104. At the clinic, the Investigators took an inventory of the controlled substances on hand and found 48,000 tablets of hydrocodone, which they seized; the Investigators also seized CMC's controlled substance purchasing records and dispensing log. Tr. at 90, 95. Later that day, Investigators went to Respondent's residence and sought consent to search her house. Tr. 103. Respondent declined to provide consent and refused to talk with Investigators without an attorney present. *Id.*

R.K. was present during the search of her residence and was interviewed. *Id.* at 104. R.K. stated that since January 17, 2006, she had stopped purchasing the drugs on her own, and that the drugs were being purchased by Respondent's husband, Dr. Surinder Dang. *Id.* at 105. R.K. stated that Respondent's husband was the clinic's ''primary dispenser'' of the drugs and that she ''dispensed drugs to the patients under the direction of * * * Dr. Surinder Dang.'' *Id.*

On March 16, 2006, the Diversion Investigator (DI) interviewed several CMC employees, including A.N.,[9] C.G.,[10] L.Y.,[11] and S.B.[12] In April 2006, the GS interviewed Dr. B., a physician who had worked at CMC on a part-time basis since approximately 2004. *Id.* 109–110. Dr. B. also worked at a facility for the local county government, but he saw some of his patients at CMC. *Id.* at 110. Dr. B. stated that while he worked at CMC, he rarely, if ever, prescribed or dispensed controlled substances to his patients. *Id.* at 111. He also stated that the patient load at CMC did not justify the quantities of controlled substances that were being purchased by the clinic. *Id.* at 114.

Using the records seized during the search of Respondent's clinic and its patient files, ARCOS data, and information provided by several of the distributors,[13] the GS conducted an audit of the hydrocodone ordered under both Respondent's and her husband's registrations between January 1, 2005 and March 16, 2006. Tr. 93–96, 67; GX 15. Because CMC did not maintain records of their inventory (notwithstanding Federal law requiring them to do so, *see* 21 U.S.C. 827(a) & (b)), the GS chose January 1, 2005 as the starting date and assumed that no controlled substances were then on hand; for the closing inventory, the GS used the inventory taken (48,000 tablets) when the search warrant was executed.[14] Tr. 92–93, 95; GX 15. To this latter figure, the GS added the hydrocodone that was seized during the January 17, 2006 traffic stop of R.K. (31,000 tablets) and the 1,200 tablets[15] found during the search of R.K.'s residence which occurred later that day. Tr. 95; GX 12, 15.

Using both the ARCOS data and distributor invoices, the GS determined that 4,037,900 tablets of hydrocodone had been ordered during the audit period. Tr. 94; GX 15. The clinic's dispensing logs, which did not identify which doctor had authorized the various dispensings, *see* GX 14, showed that only 12,000 tablets had been dispensed;[16] in addition, the GS reviewed the clinic's patient files and credited another 75,000 tablets as having been dispensed.[17] Tr. 95–96; GX 15. Accordingly, CMC could only account for approximately 167,000 tablets of hydrocodone.[18] Tr. 96–97; GX 15. While the DI combined the purchases of Respondent and her husband, the ARCOS data and distributor invoices did list whose registration was used to place the various orders. *See, e.g.,* GXs 3 & 4. This evidence shows that in 2005 alone, 2,272,800 dosage units of hydrocodone were ordered under Respondent's registration. Accordingly, Respondent still could not account for more than two million dosage units.[19] GX 3, at 13.

Respondent testified that she had no knowledge that her ''DEA registration

[9] A.N. stated that Respondent, her husband, and R.K. handled drug deliveries when they came into CMC. *Id.* at 238–39. A.N. further stated that both Respondent and her husband kept records of dispensed drugs in the patient files and dispensing logs; she identified the writing in the patient log as R.K.'s. *Id.* at 239–40.

[10] The transcript notes the coworker's initials as C.G.; however, other documents suggest that her initials are K.G. *See* Resp. Brief at 8. C.G. stated that both R.K and Respondent's husband ordered the drugs for CMC. Tr. 241, 249–250. R.K. usually accepted deliveries of drug orders; however, sometimes C.G. would sign for the delivery but not open the boxes. *Id.* at 241–42. C.G. further stated that she witnessed R.K. writing in the dispensing log the day before the search warrant was executed and heard R.K. comment that CMC's drug procedures had changed. *Id.* at 242.

[11] According to L.Y., the clinic saw twenty to twenty-five patients per day. *Id.* at 244. L.Y. also stated that R.K. handled the drugs once they arrived. *Id.* at 243. When shown the dispensing log, L.Y. identified the handwriting as belonging to R.K. *Id.* at 243–44. She further stated that Respondent only wrote prescriptions. *Id.* at 250.

[12] S.B. stated that R.K. and Respondent's husband handled the drugs that were dispensed directly to patients and that R.K. handled the drug inventory and payment for the drugs that were ordered. *Id.* at 246. S.B. also stated that R.K. handled the dispensing log. *Id.* at 247. S.B. further stated that CMC had approximately twenty-five patients per day, of whom ten saw Respondent. *Id.* According to S.B., both Sameer Dang and R.K. paid for the drugs. *Id.* She also stated that R.K. had access to the controlled substances received at the CMC office. *Id.* at 248.

[13] Moore Medical provided DEA with sales records under Respondent's registration for hydrocodone from late 2005 to early 2006. Tr. 34, 43; GX 5. ANDA provided DEA with a spreadsheet listing all sales under the registrations of Respondent and her husband from May 2000 through mid-October 2005. Tr. 47–49; GX 8. DEA also acquired sales records and a sales summary from ParMed which show Respondent's purchases of controlled substances between November 28, 2005 and January 4, 2006. Tr. 51–52; GX 9.

[14] If any controlled substances were in fact on hand on the starting date of the audit period, assigning a zero starting inventory would reduce the size of any shortage.

[15] I acknowledge that this figure differs from the quantity of 1,400 tablets which, according to the GS's testimony, was found in R.K.'s house. The difference, however, is inconsequential given the result of the audit.

[16] The dispensing logs also did not contain the name of the dispensing physician, the initials of the person dispensing the drugs, and the patient's address as required by 21 CFR 1304.22(c). Tr. 90; *see also* GX 14. Moreover, while there were some dispensing logs from 2003, the remaining logs only covered the period from February 28 through March 15, 2006. *See* GX 14.

[17] The GS credited CMC with dispensing a total of 87,000 hydrocodone tablets; this calculation counted the prescriptions issued by Respondent or her husband, because the prescriptions may have been filled in the office. Tr. 100; GX 15.

[18] Neither Respondent nor her husband had reported to DEA any thefts, losses, or destructions of controlled substances. Tr. 99–101.

[19] This calculation gives Respondent credit for all of the 167,000 tablets for which the GS could account.

number was being used to order large quantities of hydrocodone that were being delivered to CMC.'' Tr. 192. She asserted that she did not order any controlled substances between 2002 and March 16, 2006, and that she did not order any controlled substances after that period. *Id.* at 195–96. Specifically, she testified that she did not order Lorazepam in October 2006. *Id.*

Respondent testified that while during this time period, she was aware that her husband was ordering drugs for his pain management practice, she did not know how much he was ordering. *Id.* at 201. Respondent stated that she had no knowledge of the controlled substances being delivered to CMC during this time period; while she admitted to having seen boxes being delivered to the clinic, she claimed to not know what they contained. *Id.* 197–198. Respondent further stated that R.K. would open the boxes after they were delivered. *Id.* at 200.

Respondent further testified that she was unaware that R.K. had taken drugs from CMC to her residence until learning of it through these proceedings; she also stated that she was not sure if her husband had instructed R.K. regarding taking drugs to her residence. *Id.* at 204–205. However, the ALJ did not find credible Respondent's testimony that she was unaware of R.K.'s activities. ALJ at 30.

Regarding the controlled substance drug storage area, Respondent stated that she had ''no idea'' how the drugs were organized. Tr. 198–99. Respondent testified that she did not pay attention to what was in that storage area, but then stated there was a basic cabinet that was locked at night and that she did not have a key. *Id.* at 200–01. According to Respondent, the key was either kept by R.K. or in a place where her husband could find it; Respondent also did not know if the storage cabinet was locked during the day. *Id.* at 234.

While Respondent testified on direct examination that she had not dispensed drugs at CMC, on cross-examination, she stated ''I don't recall. I might have dispensed but I dispensed rarely.'' *Id.* at 195. Respondent then admitted dispensing, stating ''maybe I might have given [hydrocodone] once or twice to my patients only.'' *Id.* She stated that other people had ordered these drugs that she dispensed. *Id.* at 229. On the occasions that she did dispense, Respondent asked R.K. for the drug. *Id.* at 230. R.K. would retrieve the controlled substances from the cabinet and give them to Respondent to hand to the patient. *Id.* In these instances, R.K. would record the dispensed controlled substances in a ''separate log.'' *Id.* at 228.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that ''[a] registration pursuant to section 823 of this title to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render [her] registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In making the public interest determination in the case of a practitioner, Congress directed that the following factors be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * 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).

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie,* 68 FR 15227, 15230 (2003). I may rely on any one factor, or a combination of factors, and may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application. *Id.* Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005) (citing *Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005)).

With respect to a practitioner's registration, the Government bears the burden of proving by a preponderance of the evidence that the continuation of a registration would be inconsistent with the public interest. 21 CFR 1301.44(d). However, where the Government satisfies its *prima facie* burden by showing that a registrant has committed acts which are inconsistent with the public interest, the burden then shifts to the applicant to demonstrate why he can be entrusted with a registration. *Medicine Shoppe-Jonesboro,* 73 FR 364, 380 (2008).

In this matter, having considered the entire record and all of the factors, I agree with the ALJ's conclusions that the Government's evidence under factors two, four, and five makes out a *prima facie* that Respondent has committed acts which render her registration inconsistent with the public interest.[20] ALJ at 29. I further agree with the ALJ's conclusion that Respondent has not accepted responsibility for her misconduct and has thus not rebutted the Government's *prima facie* case.

Factors Two, Four, and Five—Respondent's Experience in Dispensing Controlled Substances, Compliance With Applicable Laws Related to Controlled Substances, and Other Conduct Which May Threaten Public Health and Safety

The Government's case implicates each of these factors. As found above, during an approximately fifteen-month period, more than four million tablets of highly abused combination drugs containing hydrocodone, a schedule III controlled substance, were purchased by R.K., Respondent's office manager, using her and her husband's DEA registrations, approximately 2.3 million of which were ordered under her registration during 2005 alone. When DEA Investigators audited Respondent's and her husband's handling of the hydrocodone, they could account for only 167,000 tablets, leaving Respondent with over two million

[20] I acknowledge that Respondent holds a valid medical license from the State of California. Moreover, the State Board has not taken action against her, nor made any recommendation in this matter (factor one). ALJ at 27.

Be that as it may, in enacting the CSA, Congress vested this Agency with ''a separate oversight responsibility [apart from that which exists in state authorities] with respect to the handling of controlled substances.'' *Mortimer B. Levin,* 55 FR 8209, 8210 (1990). DEA has therefore long recognized that it has ''a statutory obligation to make its independent determination as to whether the [continuation] of [a registration] would be in the public interest.'' *Id.* Accordingly, ''a State's failure to take action against a registrant's medical license is not dispositive in determining whether the continuation of a registration is in the public interest.'' *Jayam Krishna-Iyer,* 74 FR 459, 461 (2009); *see also Levin,* 55 FR at 8210 (holding that practitioner's reinstatement by state board ''is not dispositive'' in public interest inquiry). Thus, that the Medical Board of California has taken no action with respect to Respondent's medical license is not dispositive in determining whether her continued registration is consistent with the public interest.

There is also no evidence that Respondent has been convicted of an offense related to the manufacture, distribution, or dispensing of controlled substances under either Federal or state law (factor three). ALJ at 27–28. However, while a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of (or even prosecuted for) such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry. *Krishna-Iyer,* 74 FR at 461; *Edmund Chein,* 72 FR 6580, 6593 n.22 (2007). Accordingly, that Respondent has not been convicted of an offense related to the distribution or dispensing of controlled substances is not dispositive of whether the continuation of her registration is consistent with the public interest.

tablets unaccounted for. In addition, law enforcement authorities found that R.K. had large quantities of hydrocodone in her possession during both a traffic stop and a search of her residence; Investigators also found a large quantity of cash in R.K.'s home.

At a minimum, the evidence clearly shows that Respondent violated the CSA's various recordkeeping provisions. Under Federal law, as soon as Respondent ''first engage[d] in the * * * distribution[] or dispensing of controlled substances, and every second year thereafter,'' she was required ''*to make a complete and accurate record of all stocks thereof on hand.''* 21 U.S.C. 827(a)(1) (emphasis added); *see also* 21 CFR 1304.03(a)–(b), 1304.04(a), (g), 1304.11. However, as found above, during the audit, Respondent could not produce an inventory record for any of the controlled substances that were purchased under her registration.

Under Federal law, Respondent was also required to ''maintain, on a current basis, *a complete and accurate record of each such substance * * * received, sold, delivered, or otherwise disposed of by [her].''* 21 U.S.C. 827(a)(3) (emphasis added). With respect to a practitioner who engages in dispensing, DEA regulations require that the record include ''the number of units or volume of such finished form dispensed, * * * the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed and the written or typewritten name or initials of the individual who dispensed * * * the substance on behalf of the dispenser.'' 21 CFR 1304.22(c); *see also id.;* 21 CFR 1304.03(a)–(b), 1304.04(a), (g), 1304.21. However, as found above, while large quantities of controlled substances were purchased under her registration throughout 2004 and 2005, Respondent had no dispensing logs for these years and the 2006 logs covered only from February 28 through March 15. Moreover, the logs that were maintained lacked required information such as the name of the dispensing doctor, the initials/name of the person doing the dispensing, and the address of the patient. GX 14.

Recordkeeping is one of the central features of the CSA's closed system of distribution. *See Paul H. Volkman,* 73 FR 30630, 30644 (2008), *pet. for rev. denied* 567 F.3d 215, 224 (6th Cir. 2009). ''[A] registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.'' *Id.* Given that millions of dosage units of a highly abused controlled substance that were ordered under Respondent's registration cannot be accounted for, her failure to comply with the CSA's recordkeeping requirements is egregious. This finding provides reason alone to conclude (with respect to factors two and four) that her continued registration ''is inconsistent with the public interest.'' 21 U.S.C. 823(f); *see also Volkman,* 73 FR at 30644 (holding that recordkeeping violations alone supported denial of practitioner's application).

In her Exceptions to the ALJ's decision, Respondent argues that ''she had no knowledge that her DEA Registration was being used by her husband or [R.K.] to order controlled substances'' until DEA executed the search warrant on March 16, 2006. However, DEA has long held that a registrant is strictly liable for the misuse of her registration by a person to whom she entrusts her registration. *See also Harrell E. Robinson,* 74 FR 61370, 61377 (2009); *Paul H. Volkman,* 73 FR 30630, 30644 n.42 (2008); *Rose Mary Jacinta Lewis,* 72 FR 4035, 4041 (2007) (citing *Anthony L. Capelli,* 59 FR 42288 (1994)*; Leonard Merkow,* 60 FR 22075, 22076 (1995); *Capelli,* 59 FR at 49288. The record clearly supports the conclusion that Respondent entrusted her registration number to R.K. Thus, even if it were the case that Respondent was unaware of R.K.'s illegal activities, she is still strictly liable for R.K.'s misuse of her registration and her failure to properly monitor how her registration was being used. *See Jacinta Lewis,* 72 FR at 4041–42; *Robinson,* 74 FR at 61377; *Volkman,* 73 FR at 30644 n.42; *Capelli,* 59 FR at 49288.

Contrary to Respondent's understanding, the purpose of this proceeding is to protect the public interest, and in determining whether a registrant has committed acts which render her registration ''inconsistent with the public interest,'' 21 U.S.C. 824(a)(4), the standards of *mens rea* for imposing criminal liability are not controlling. Accordingly, the Government is not required to show that Respondent had knowledge that her DEA Registration was being used by her husband or R.K. to order controlled substances.

In any event, the ALJ did not find credible Respondent's testimony that she was unaware of R.K.'s activities. ALJ at 30. I agree. Given the duration and scope of R.K.'s activities, Respondent's denial of knowledge is implausible.

In her Exceptions, Respondent also argues that the ALJ's decision ''fails to distinguish between the drugs ordered under Respondent's DEA Registration and the drugs ordered under her husband's.'' Res. Exc. at 22. This is true. However, as ultimate factfinder, I have reviewed the evidence and found that the ARCOS data shows that in 2005 alone, more than 2.27 million dosage units of hydrocodone were ordered under Respondent's registration, and that at most, 167,000 dosage units can be accounted for. Thus, Respondent is responsible for more than two million dosage units that cannot be accounted for and were likely diverted.

Respondent's misconduct thus clearly threatened public health and safety. *See* 21 U.S.C. § 823(f)(5). Moreover, the scope of the diversion is egregious. I therefore conclude that the Government has satisfied its *prima facie* burden of showing that Respondent has committed acts which render her registration is ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4); 823(f).

Sanction

Under Agency precedent, where the Government has made out a *prima facie* case that a registrant has committed acts which render her ''registration inconsistent with the public interest,'' she must '''present[] sufficient mitigating evidence to assure the Administrator that [she] can be entrusted with the responsibility carried by such a registration.' '' *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988)). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), this Agency has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [her] actions and demonstrate that [she] will not engage in future misconduct.'' *Medicine Shoppe-Jonesborough,* 73 FR at 387.

During her testimony, Respondent continued to deny that she was responsible for the unaccounted-for hydrocodone and blamed her husband and R.K. Furthermore, the ALJ found incredible Respondent's denial that she had knowledge of R.K.'s illegal activities. DEA has repeatedly held that a registrant's lack of candor is a highly relevant consideration in determining the appropriate sanction. *See Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005); *Robert F. Hunt,* 75 FR 49995, 50004 (2010); *Rosemary Jacinta Lewis,* 72 FR 4035, 4042 (2007). Respondent's lack of candor further supports the revocation of her registration.

Given the scope of the diversion which likely occurred here and what the ALJ characterized as Respondent's minimal acceptance of responsibility

(which was limited to the statements of counsel in a post-hearing brief and which do not constitute evidence, *see INS* v. *Phinpathya,* 464 U.S. 183, 186 n.6 (1984)), I conclude that none of the ''favorable facts'' cited by the ALJ provide any reason to impose a sanction less than revocation. *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009). Indeed, none of Respondent's proposed remedial measures mitigate the egregious harm Respondent has caused to public health and safety.

I therefore conclude that it would be inconsistent with the public interest to grant her even a restricted registration. Accordingly, I will order that Respondent's registration be revoked and that any pending application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as by 28 CFR 0.100(b), I hereby order that DEA Certificate of Registration, AD9234446, issued to Satinder K. Dang, M.D., be, and it hereby is, revoked. I further order that any pending application of Satinder K. Dang, M.D., to renew or modify her registration be, and it hereby is, denied. This Order is effective September 22, 2011.

Dated: August 9, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–21065 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Roots Pharmaceuticals, Inc.; Revocation of Registration

On September 9, 2010, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Roots Pharmaceuticals, Inc. (Registrant), of American Fork, Utah. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration BR9610571, which authorizes it to dispense controlled substances as a retail pharmacy, on the ground that Registrant's state pharmacy and controlled substance licenses had expired on September 30, 2009, and that it therefore lacks authority under the laws of the State in which it is registered with DEA to dispense controlled substances. Show Cause Order at 1 (citing 21 U.S.C. 823(f) and 824(a)(3)). The Show Cause Order also notified Registrant of its right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for doing either, and the consequence for failing to do either. *Id.* at 2.

The Government's initial attempt to serve Registrant by certified mail was unsuccessful. Thereafter, as evidenced by the signed return receipt card, on January 14, 2011, the Government accomplished service by mailing the Show Cause Order to Registrant's Registered Agent. On January 11, 2011, the Government also sent an electronic version of the Show Cause Order to Registrant's Registered Agent at the e-mail address he had previously provided to the Agency. However, since the date of service of the Show Cause Order, no person has requested a hearing, or submitted a written statement in lieu of a hearing, on behalf of Registrant. Because thirty days have now passed since service of the Show Cause Order, I find that Registrant has waived its right to request a hearing or to submit a written statement in lieu of a hearing. *See* 21 CFR 1301.43(a), (c), and (d). I therefore issue this Decision and Final Order without a hearing based on relevant evidence contained in the record submitted by the Government. *Id.* § 1301.43(e).

Findings

Registrant is the holder of DEA Certificate of Registration BR9610571, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered location of 12 W 100N, Suite 201B, American Fork, Utah. GX A. Registrant's registration does not expire until April 30, 2012. *Id.*

According to a Pharmacy Licensing Specialist with the State of Utah, Department of Commerce, Division of Occupational and Professional Licensing, Registrant's Utah Pharmacy License and Utah Controlled Substance Dispensing License expired on September 30, 2009. GX B. Registrant did not renew either license. *Id.*

Discussion

Under the Controlled Substances Act (CSA), a practitioner must be currently authorized to handle controlled substances in the ''jurisdiction in which [it] practices'' in order to maintain a DEA registration. *See* 21 U.S.C. 802(21) (''[t]he term 'practitioner' means a * * * pharmacy * * * licensed, registered, or otherwise permitted, by * * * the jurisdiction in which [it] practices * * * to * * * dispense * * * a controlled substance in the course of professional practice''). *See also id.* § 823(f) (The Attorney General shall register practitioners * * * to dispense * * * controlled substances * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which [it] practices.''). As these provisions make plain, possessing authority under state law to handle controlled substances is an essential condition for obtaining and maintaining a DEA registration.

The CSA further authorizes the Agency to revoke a registration ''upon a finding that the registrant * * * has had [its] State license or registration suspended [or] revoked * * * and is no longer authorized by State law to engage in the * * * distribution [or] dispensing of controlled substances.'' 21 U.S.C. 824(a)(3). Moreover, because holding state authority is a statutory requirement for registration as a practitioner, *see* 21 U.S.C. 802(21) and 823(f), DEA has held that revocation is warranted even when a registrant has merely allowed his state licenses to expire. *James Stephen Ferguson*, 75 FR 49994, 49995 (2010); *Mark L. Beck*, 64 FR 40899, 40900 (1999). *See also Anne Lazar Thorn*, 62 FR 12847, 12848 (1997) (''the controlling question is not whether a practitioner's license to practice medicine in the state is suspended or revoked; rather, it is whether the Respondent is currently authorized to handle controlled substances'').

As found above, Registrant allowed its state pharmacy and controlled substance licenses to expire, and thus, it no longer holds authority under Utah law to dispense controlled substances. *See* Utah Code Ann. §§ 58–17b–302(1); 58–37–6(2)(a)(i). Accordingly, Registrant no longer satisfies the CSA's requirement that it be currently ''authorized to dispense controlled substances'' under Utah law. 21 U.S.C. 823(f). Accordingly, its DEA registration will be revoked. *Id.* § 824(a)(3).

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(3), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BR9610571, issued to Roots Pharmaceuticals, Inc., be, and it hereby is, revoked. I further order that any pending application of Roots Pharmaceuticals, Inc., to renew or modify its registration, be, and it hereby is, denied. This Order is effective September 19, 2011.

Dated: August 5, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–21063 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Prohibited Transaction Exemptions and Grant of Individual Exemptions

Notice of Technical Correction

Prohibited Transaction Exemptions and Grant of Individual Exemptions Involving D–11468 and D–11469, The Krispy Kreme Doughnut Corporation Retirement Savings Plan and The Krispy Kreme Profit-Sharing Stock Ownership Plan, 2011–14; D–11634, The United Brotherhood of Carpenters Pension Fund, 2011–15; L–11651 and L–11652, Verizon Communications, Inc. and Cellco Partnership, 2011–16, *et al.*

In the **Federal Register** notice document 2011–20342, beginning on page 49788 of the Thursday, August 11, 2011 issue, the prohibited transaction exemption numbers were incorrectly cited. Accordingly, the Department is hereby making the following technical corrections to above referenced grant notices:

1. On page 49788, in the third column, above the heading ''Exemption,'' for ''The Krispy Kreme Doughnut Corporation Retirement and Savings Plan (the Savings Plan) and the Krispy Kreme Profit-Sharing Stock Ownership Plan the KSOP; together, the Plans)'' replace the bracketed text ''[Prohibited Transaction Exemption 2011–10;]'' with ''[Prohibited Transaction Exemption 2011–14;].''

2. On page 49790, in the second column, above the heading ''Exemption,'' for ''The United Brotherhood of Carpenters Pension Fund (the Plan),'' replace the bracketed text ''[Prohibited Transaction Exemption 2011–11;]'' with ''[Prohibited Transaction Exemption 2011–15;].''

3. On page 49790, in the third column, above the heading ''Exemption,'' for ''Verizon Communications, Inc. (Verizon) and Cellco Partnership, doing business as Verizon Wireless (Verizon Wireless; collectively, the Applicants),'' replace the bracketed text ''[Prohibited Transaction Exemption 2011–12;]'' with ''[Prohibited Transaction Exemption 2011–16;].''

Signed at Washington, DC, this 12th day of August, 2011.

Ivan L. Strasfeld,

Director of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2011–21033 Filed 8–17–11; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–75,056; TA–W–75,056A]

Ericsson Services, Inc., Currently Known as Ericsson, Inc., Service Assurance, Deployment and Integration, and Engineering and IS/IT Divisions, Including On-Site Leased Workers From Brook Consultants, Inc., Cortech LLC, Adex Corporation, American Cybersystems, Inc., Apeiron, Inc., Apex Systems, Inc., ARC Partners, Inc., Avion Systems, Inc., BCI Communications, Inc., Brosna Communications, Collaborative, LLC, Convergenz, LLC, Fusion Solutions, Inc., GCB Services LLC, Global Technology Associates, HCONN, Inc., J.M. Neil and Associates, Inc., JMA Chartered, Makro Technologies, Inc., Multi Services, Inc., Multipoint International, Nexius, Inc., Technisource, Inc., Teksystems, Inc., T–Force, Inc., Thinktel, Inc., United Information Technologies, Wireless Facilities, Inc., Overland Park, KS; Ericsson Services, Inc., Currently Known as Ericsson, Inc., Service Assurance, Deployment and Integration, and Engineering and IS/IT Divisions, Including On-Site Leased Workers From Convergenz, LLC, Kansas City, MO; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on February 3, 2011, applicable to workers of Ericsson Services, Inc., currently known as Ericsson, Inc., Service Assurance, Deployment and Integration, and Engineering and IS/IT Division, including on-site leased workers from Brook Consultants Inc., Cortech LLC, Adex Corporation, American Cybersystems Inc., Apeiron Inc., Apex Systems Inc., ARC Partners Inc., Avion Systems Inc., BCI Communications Inc., Brosna Communications, Collaborative LLC, Convergenz LLC, Corestaff Services LP, FMHC Corporation, Fusion Solutions Inc., GCB Services LLC, Global Technology Associates, HCONN Inc., J.M. Neil and Associates Inc., JMA Chartered, Makro Technologies Inc., Multi Services Inc., Multipoint International, Nexius Inc., Technisource Inc., Teksystems Inc., T–Force Inc., Thinktel Inc., United Information Technologies, and Wireless Facilities, Inc., Overland Park, Kansas. The workers provide telecommunications services. The notice was published in the **Federal Register** on February 24, 2011 (76 FR 10399).

At the request of a company official, the Department reviewed the certification for workers of the subject firm.

New information provided by the company confirms that workers at the Kansas City, Missouri location of Ericsson Services, Inc., currently known as Ericsson, Inc., Service Assurance, Deployment and Integration, and Engineering and IS/IT Divisions are part of the same worker group as the group certified under TA–W–75,056. Moreover, worker separations at the Kansas City, Missouri facility are attributable to the same shift of services that was the basis for certification TA–W–75,056.

Based on these findings, the Department is amending this certification to include employees of the Kansas City, Missouri location of Ericsson Services, Inc., currently known as Ericsson, Inc., Service Assurance, Deployment and Integration, and Engineering and IS/IT Division, including on-site leased workers from Convergenz, LLC.

The amended notice applicable to TA–W–75,056 is hereby issued as follows:

All workers of Ericsson Services, Inc., currently known as Ericsson, Inc., Service Assurance, Deployment and Integration, and Engineering and IS/IT Divisions including on-site leased workers from Brook Consultants Inc., Cortech LLC, Adex Corporation, American Cybersystems Inc., Apeiron Inc., Apex Systems Inc., ARC Partners Inc., Avion Systems Inc., BCI Communications Inc., Brosna Communications, Collaborative LLC, Convergenz LLC, Corestaff Services LP, FMHC Corporation, Fusion Solutions Inc., GCB Services LLC, Global Technology Associates, HCONN Inc., J.M. Neil and Associates Inc., JMA Chartered, Makro Technologies Inc., Multi Services Inc., Multipoint International, Nexius, Inc., Technisource Inc., Teksystems Inc., T–Force Inc., Thinktel Inc., United Information Technologies, and Wireless Facilities, Inc. Overland Park, Kansas (TA–W–75,056) and Ericsson Services, Inc., currently known as Ericsson, Inc., Service Assurance, Deployment and Integration, and Engineering and IS/IT Divisions, including on-site leased workers from Convergenz, LLC, Kansas City, Missouri (TA–W–75,056A) who became totally or partially separated from employment on or after December 29, 2009, through February 3, 2013, and all workers in the group threatened with total or partial separation from employment on February 3, 2011 through February 3, 2013, are eligible to apply for adjustment assistance under

Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 4th day of August, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–21054 Filed 8–17–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–70,520; TA–W–70,520A]

The Boeing Company; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In The Matter of: TA–W–70,520; The Boeing Company,

Commercial Aircraft Group; Including On-Site Leased Workers From Comforce Corporation, Adecco, Multax, Inconen, CTS, Hi-Tec, Woods, Ciber, Kelly Services, Analysts Internatinal Corp, Comsys, Filter LLC, Excell, Entegee, Chipton-Ross, Ian Martin, Can-Tech, IT Services, IDEX Solutions (NWCAD), Media Logic, HL YOH, Volt, PDS, CDI Corp, Teksystems, Innovative Systems, Inc., Murphy & Associates, Dell, PFI Tech, RMS and PSC Industrial Services, Inc.; Puget Sound, Washington.

In the matter of; TA–W–70,520A; The Boeing Company, Commercial Aircraft Group; Including On-Site Leased Workers From Comforce Corporation, Adecco, Multax, Inconen, CTS, Hi-Tec, Woods, Ciber, Kelly Services, Analysts Internatinal Corp, Comsys, Filter LLC, Excell, Entegee, Chipton-Ross, Ian Martin, Can-Tech, IT Services, IDEX Solutions (NWCAD), Media Logic, HL YOH, Volt, PDS, CDI Corp, Teksystems, Innovative Systems, Inc., Murphy & Associates, Dell, PFI Tech, RMS And PSC Industrial Services, Inc., Portland, Oregon; Amended Certification Regarding Eligibility To Apply For Worker Adjustment Assistance.

In accordance with section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to apply for Worker Adjustment Assistance on October 19, 2009, applicable to workers of The Boeing Company, Commercial Aircraft Group, Puget Sound, Washington, (TA–W–70,520), and The Boeing Company, Commercial Aircraft Group, Portland, Oregon (TA–W–70,520A). The notice was published in the **Federal Register** on December 11, 2009 (74 FR 65794–65795). The notice was amended on January 8, 2010 and March 26, 2010 to include on-site leased workers. The notices were published in the **Federal Register** on January 20, 2010 (75 FR 3250–3251) and on April 19, 2010 (75 FR 20385–20386), respectively. The workers are engaged in activities related to the production of large commercial aircraft.

The company reports that on-site leased workers from PSC Industrial Services, Inc. were employed on-site at both the Puget Sound, Washington and Portland, Oregon locations of The Boeing Company, Commercial Aircraft Group. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending the certification to include leased workers from PSC Industrial Services, Inc. working on-site at the Puget Sound, Washington and Portland, Oregon locations of The Boeing Company, Commercial Aircraft Group.

The amended notice applicable to the TA–W–70,520 and TA–W 70,520A are hereby issued as follows:

All workers of The Boeing Company, Commercial Aircraft Group, including on-site leased workers from Comforce Corporation, Adecco, Multax, Inconen, CTS, Hi-Tec, Woods, Ciber, Kelly Services, Analysts International Corp, Comsys, Filter LLC, Excell, Entegee, Chipton-Ross, Ian Martin, Can-Tech, IT Services, IDEX Solutions (NW CAD), Media Logic, HL YOH, Volt, PDS, CDI Corp, Teksystems, Innovative Systems, Inc., Murphy & Associates, Dell, PFI Tech, RMS and PSC Industrial Services, Inc., Puget Sound, Washington (TA–W–70,520), and Portland, Oregon (TA–W–70,520A), who became totally or partially separated from employment on or after May 22, 2008, through October 19, 2011, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 4th day of August, 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–21057 Filed 8–17–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of July 25, 2011 through July 29, 2011.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. the sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding

eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA–W–80,093; The Pearlson Company, LLC, Montpelier, Ohio: March 7, 2010.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–80,002; Babcock & Wilcox Power Generation Group, Inc., Barberton, Ohio: February 15, 2010

TA–W–80,046; General Aluminum, Rome, Georgia: March 14, 2010

TA–W–80,226; Camco Cedar, Tacoma, Washington: June 28, 2010

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–80,107; Muller Martini Manufacturing Corp., Newport News, Virginia: April 13, 2010

TA–W–80,149; Doral Manufacturing, Inc., Doral, Florida: July 1, 2011

TA–W–80,158; Flextronics, San Diego, California: May 3, 2010

TA–W–80,169; Boardman Molded Products, Kessler Marketing Group, Youngstown, Ohio: April 30, 2010

TA–W–80,181; L'Oreal, USA Products, Clark, New Jersey: May 9, 2010

TA–W–80,237; Inteva Products, LLC, Gadsden, Alabama: June 15, 2010

TA–W–80,255; Technicolor Business Group, Camarillo, California: October 3, 2011

TA–W–80,259; Welded Tube of Canada, Inc., Delta, Ohio: June 15, 2010

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of Section 246 has not been met. The firm does not have a significant number of workers 50 years of age or older.

TA–W–80,093; The Pearlson Company, LLC, Montpelier, Ohio: Negative Determinations For Worker Adjustment Assistance And Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

TA–W–208; General Motors Components Holdings, LLC, Rochester, New York

TA–W–80,247; DMAX Ltd., LLC, Moraine, Ohio

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–80,015; ACS Commercial Solutions, Inc., Liberty, Kentucky

TA–W–80,028; Affiliated Computer Services, Inc., Hillsboro, Oregon

TA–W–80,052; Lancaster Eagle-Gazette, Lancaster, Ohio

TA–W–80,053; Shiloh Steel Fabricators, Bethel Heights, Arkansas

TA–W–80,057; Orchard Brands, Athens, Georgia

TA–W–80,266; BAE Systems, Survivability Systems, LLC, Fairfield, Ohio

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–80,013; Robb & Stucky Limited, LLP, Fort Myers, Florida

Determinations Terminating Investigations Of Petitions For Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 USC 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioning groups of workers are covered by active certifications. Consequently, further investigation in these cases would serve no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

TA–W–80,012; Siemens Medical Solutions USA, Inc., Malvern PA

TA–W–80,171; Panasonic Corporation of North America, Rolling Meadow, Illinois

I hereby certify that the aforementioned determinations were issued during the period of *July 25, 2011 through July 29, 2011.* Copies of these determinations may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA),

U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or *tofoiarequest@dol.gov.* These determinations also are available on the Department's Web site at http://*www.doleta.gov/tradeact* under the searchable listing of determinations.

Dated: August 5, 2011.

Del Min Amy Chen,

Certifying Officer, Office, Trade Adjustment Assistance.

[FR Doc. 2011–21055 Filed 8–17–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of *August 1, 2011 through August 5, 2011.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (*i.e.,* conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–80,081; SuperMedia, LLC, Los Alamitos, Texas; March 29, 2010.

TA–W–80,130; Oak Patch Gifts, LLC, Eugene, Oregon: April 19, 2010.

TA–W–80,133; Nevion USA, Inc., Oxnard, California; April 26, 2010.

TA–W–80,276; Foster Needle Co., Inc., Manitowoc, Wisconsin; June 30, 2010.

TA–W–80,296; B&H Flowers, Inc., Watsonville, California; July 31, 2010.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–80,254; PI. US Holding, Inc., Fort Smith, Arkansas; June 24, 2010.

TA–W–80,277; Vermont Transformer, Inc., Saint Albans, Vermont; July 7, 2010.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–80,210; United Solar Ovonic, Greenville, Michigan; June 1, 2010.

TA–W–80,283; Craftwood, Inc., High Point, North Carolina; February 7, 2011.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the

workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–80,066; Ivex Packaging Paper, LLC, Joliet, Illinois.

TA–W–80,195; Preferred Dental Lab, Roseland, New Jersey.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–80,008; Twin County Ford, Woodlawn Virginia.

TA–W–80,152; Compone Services, LTD, Ithaca, New York.

TA–W–80,154; State Street Corporation, Irvine, California.

TA–W–80,192; Sykes Enterprises, Inc., Morganfield, Kentucky.

TA–W–80,257; Liz Claiborne, Inc., West Chester, Ohio.

TA–W–80,281; Priceline.com, Inc., Grand Rapids, Michigan.

TA–W–80,800; Rancho La Puerta, LLC, San Diego, California.

I hereby certify that the aforementioned determinations were issued during the period of *August 1, 2011 through August 5, 2011.* Copies of these determinations may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or *tofoiarequest@dol.gov.* These determinations also are available on the Department's Web site at *http://www.doleta.gov/tradeact* under the searchable listing of determinations.

Dated: August 8, 2011

Michael W. Jaffe,

Certifying Officer, Office, Trade Adjustment Assistance.

[FR Doc. 2011–21056 Filed 8–17–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Request for Certification of Compliance; Rural Industrialization Loan and Grant Program

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The Employment and Training Administration is issuing this notice to announce the receipt of a ''Certification of Non-Relocation and Market and Capacity Information Report'' (Form 4279–2) for the following:

Applicant/Location: LWRC International, LLC, Cambridge, Maryland.

Principal Product/Purpose: The loan, guarantee, or grant application is to support the expansion of business to the international market. The project will be located in Cambridge, Maryland. The NAICS industry code for this enterprise is: 332994 (rifles and services).

DATES: All interested parties may submit comments in writing no later than September 1, 2011.

Copies of adverse comments received will be forwarded to the applicant noted above.

ADDRESSES: Address all comments concerning this notice to Anthony D. Dais, U.S. Department of Labor, Employment and Training Administration, 200 Constitution Avenue, NW., Room S–4231, Washington, DC 20210; or e-mail *Dais.Anthony@dol.gov;* or transmit via fax (202) 693–3015 (this is not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Anthony D. Dais, at telephone number (202) 693–2784 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 188 of the Consolidated Farm and Rural Development Act of 1972, as established under 29 CFR part 75, authorizes the United States Department of Agriculture to make or guarantee loans or grants to finance industrial and business activities in rural areas. The Secretary of Labor must review the application for financial assistance for the purpose of certifying to the Secretary of Agriculture that the assistance is not calculated, or likely, to result in: (a) A transfer of any employment or business activity from one area to another by the loan applicant's business operation; or, (b) An increase in the production of goods, materials, services, or facilities in an area where there is not sufficient demand to employ the efficient capacity of existing competitive enterprises unless the financial assistance will not have an adverse impact on existing competitive enterprises in the area. The Employment and Training Administration within the Department of Labor is responsible for the review and certification process. Comments should address the two bases for certification and, if possible, provide data to assist in the analysis of these issues.

Signed: at Washington, DC this 15th day of August, 2011.

Jane Oates,

Assistant Secretary for Employment and Training.

[FR Doc. 2011–21093 Filed 8–17–11; 8:45 am]

BILLING CODE 4510–FN–P

POSTAL REGULATORY COMMISSION

[Docket No. A2011–44; Order No. 800]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Grant, Iowa post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: *Administrative record due (from Postal Service*): August 26, 2011; *deadline for notices to intervene:* September 6, 2011. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on August 11, 2011, the Commission received a petition for review of the Postal Service's determination to close the post office in Grant, Iowa. The petition was filed by Laurenda Mifflin (Petitioner) and is postmarked August 5, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2011–44 to consider Petitioner's appeal. If Petitioner would like to further explain her position with supplemental information or facts, Petitioner may

either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than September 15, 2011.

Categories of issues apparently raised. Petitioner contends that: (1) The Postal Service failed to consider the effect of the closing on the community (*see* 39 U.S.C. 404(d)(2)(A)(i)); and (2) the Postal Service failed to adequately consider the economic savings resulting from the closure (*see* 39 U.S.C. 404(d)(2)(A)(iv)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than those set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record with the Commission is August 26, 2011. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service to this notice is August 26, 2011.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participants' submissions also will be posted on the Commission's Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at 202–789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., eastern time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at 202–789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov*, unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at 202–789–6846.

The Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than Petitioner and respondent, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before September 6, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by the Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The Postal Service shall file the applicable administrative record regarding this appeal no later than August 26, 2011.
2. Any responsive pleading by the Postal Service to this notice is due no later than August 26, 2011.
3. The procedural schedule listed below is hereby adopted.
4. Pursuant to 39 U.S.C. 505, Emmett Rand Costich is designated officer of the Commission (Public Representative) to represent the interests of the general public.
5. The Secretary shall arrange for publication of this notice and order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

PROCEDURAL SCHEDULE

August 11, 2011	Filing of Appeal.
August 26, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
August 26, 2011	Deadline for the Postal Service to file any responsive pleading.
September 6, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
September 15, 2011	Deadline for Petitioner's Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
October 5, 2011	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
October 20, 2011	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
October 27, 2011	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
December 5, 2011	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–21022 Filed 8–17–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2011–45; Order No. 801]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Sublime, Texas post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: *Administrative record due (from Postal Service*): August 26, 2011; *deadline for notices to intervene:* September 6, 2011. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on August 11, 2011, the Commission received a petition for review of the Postal Service's determination to close the post office in Sublime, Texas. The petition was filed by Betty Bunch on behalf of the Save the Sublime Post Office Committee (Petitioner) and is postmarked August 6, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2011–45 to consider Petitioner's appeal. If Petitioner would like to further explain her position with supplemental information or facts, Petitioner may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than September 15, 2011.

Categories of issues apparently raised. Petitioner contends that the Postal Service failed to consider whether or not it will continue to provide a maximum degree of effective and regular postal services to the community. *See* 39 U.S.C. 404(d)(2)(A)(iii).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than the one set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record with the Commission is August 26, 2011. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service to this notice is August 26, 2011.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participants' submissions also will be posted on the Commission's Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at 202–789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., eastern time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at 202–789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at 202–789–6846.

The Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than Petitioner and respondent, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before September 6, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by the Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The Postal Service shall file the applicable administrative record regarding this appeal no later than August 26, 2011.
2. Any responsive pleading by the Postal Service to this notice is due no later than August 26, 2011.
3. The procedural schedule listed below is hereby adopted.
4. Pursuant to 39 U.S.C. 505, Cassandra L. Hicks is designated officer of the Commission (Public Representative) to represent the interests of the general public.
5. The Secretary shall arrange for publication of this notice and order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

PROCEDURAL SCHEDULE

August 11, 2011	Filing of Appeal
August 26, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
August 26, 2011	Deadline for the Postal Service to file any responsive pleading.
September 6, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
September 15, 2011	Deadline for Petitioner's Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
October 5, 2011	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
October 20, 2011	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).

PROCEDURAL SCHEDULE—Continued

October 27, 2011	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
December 6, 2011	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–21023 Filed 8–17–11; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549.

Extension:

Rule 17f–2(e); SEC File No. 270–37; OMB Control No. 3235–0031.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for approval of extension of the previously approved collection of information provided for in Rule 17f–2(e) (17 CFR 240.17f–2(e)) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17f–2(e) requires members of national securities exchanges, brokers, dealers, registered transfer agents, and registered clearing agencies claiming exemption from the fingerprinting requirements of Rule 17f–2 to prepare and maintain a statement supporting their claim exemption. There is no filing requirement. Instead, Rule 17f–2(e)(2) requires covered entities to make and keep current a copy of the notice required by Rule 17f–2(e) in an easily accessible place at the organization's principal office and at the office employing the persons for whom exemptions are claimed and shall be made available upon request for inspection by the Commission, appropriate regulatory agency (if not the Commission) or other designated examining authority. Notices prepared pursuant to Rule 17f–2(e) must be maintained for as long as the covered entity claims an exemption from the fingerprinting requirements of Rule 17f–2. The recordkeeping requirement under Rule 17f–2(e) assists the Commission and other regulatory agencies with ensuring compliance with Rule 17f–2. This rule does not involve the collection of confidential information.

We estimate that approximately 75 respondents will incur an average burden of 30 minutes per year to comply with this rule, which represents the time it takes for a staff person at a covered entity to properly document a claimed exemption from the fingerprinting requirements of Rule 17f–2, and properly retain that document according to the entities record retention policies and procedures. The total annual burden for all covered entities is approximately 38 hours (75 entities × .5 hours).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number.

Background documentation for this information collection may be viewed at the following link, *http://www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an e-mail to: *Shagufta_Ahmed@omb.eop.gov*; and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

August 12, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–21030 Filed 8–17–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 17a–10; SEC File No. 270–154; OMB Control No. 3235–0122.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 17a–10 (17 CFR 240.17a–10) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'').

Paragraph (a)(1) of Rule 17a–10 generally requires broker-dealers that are exempted from the requirement to file monthly and quarterly reports pursuant to paragraph (a) of Exchange Act Rule 17a–5 (17 CFR 240.17a–5) to file with the Commission the Facing Page, a Statement of Income (Loss), and balance sheet from Part IIA of Form X–17A–5 [1] (17 CFR 249.617), and Schedule I of Form X–17A–5 not later than 17 business days after the end of each calendar year.

Paragraph (a)(2) of Rule 17a–10 requires a broker-dealer subject to Rule 17a–5(a) to submit Schedule I of Form X–17A–5 with its Form X–17A–5 for the calendar quarter ending December 31 of each year. The burden associated with filing Schedule I of Form X–17A–5 is accounted for in the PRA filing associated with Rule 17a–5.

[1] Form X–17A–5 is the Financial and Operational Combined Uniform Single Report (''FOCUS Report''), which is used by brokers and dealers to provide certain required information to the Commission.

Paragraph (b) of Rule 17a–10 provides that the provisions of paragraph (a) do not apply to members of national securities exchanges or registered national securities associations that maintain records containing the information required by Form X–17A–5 and which transmit to the Commission copies of the records pursuant to a plan which has been declared effective by the Commission.

The primary purpose of Rule 17a–10 is to obtain the economic and statistical data necessary for an ongoing analysis of the securities industry. As originally adopted in 1968, Rule 17a–10 required brokers and dealers to provide their revenue and expense data on a special form. The Rule was amended in 1977 to eliminate the form. The data previously reported on the form is now reported using Form X–17A–5 and its supplementary schedules.

The Commission estimates that approximately 103 broker-dealers will spend an average of approximately 12 hours per year complying with Rule 17a–10. Thus, the total compliance burden is estimated to be approximately 1,236 burden-hours per year.[2]

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

Background documentation for this information collection may be viewed at the following link, *http://www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an e-mail to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

August 12, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–21031 Filed 8–17–11; 8:45 am]

BILLING CODE 8011–01–P

[2] The number of burden hours stated in this notice is lower than the number of burden hours stated in the 60 day notice (''Proposed Collection; Comment Request'') published earlier this year in connection with this OMB control number. The reason for this difference is that the burden hours stated in the 60-day notice had been based on the number of respondent broker-dealers who had complied with Rule 17a–10 during 2009 (*i.e.,* 168 respondents), whereas the burden hours in this notice reflect the more updated number of respondent broker-dealers who complied with Rule 17a–10 during 2010 (*i.e.,* 103 respondents).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65114; File No. SR–NSX–2011–10]

Self-Regulatory Organizations; National Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend NSX Rule 11.19(c) Relating to Clearly Erroneous Transactions

August 11, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 11, 2011, National Stock Exchange, Inc. filed with the Securities and Exchange Commission (''Commission'') the proposed rule change, as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comment on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

National Stock Exchange, Inc. (''NSX®'' or ''Exchange'') proposes to amend its rules to ensure NSX Rule 11.19(c) will continue to operate in the same way after changes to the single stock trading pauses are effective.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nsx.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

The exchanges [3] and FINRA (collectively, the ''Markets''), in consultation with the Securities and Exchange Commission (''SEC'' or the ''Commission''), have made changes to their respective rules in a concerted effort to strengthen the markets after the severe market disruption that occurred on May 6, 2010. One such effort by the Markets was to adopt a uniform trading pause process during periods of extraordinary market volatility as a pilot in S&P 500 Index stocks (''Pause Pilot''), approved by the Commission on June 10, 2010.[4] On September 10, 2010, the Commission approved the Market's proposals to add the securities included in the Russell 1000 Index and specified ETPs to the Pause Pilot.[5] On September 10, 2010, the Commission also approved changes proposed by the Markets to amend certain of their respective rules to set forth clearer standards and curtail their discretion with respect to breaking erroneous trades.[6] The changes, among other things, provided uniform treatment of clearly erroneous execution

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] For purposes of this filing, the term ''Exchanges'' refers collectively to BATS Exchange, Inc., BATS Y–Exchange, Inc., NASDAQ OMX BX, Inc., Chicago Board Options Exchange, Inc., Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., International Securities Exchange LLC, The NASDAQ Stock Market LLC, New York Stock Exchange LLC, NYSE Amex LLC, NYSE Arca, Inc., National Stock Exchange, Inc., and NASDAX [sic] OMX PHLX LLC.

[4] Securities Exchange Act Release Nos. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010– 01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047); 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[5] *See e.g.,*Securities Exchange Act Release Nos. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08); and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033).

[6] Securities Exchange Act Release No. 62886 (September 16, 2010), 75 FR 56613 (September 16, 2010) (File Nos. SR–BATS–2010–016; SR–BX–2010–040; SR–CBOE–2010–056; SR–CHX–2010–13; SR–EDGA–2010–03; SR–EDGX–2010–03; SR–ISE–2010–62; SR–NASDAQ–2010–076; SR–NSX–2010–07; SR–NYSE–2010–47; SR–NYSEAmex–2010–60; and SR–NYSEArca–2010–58).

reviews in the event of transactions that result in the issuance of an individual stock trading pause pursuant to the Pause Pilot on the listing market and those that occur up to the time the trading pause message is received by the other markets from the single plan processor responsible for consolidation and dissemination of information for the security (''Latency Trades'').

As part of the changes to the clearly erroneous process under Rule 11.19, the Exchange replaced existing Rule 11.19(c)(4) with all new text to provide clarity in the clearly erroneous process when a Pause Pilot trading pause is triggered. Pursuant to Rule 11.19(c)(4), Latency Trades will be broken by the Exchange if they exceed the applicable percentage from the Reference Price, as noted in the table found under Rule 11.19(c)(1).[7] The Reference Price, for purposes of Rule 11.19(c)(4), is the price that triggered a trading pause pursuant to the Pause Pilot (the ''Trading Pause Trigger Price''). As such, Latency Trades that occur on the Exchange would be broken by the Exchange pursuant to Rule 11.19(c)(4) if the transaction occurred at either three, five or ten percent above the Trading Pause Trigger Price.[8]

On June 23, 2011, the Commission approved a joint proposal to expand the respective Pause Pilot rules of the Markets to include all remaining NMS stocks (''Phase III Securities'').[9] The new pilot rules, which will be implemented on August 8, 2011, not only expand the application of the Pause Pilot, but also apply larger percentage moves that trigger a pause to the Phase III Securities. Specifically, the rules of the listing markets were amended so that a pause in a Phase III Security with a closing price on the previous trading day of $1 or more is triggered by a 30 percent price move within a five minute period. A pause in a Phase III Security with closing price on the previous trading day of less than $1 is triggered by a 50 percent price move within a five minute period. If no prior day closing price is available, the last sale reported to the Consolidated Tape on the previous trading day is used.

The Issue

The recently-approved changes to the Pause Pilot will have the unintended effect of removing the Phase III Securities from the normal clearly erroneous process and potentially result in unfair outcomes in the face of severe volatility in such securities. Phase III Securities are currently subject to the clearly erroneous process under Rules 11.19(c)(1) to 11.19(c)(3), which apply to all securities except the current Pause Pilot securities subject to a pause. For purposes of transactions in securities not involving Pause Pilot securities, or transactions involving Pause Pilot securities that occur when there is not a pause pursuant to the Pause Pilot, the Reference Price is the consolidated last sale price immediately prior to the execution(s) under review, subject to certain exceptions.[10] As noted above, the Trading Pause Trigger Price is used as the Reference Price when a Pause Pilot pause is in effect. As a consequence, under the current rules, a Latency Trade is subject to the clearly erroneous thresholds based on the Trading Pause Trigger Price, which represents a ten percent or greater move in the transacted price of the security in a five minute period.

Under the new Pause Pilot rules, a Latency Trade in a Phase III Security occurs only after either a 30 or 50 percent (or greater) move in the transacted price of the security in a five minute period. As a result, a ETP Holder that trades in a Phase III Security that triggers a clearly erroneous threshold of three, five or ten percent from the Reference Price, yet falls below the Pause Pilot trigger of either 30 or 50 percent, would be able to avail themselves of a clearly erroneous review. A similarly situated ETP Holder that transacts in the same security as a Latency Trade at a price equal to or greater than the Phase III Security thresholds, yet less than the clearly erroneous thresholds under Rule 11.19(c)(1), would not be able to avail themselves of the clearly erroneous process. Another ETP Holder that transacts in the same security as a Latency Trade that exceeds three, five or ten percent from the Trading Pause Trigger Price would automatically receive clearly erroneous relief. The Exchange believes that this would be an inequitable result and an arbitrary application of the clearly erroneous process. Specifically, the Exchange believes that, since the 30 and 50 percent triggers of the Pause Pilot are substantially greater than the 10 percent threshold of the original Pause Pilot, the Phase III Securities should remain under the current clearly erroneous process of Rules 11.19(c)(1)–(3).

Applying the clearly erroneous process under Rules 11.19(c)(1)–(3) to the Phase III Securities would allow the Exchange to review all transactions that exceed the normal clearly erroneous thresholds and Reference Price, and, importantly, avoid arbitrary selection of ''winners'' and ''losers'' in the face of severe volatile moves in a security of 30 or 50 percent over a five minute period. For example, an ETP Holder that trades in a Phase III Security that triggers a clearly erroneous threshold of three, five or ten percent, yet falls below the Pause Pilot trigger threshold trading at 29 percent from the prior day's closing price, would be potentially entitled to a clearly erroneous break pursuant Rule 11.19(c)(1). Should trading in that same stock trigger a trading pause at a price of 30 or 50 percent greater than the prior day's close, the ETP Holder would not be entitled to a clearly erroneous trade break unless that trade exceeded three, five or ten percent beyond the price that triggered the pause. This scenario causes an inequity among a group of ETP Holders that have transactions in the Phase III Securities falling between the three, five and ten percent thresholds from the Reference Price under the normal Rule 11.19(c)(1) clearly erroneous process and the Pause Pilot clearly erroneous triggers of three, five or ten percent away from the Trading Pause Trigger Price. Such ETP Holders would not be provided relief under the clearly erroneous rules merely due to the imposition of a Pause Pilot halt, notwithstanding that other ETP Holders with transactions that occur at the same rolling five minute percentage difference. The Exchange believes a better outcome is to afford all ETP Holders transacting in Phase III Securities the opportunity of having such trades reviewed.

Summary

The expansion of the Pause Pilot to the Phase III Securities will have the unintended consequence of setting the point at which a clearly erroneous transaction occurs once a Pause Pilot pause is initiated far beyond the triggers applied prior to the expansion, which will, in turn, prevent certain market participants from availing themselves of the clearly erroneous rules, notwithstanding that other similarly situated participants are able to do so. The Exchange believes that this would be an arbitrary application of the clearly erroneous process in a manner that is

[7] Pursuant to Rule 11.19(c)(1), a security with a Reference Price of greater than zero and up to and including $25 is subject to a 10% threshold; a security with a Reference Price of greater than $25 and up to and including $50 is subject to a 5% threshold; and a security with a Reference Price of greater than $50 is subject to a 3% threshold.

[8] Rule 11.19 (c)(4).

[9] Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (File Nos. SR–BATS–2011–016; SR–BYX–2011–011; SR–BX–2011–025; SR–CBOE–2011–049; SR–CHX–2011–09; SR–EDGA–2011–15; SR–EDGX–2011–14; SR–FINRA–2011–023; SR–ISE–2011–028; SR–NASDAQ–2011–067; SR–NYSE–2011–21; SR–NYSEAmex–2011–32; SR–NYSEArca–2011–26; SR–NSX–2011–06; SR–Phlx–2011–64).

[10] *Id.*

unfair and not consistent with the spirit and purpose of the rule. Accordingly, the Exchange is proposing to amend Rules 11.19(c)(1)–(4) to specify that Rule 11.19(c)(4) applies only to the current securities of Pause Pilot, and not to Phase III Securities.[11]

2. Statutory Basis

The statutory basis for the proposed rule change is Section 6(b)(5) of the Securities Exchange Act of 1934 (the ''Act''),[12] which requires the rules of an exchange 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. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[13] of the Act in that it seeks to assure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule meets these requirements in that it promotes transparency and uniformity across markets concerning decisions to break erroneous trades, yet also ensures fair application of the process so that similarly situated ETP Holders are provided the same opportunity of a clearly erroneous review. The Exchange notes that the changes proposed herein will in no way interfere with the operation of the Pause Pilot process, as amended.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate 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 written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6)(iii) thereunder.[15] The Exchange has asked the Commission to waive the 5-day written notice requirement and the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver will allow the clearly erroneous rules to continue to operate as they did prior to the effectiveness of the Pause Pilot expansion to Phase III Securities so that similarly situated ETP Holders are provided the same opportunity of a clearly erroneous review. Accordingly, the Commission waives the 30-day operative delay requirement and designates the proposed rule change as operative upon filing with the Commission.[16]

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 e-mail to *rule-comments@sec.gov.* Please include File Number SR–NSX–2011–10 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–NSX–2011–10. This file number should be included on the subject line if e-mail 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 a.m. and 3 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–NSX–2011–10 and should be submitted on or before September 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–21025 Filed 8–17–11; 8:45 am]

BILLING CODE 8011–01–P

[11] NSX notes that the Exchanges are filing similar proposals to make the changes proposed herein.

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78k–1(a)(1).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6)(iii) requires that a self-regulatory organization submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission is waiving the five day written notice requirement in this case. Therefore, the Commission notes that the Exchange has satisfied this requirement.

[16] For 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).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65126; File No. SR–NYSEArca–2011–51]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To List and Trade Managed Fund Shares of TrimTabs Float Shrink ETF Under NYSE Arca Equities Rule 8.600

August 12, 2011.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'' or ''Exchange Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 29, 2011, 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, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade TrimTabs Float Shrink ETF under NYSE Arca Equities Rule 8.600. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.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 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 list and trade the following Managed Fund Shares [4] (''Shares'') under NYSE Arca Equities Rule 8.600: the TrimTabs Float Shrink ETF (''Fund'').[5] The Shares will be offered by AdvisorShares Trust (the ''Trust''), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company.[6] The investment adviser to the Fund is AdvisorShares Investments, LLC (the ''Adviser''). Trim Tabs Asset Management, LLC (''TrimTabs'' or ''Sub-Adviser'') is the Fund's sub-adviser and provides day-to-day portfolio management of the Fund. Foreside Fund Services, LLC (the ''Distributor'') is the principal underwriter and distributor of the Fund's Shares.

Commentary .06 to Rule 8.600 provides that, if the investment adviser to the Investment Company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Investment Company portfolio. In addition, Commentary .06 further requires that personnel who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the open-end fund's portfolio.[7] Commentary .06 to Rule 8.600 is similar to Commentary .03(a)(i) and (iii) to NYSE Arca Equities Rule 5.2(j)(3); however, Commentary .06 in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. Neither the Adviser nor the Sub-Adviser is affiliated with a broker-dealer. In the event (a) the Adviser or the Sub-Adviser becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser becomes affiliated with a broker-dealer, it will implement a fire wall with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

Description of the Fund

According to the Registration Statement, the Fund is an actively managed exchange-traded fund that seeks to achieve its investment objective primarily by investing in the broad U.S. equity market, as represented by the

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] A Managed Fund Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a) (''1940 Act'') organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Investment Company Units, listed and traded on the Exchange under NYSE Arca Equities Rule 5.2(j)(3), seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

[5] The Commission approved NYSE Arca Equities Rule 8.600 and the listing and trading of certain funds of the PowerShares Actively Managed Exchange-Traded Funds Trust on the Exchange pursuant to Rule 8.600 in Securities Exchange Act Release No. 57619 (April 4, 2008), 73 FR 19544 (April 10, 2008) (SR–NYSEArca–2008–25). The Commission also has approved listing and trading on the Exchange of a number of actively managed funds under Rule 8.600. *See, e.g.,* Securities Exchange Act Release Nos. 57801 (May 8, 2008), 73 FR 27878 (May 14, 2008) (SR–NYSEArca–2008–31) (order approving Exchange listing and trading of twelve actively-managed funds of the WisdomTree Trust); 60460 (August 7, 2009), 74 FR 41468 (August 17, 2009) (SR–NYSEArca–2009–55) (order approving listing of Dent Tactical ETF); 63737 (January 19, 2011), 76 FR 4968 (January 27, 2011) (SR–NYSEArca–2010–107) (order approving Exchange listing and trading of AdvisorShares Active Bear ETF); 63802 (January 31, 2011), 76 FR 6503 (February 4, 2011) (SR–NYSEArca–2010–118) (order approving Exchange listing and trading of SiM Dynamic Allocation Diversified Income ETF and SiM Dynamic Allocation Growth Income ETF).

[6] The Trust is registered under the 1940 Act. On January 19, 2011, the Trust filed with the Commission Form N–1A under the Securities Act of 1933 (15 U.S.C. 77a), and under the 1940 Act relating to the Fund (File Nos. 333–157876 and 811–22110) (''Registration Statement''). The description of the operation of the Trust and the Fund herein is based in part on the Registration Statement. In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the1940 Act. *See* Investment Company Act Release No. 29291 (May 28, 2010) (File No. 812–13677) (''Exemptive Order'').

[7] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser and Sub-Adviser and their related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)– 7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

Russell 3000® Index (''Index''). The Fund seeks to achieve this goal by investing in stocks with liquidity and fundamental characteristics that are historically associated with superior long-term performance. The Sub-Adviser has designed the following quantitative stock selection rules to make allocation decisions and to protect against dramatic over or under weighting of individual securities in the Fund's portfolio.

Decile Ranking of Russell 3000 Stocks. The Sub-Adviser ranks stocks in the Index based on the following criteria:

I. The decrease in their outstanding shares over approximately the past 120 days (''float shrink'');

II. The increase in free cash flow (the money available to the company that is not used to pay for its daily operations) over approximately the past 120 days; and

III. The decrease in leverage over approximately the past 120 days. Leverage is measured as the ratio of total liabilities to total assets. The Sub-Adviser uses the relative decrease in leverage rather than amount of leverage itself as a criterion because the degree of leverage varies across industries.

The top decile of each respective ranking consists of the stocks of the companies with (I) the strongest reduction in shares outstanding, (II) the strongest growth in free cash flow, and (III) the largest decrease in leverage, respectively.

Stock Selection Algorithm

The Sub-Adviser uses an algorithm to give a relative weight to the three decile rankings, combining them in a single ranking (combined ranking). The algorithm places a higher weight on the float shrink ranking, followed by the free cash flow ranking, followed by the leverage ranking. The Fund under normal circumstances [8] will invest in 80 to 120 stocks from among the top 10% of stocks in the combined ranking.

According to the Registration Statement, the Sub-Adviser's investment process is quantitative. Based on extensive historical research, the Sub-Adviser designed the following stock selection rules, which involve rebalancing, weighting, liquidity, and trading considerations:

Liquidity Screening

Before trading, the Fund will estimate the liquidity impact of its suggested trades. Specifically, the Fund will avoid stocks whose average trading volume over the past 30 days would be less than 50% of the size of the Fund's proposed trades. As a result, the Fund will not invest in stocks that meet its investment criteria in terms of float shrink, free cash flow growth and leverage if their trading volume is below such levels. As a result, the Fund will not invest in stocks that it deems to be illiquid.

Weighting and Sector Allocation

Although the Fund initially will invest an equal dollar amount in the stocks that meet its investment criteria, the Fund is not market capitalization weighted. As a result, the Fund will overweight small-cap stocks and mid-cap stocks relative to traditional, market cap weighted indices.[9]

The relative weights of the sectors in the Fund may vary significantly from those of traditional, market cap weighted indices. Stocks with favorable liquidity characteristics may be concentrated in certain sectors. Sector concentration might increase the Fund's volatility over the short term. According to the Registration Statement, the Fund will not correct these sector effects because the Sub-Adviser's research shows that historically they are a source of long-term outperformance.

Other Investments

To respond to adverse market, economic, political or other conditions, the Fund may invest 100% of its total assets, without limitation, in short-term, high-quality debt securities and money market instruments. The Fund may invest in these instruments for extended periods, depending on the Sub-Adviser's assessment of market conditions. These debt securities and money market instruments include shares of other mutual funds, commercial paper, certificates of deposit, bankers' acceptances, U.S. Government securities, including U.S. Treasury zero-coupon bonds, repurchase and reverse repurchase agreements [10] and bonds that are BBB or higher.

Diversification. The Fund may not (i) with respect to 75% of its total assets, purchase securities of any issuer (except securities issued or guaranteed by the U.S. Government, its agencies or instrumentalities or shares of investment companies) if, as a result, more than 5% of its total assets would be invested in the securities of such issuer; or (ii) acquire more than 10% of the outstanding voting securities of any one issuer.[11]

Concentration. The Fund may not invest 25% or more of its total assets in the securities of one or more issuers conducting their principal business activities in the same industry or group of industries. This limitation does not apply to investments in securities issued or guaranteed by the U.S. Government, its agencies or instrumentalities, or shares of investment companies. The Fund will not invest 25% or more of its total assets in any investment company that so concentrates.[12]

The Fund will not purchase illiquid securities.[13] In addition, the Fund will not invest in non-U.S.-registered equity securities, loan participation agreements and Rule 144A securities.

According to the Registration Statement, the Fund will seek to qualify for treatment as a Regulated Investment Company (''RIC'') under Subchapter M of the Internal Revenue Code.[14]

[8] The term ''under normal market circumstances'' includes, but is not limited to, the absence of extreme volatility or trading halts in the fixed income markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

[9] According to the Registration Statement, mid-sized companies may be more volatile than large-capitalization companies and returns on investments in stocks of mid-size companies could trail the returns on investments in stocks of larger or smaller companies. Stock prices of small capitalization companies may be more volatile than those of larger companies and therefore the Fund's Share price may be more volatile than those of funds that invest a larger percentage of their assets in stocks issued by larger-capitalization companies.

[10] According to the Registration Statement, the Fund may enter into repurchase agreements with financial institutions, which may be deemed to be loans. The Fund follows certain procedures designed to minimize the risks inherent in such agreements. These procedures include effecting repurchase transactions only with large, well-capitalized and well-established financial institutions whose condition will be continually monitored by the Sub-Adviser. The Fund may enter into reverse repurchase agreements without limit as part of the Fund's investment strategy. Reverse repurchase agreements involve sales by the Fund of portfolio assets concurrently with an agreement by the Fund to repurchase the same assets at a later date at a fixed price.

[11] The diversification standard is contained in Section 5(b)(1) of the 1940 Act.

[12] *See* Form N–1A, Item 9. The Commission has taken the position that a fund is concentrated if it invests more than 25% of the value of its total assets in any one industry. *See, e.g.*, Investment Company Act Release No. 9011 (October 30, 1975), 40 FR 54241 (November 21, 1975).

[13] A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the ETF. *See* Investment Company Act Release No. 14983 March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

[14] 26 U.S.C. 851. One of several requirements for RIC qualification is that a Fund must receive at least

Continued

Pursuant to the terms of the Exemptive Order, the Fund will not invest in options contracts, futures contracts or swap agreements. The Fund's investments will be consistent with the Fund's investment objective and will not be used to enhance leverage.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.600. The Exchange represents that, for initial and/or continued listing, the Fund will be in compliance with Rule 10A–3 [15] under the Exchange Act, as provided by NYSE Arca Equities Rule 5.3. A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the net asset value (''NAV'') per Share will be calculated daily and that the NAV and the Disclosed Portfolio, as defined in NYSE Arca Equities Rule 8.600(c)(2), will be made available to all market participants at the same time.

Creation and Redemption of Shares

The Fund issues and redeems Shares on a continuous basis at NAV only in a large specified number of Shares called a ''Creation Unit.'' The Shares of the Fund that trade on the Exchange are ''created'' at their NAV by Authorized Participants only in block-size Creation Units of at least 25,000 Shares. An Authorized Participant enters into an agreement (''Participant Agreement'') with the Distributor or uses a Depository Trust Company participant who has executed a Participant Agreement, and deposits into the Fund a portfolio of securities closely approximating the holdings of the Fund and a specified amount of cash, together totaling the NAV of the Creation Unit(s), in exchange for 25,000 Shares of the Fund (or multiples thereof). Shares are not redeemable from the Fund except when aggregated in Creation Units. The prices at which creations and redemptions occur are based on the next calculation of NAV after an order is received in a form prescribed in the Participant Agreement.

Availability of Information

The Fund's Web site (*http://www.advisorshares.com*), which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund that may be downloaded. The Fund's Web site will include additional quantitative information updated on a daily basis, including, for the Fund, (1) daily trading volume, the prior business day's reported closing price, NAV and mid-point of the bid/ask spread at the time of calculation of such NAV (the ''Bid/Ask Price''),[16] and a calculation of the premium and discount of the Bid/Ask Price against the NAV, and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day.[17]

On a daily basis, the Adviser will disclose on the Fund's Web site for each portfolio security or other financial instrument of the Fund the following information: ticker symbol (if applicable), name of security or financial instrument, number of shares or dollar value of financial instruments held in the portfolio, and percentage weighting of the security or financial instrument in the portfolio. The Web site information will be publicly available at no charge.

In addition, a basket composition file, which includes the security names and share quantities required to be delivered in exchange for Fund Shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of the New York Stock Exchange (''NYSE'') via the National Securities Clearing Corporation. The basket will represent one Creation Unit of the Fund.

The NAV of the Fund will normally be determined as of the close of the regular trading session on the NYSE (ordinarily 4 p.m. Eastern Time) on each business day.

The Fund will calculate its NAV by: (i) Taking the current market value of its total assets; (ii) subtracting any liabilities; and (iii) dividing that amount by the total number of Shares owned by shareholders. The Fund will calculate NAV once each business day as of the regularly scheduled close of normal trading on the Exchange (normally, 4 p.m., Eastern Time). In calculating NAV, the Fund generally will value its investment portfolio at market price. If market prices are unavailable or the Fund thinks that they are unreliable, or when the value of a security has been materially affected by events occurring after the relevant market closes, the Fund will price those securities at fair value as determined in good faith using methods approved by the Fund's Board of Trustees.

Investors can also obtain the Trust's Statement of Additional Information (''SAI''), the Fund's Shareholder Reports, and its Form N–CSR and Form N–SAR, filed twice a year. The Trust's SAI and Shareholder Reports are available free upon request from the Trust, and those documents and the Form N–CSR and Form N–SAR may be viewed on-screen or downloaded from the Commission's Web site at *http://www.sec.gov.* Information regarding market price and trading volume of the Shares is and will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the Shares will be available via the Consolidated Tape Association (''CTA'') high-speed line. In addition, the Portfolio Indicative Value, as defined in NYSE Arca Equities Rule 8.600(c)(3), will be disseminated by the Exchange at least every 15 seconds during the Core Trading Session by one or more major market data venders. The dissemination of the Portfolio Indicative Value, together with the Disclosed Portfolio, will allow investors to

90% of the Fund's gross income each year from dividends, interest, payments with respect to securities loans, gains from the sale or other disposition of stock, securities or foreign currencies, or other income derived with respect to the Fund's investments in stock, securities, foreign currencies and net income from an interest in a qualified publicly traded partnership (the ''90% Test''). A second requirement for qualification as a RIC is that a Fund must diversify its holdings so that, at the end of each fiscal quarter of the Fund's taxable year: (a) At least 50% of the market value of the Fund's total assets is represented by cash and cash items, U.S. Government securities, securities of other RICs, and other securities, with these other securities limited, in respect to any one issuer, to an amount not greater than 5% of the value of the Fund's total assets or 10% of the outstanding voting securities of such issuer; and (b) not more than 25% of the value of its total assets are invested in the securities (other than U.S. Government securities or securities of other RICs) of any one issuer or two or more issuers which the Fund controls and which are engaged in the same, similar, or related trades or businesses, or the securities of one or more qualified publicly traded partnership (the ''Asset Test'').

[15] 17 CFR 240.10A–3.

[16] The Bid/Ask Price of the Fund will be determined using the highest bid and the lowest offer on the Exchange as of the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Fund and its service providers.

[17] 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.

determine the value of the underlying portfolio of the Fund on a daily basis and to provide a close estimate of that value throughout the trading day. The intra-day, closing and settlement prices of the portfolio securities are also readily available from the national securities exchanges trading such securities, automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters.

Additional information regarding the Trust and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, distributions and taxes is included in the Registration Statement. All terms relating to the Fund that are referred to, but not defined in, this proposed rule change are defined in the Registration Statement.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.[18] Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments comprising the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4 a.m. to 8 p.m. Eastern Time in accordance with NYSE Arca Equities Rule 7.34 (Opening, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Equities Rule 7.6, Commentary .03, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

Surveillance

The Exchange intends to utilize its existing surveillance procedures applicable to derivative products (which include Managed Fund Shares) to monitor trading in the Shares. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable Federal securities laws.

The Exchange's current trading surveillance focuses on detecting securities trading outside their normal patterns. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange may obtain information via the Intermarket Surveillance Group (''ISG'') from other exchanges that are members of ISG or with which the Exchange has entered [sic] a comprehensive surveillance sharing agreement.[19] In addition, the Exchange could obtain information from the U.S. exchanges on which the securities held by the Fund are listed and traded.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit (''ETP'') Holders in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Unit aggregations (and that Shares are not individually redeemable); (2) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated Portfolio Indicative Value will not be calculated or publicly disseminated; (4) how information regarding the Portfolio Indicative Value is disseminated; (5) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Bulletin will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Bulletin will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Exchange Act. The Bulletin will also disclose that the NAV for the Shares will be calculated after 4 p.m. Eastern Time each trading day.

2. Statutory Basis

The basis under the Exchange Act for this proposed rule change is the requirement under Section 6(b)(5)[20] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Equities Rule 8.600. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable Federal securities laws. The Exchange may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. The Fund will achieve its investment objective primarily by investing in the broad U.S. equity market as represented by the Russell 3000® Index, the components of which are listed and traded on U.S. exchange markets. The Fund will not purchase illiquid securities. In addition, the Fund will not invest in non-U.S.-registered equity securities, loan participation agreements and Rule 144A securities. Further, the Fund will not invest in options, futures or swaps. The Fund's investments will be consistent with the Fund's investment objective

[18] *See* NYSE Arca Equities Rule 7.12, Commentary .04.

[19] For a list of the current members of ISG, *see http://www.isgportal.org.* The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[20] 15 U.S.C. 78f(b)(5).

and will not be used to enhance leverage.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information is publicly available regarding the Fund and the Shares, thereby promoting market transparency. The Fund's portfolio holdings will be disclosed on its Web site daily after the close of trading on the Exchange and prior to the opening of trading on the Exchange the following day. Moreover, the Portfolio Indicative Value will be disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Core Trading Session. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day. Information regarding market price and trading volume of the Shares is and will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last sale information will be available via the CTA high-speed line. The Web site for the Fund will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Moreover, prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable, and trading in the Shares will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Portfolio Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Portfolio Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca-2011–51 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–2011–51. This file number should be included on the subject line if e-mail 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 Section, 100 F Street, NE., Washington, DC 20549–1090, on official business days between 10 a.m. and 3 p.m. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *http://www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca-2011–51 and should be submitted on or before September 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–21029 Filed 8–17–11; 8:45 am]

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[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65115; File No. SR–CHX–2011–22]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing of Proposed Rule Change To Amend Article 20, Rule 10, Governing Clearly Erroneous Executions

August 11, 2011.

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 August 10, 2011, the Chicago Stock Exchange, Inc. (''CHX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the CHX. CHX has filed this proposal pursuant to Exchange Act Rule 19b–4(f)(6) [3] which is effective upon filing with the Commission.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CHX proposes to amend Article 20, Rule 10, governing clearly erroneous executions, so that the rule will continue to operate in the same manner after changes to the single stock trading pause process are effective. The text of this proposed rule change is available on the Exchange's Web site at (*http://www.chx.com*) and in 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 CHX included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments it received regarding the proposal. The text of these statements may be examined at the places specified in Item IV below. The CHX 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

The Exchanges[4] and FINRA, in consultation with the Commission, have made changes to their respective rules in a concerted effort to strengthen the markets after the severe market disruption that occurred on May 6, 2010. One such effort by the Exchanges and FINRA was to adopt a uniform trading pause process during periods of extraordinary market volatility as a pilot in S&P 500 Index stocks (''Pause Pilot''),[5] approved by the Commission on June 10, 2010.[6] On September 10, 2010, the Commission approved the Exchanges' and FINRA's proposals to add the securities included in the Russell 1000 Index and specified ETPs to the Pause Pilot.[7] On September 10, 2010, the Commission also approved changes proposed by the Exchanges to amend certain of their respective rules to set forth clearer standards and curtail their discretion with respect to breaking erroneous trades.[8] The changes, among other things, provided uniform treatment of clearly erroneous execution reviews in the event of transactions that result in the issuance of an individual stock trading pause pursuant to the Pause Pilot on the listing market and those that occur up to the time the trading pause message is received by the other markets from the single plan processor responsible for consolidation and dissemination of information for the security (''Latency Trades'').

As part of the changes to the clearly erroneous process under Article 20, Rule 10, CHX replaced existing Rule 10(c)(4) with all new text to provide clarity in the clearly erroneous process when a Pause Pilot trading pause is triggered. Pursuant to Rule 10(c) (4), Latency Trades will be broken by the exchange if they exceed the applicable percentage from the Reference Price, as noted in the table found under Rule 10(c)(1).[9] The Reference Price, for purposes of Rule 10(c)(4), is the price that triggered a trading pause pursuant to the Pause Pilot (the ''Trading Pause Trigger Price''). As such, Latency Trades that occur on CHX would be broken by the exchange pursuant to Rule 10(c)(4) if the transaction occurred at either three, five or ten percent above the Trading Pause Trigger Price.[10]

On June 23, 2011, the Commission approved a joint proposal to expand the respective Pause Pilot rules of the Exchanges and FINRA to include all remaining NMS stocks (''Phase III Securities'').[11] The new pilot rules, which will be implemented on August 8, 2011, not only expand the application of the Pause Pilot, but also apply larger percentage moves that trigger a pause to the Phase III Securities. CHX amended its Pause Pilot rule, Rule 2(e), by adding three new subparagraphs to address the treatment of the Phase III Securities. The rule applicable to the original Pause Pilot securities was placed in new Rule 2(e)(i). The rules applicable to the Phase III Securities were placed in new Rules 2(e)(ii) and (iii). A pause under Rule 2(e)(ii) is triggered by a 30 percent price move within a five minute period in a Phase III Security that had a closing price on the previous trading day of $1 or more. A pause under Rule 2(e)(iii) is triggered by a 50 percent price move within a five minute period in a Phase

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] For purposes of this filing, the term ''Exchanges'' refers collectively to BATS Exchange, Inc., BATS Y–Exchange, Inc., NASDAQ OMX BX, Inc., Chicago Board Options Exchange, Inc., Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., International Securities Exchange LLC, The NASDAQ Stock Market LLC, New York Stock Exchange LLC, NYSE Amex LLC, NYSE Arca, Inc., National Stock Exchange, Inc., and NASDAX [sic] OMX PHLX LLC.

[5] Rule 4120(a)(11). The pauses under Rule 4120(a)(11) occur when a security's price moves by the applicable percentage within a five minute period between 9:45 a.m. and 3:35 p.m., or in the case of an early scheduled close, 25 minutes before the close of trading. Such pauses last for five minutes. At the conclusion of the pause period, the security is opened pursuant to the Halt Cross process under Rule 4753.

[6] Securities Exchange Act Release Nos. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010– 01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047); 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[7] *See e.g.,*Securities Exchange Act Release Nos. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08); and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033).

[8] Securities Exchange Act Release No. 62886 (September 16, 2010), 75 FR 56613 (September 16, 2010) (File Nos. SR–BATS–2010–016; SR–BX–2010–040; SR–CBOE–2010–056; SR–CHX–2010–13; SR–EDGA–2010–03; SR–EDGX–2010–03; SR–ISE–2010–62; SR–NASDAQ–2010–076; SR–NSX–2010–07; SR–NYSE–2010–47; SR–NYSEAmex-2010–60; and SR–NYSEArca–2010–58).

[9] Pursuant to Rule 10(c)(1), a security with a Reference Price of greater than zero and up to an including $25 is subject to a 10% threshold; a security with a Reference Price of greater than $25 and up to and including $50 is subject to a 5% threshold; and a security with a Reference Price of greater than $50 is subject to a 3% threshold.

[10] Rule 10(c)(4).

[11] Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (File Nos. SR–BATS–2011–016; SR–BYX–2011–011; SR–BX–2011–025; SR–CBOE–2011–049; SR–CHX–2011–09; SR–EDGA–2011–15; SR–EDGX–2011–14; SR–FINRA–2011–023; SR–ISE–2011–028; SR–NASDAQ–2011–067; SR–NYSE–2011–21; SR–NYSEAmex–2011–32; SR–NYSEArca–2011–26; SR–NSX–2011–06; SR–Phlx–2011–64).

III Security that had a closing price on the previous trading day of less than $1. If no prior day closing price is available, the last sale reported to the Consolidated Tape on the previous trading day is used.

The Issue

The recently-approved changes to the Pause Pilot will have the unintended effect of removing the Phase III Securities from the normal clearly erroneous process and potentially result in unfair outcomes in the face of severe volatility in such securities. Phase III Securities are currently subject to the clearly erroneous process under Rules 10(c)(1)–(3), which apply to all securities except the current Pause Pilot securities subject to a pause. For purposes of transactions in securities not involving Pause Pilot securities, or transactions involving Pause Pilot securities that occur when there is not a pause pursuant to the Pause Pilot, the Reference Price is the consolidated last sale price immediately prior to the execution(s) under review, subject to certain exceptions.[12] As noted above, the Trading Pause Trigger Price is used as the Reference Price when a Pause Pilot pause is in effect. As a consequence, under the current rules a Latency Trade is subject to the clearly erroneous thresholds based on the Trading Pause Trigger Price, which represents a ten percent or greater move in the transacted price of the security in a five minute period.

Under the new Pause Pilot rules, a Latency Trade in a Phase III Security occurs only after either a 30 or 50 percent (or greater) move in the transacted price of the security in a five minute period. As a result, a member firm that trades in a Phase III Security that triggers a clearly erroneous threshold of three, five or ten percent from the Reference Price, yet falls below the Pause Pilot trigger of either 30 or 50 percent, would be able to avail themselves of a clearly erroneous review. A similarly situated member firm that transacts in the same security as a Latency Trade at a price equal to or greater than the Phase III Security thresholds, yet less than the clearly erroneous thresholds under Rule 10(c)(1), would not be able to avail themselves of the clearly erroneous process. Another member firm that transacts in the same security as a Latency Trade that exceeds three, five or ten percent from the Trading Pause Trigger Price would automatically receive clearly erroneous relief. CHX believes that this would be an inequitable result and an arbitrary application of the clearly erroneous process. Specifically, CHX believes that, since the 30 and 50 percent triggers of the Pause Pilot are substantially greater than the 10 percent threshold of the original Pause Pilot, the Phase III Securities should remain under the current clearly erroneous process of Rules 10(c)(1)–(3).

Applying the clearly erroneous process under Rules 10(c)(1)–(3) to the Phase III Securities would allow CHX to review all transactions that exceed the normal clearly erroneous thresholds and Reference Price, and, importantly, avoid arbitrary selection of ''winners'' and ''losers'' in the face of severe volatile moves in a security of 30 or 50 percent over a five minute period. For example, A member firm that trades in a security subject to Rule 2(e)(ii) or (iii) that triggers a clearly erroneous threshold of three, five or ten percent, yet falls below the Pause Pilot trigger threshold trading at 29 percent from the prior day's closing price, would be potentially entitled to a clearly erroneous break pursuant Rule 10(c)(1). Should trading in that same stock trigger a trading pause at a price of 30 or 50 percent greater than the prior day's close, the member firm would not be entitled to a clearly erroneous trade break unless that trade exceeded three, five or ten percent beyond the price that triggered the pause. This scenario causes an inequity among a group of member firms that have transactions in the Phase III Securities falling between the three, five and ten percent thresholds from the Reference Price under the normal Rule 10(c)(1) clearly erroneous process and the Pause Pilot clearly erroneous triggers of three, five or ten percent away from the Trading Pause Trigger Price. Such member firms would not be provided relief under the clearly erroneous rules merely due to the imposition of a Pause Pilot halt, notwithstanding that other member firms with transactions that occur at the same rolling five minute percentage difference. CHX believes a better outcome is to afford all members transacting in Phase III Securities the opportunity of having such trades reviewed.

Summary

The expansion of the Pause Pilot to the Phase III Securities will have the unintended consequence of setting the point at which a clearly erroneous transaction occurs once a Pause Pilot pause is initiated far beyond the triggers applied prior to the expansion, which will, in turn, prevent certain market participants from availing themselves of the clearly erroneous rules, notwithstanding that other similarly situated participants are able to do so. CHX believes that this would be an arbitrary application of the clearly erroneous process in a manner that is unfair and not consistent with the spirit and purpose of the rule. Accordingly, CHX is proposing to amend Rules 10(c)(1)–(4) to specify that Rule 10(c)(4) applies only to the current securities of Pause Pilot, as found under Rule 2(e)(i).[13]

2. Statutory Basis

The statutory basis for the proposed rule change is Section 6(b)(5) of the Securities Exchange Act of 1934 (the ''Act''),[14] which requires the rules of an exchange 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. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[15] of the Act in that it seeks to assure fair competition among brokers and dealers and among exchange markets. CHX believes that the proposed rule meets these requirements in that it promotes transparency and uniformity across markets concerning decisions to break erroneous trades, yet also ensures fair application of the process so that similarly situated member firms are provided the same opportunity of a clearly erroneous review. CHX notes that the changes proposed herein will in no way interfere with the operation of the Pause Pilot process, as amended.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

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

[12] *Id.*

[13] CHX notes that the Exchanges are filing similar proposals to make the changes proposed herein.

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78k–L(a)(1).

operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [16] and Rule 19b–4(f)(6)(iii) thereunder.[17] The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver will allow the clearly erroneous rules to continue to operate as they did prior to the effectiveness of the Pause Pilot expansion to Phase III Securities so that similarly situated member firms are provided the same opportunity of a clearly erroneous review. Accordingly, the Commission waives the 30-day operative delay requirement and designates the proposed rule change as operative upon filing with the Commission.[18]

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 e-mail to *rule-comments@sec.gov*. Please include File Number SR–CHX–2011–22 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–CHX–2011–22. This file number should be included on the subject line if e-mail 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 a.m. and 3 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–CHX–2011–22 and should be submitted on or before September 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–21026 Filed 8–17–11; 8:45 am]

BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6)(iii) requires that a self-regulatory organization submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission is waiving the five day written notice requirement in this case. Therefore, the Commission notes that the Exchange has satisfied this requirement.

[18] For 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).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65127; File No. SR–NYSE–2011–20]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Granting Approval of Proposed Rule Change To Add New Section 907.00 to the Listed Company Manual that Sets Forth Certain Complimentary Products and Services That Are Offered to Currently and Newly Listed Issuers

August 12, 2011.

I. Introduction

On May 5, 2011, the New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the Listed Company Manual (''Manual'') setting forth certain complimentary products and services offered to currently and newly listed issuers. The proposed rule change was published in the **Federal Register** on May 23, 2011.[3] The Commission received seventeen comments from 14 commenters on the proposal.[4] NYSE submitted a letter in response to the comments.[5] On July 5, 2011, the Commission extended the time period

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 64506 (May 17, 2011), 76 FR 29806 (''Notice'').

[4] *See* Letters to the Commission, from Ronald Russo, GLX, Inc., dated May 18, 2011 (''GLX Letter''); Bryan Degnan, Taylor Rafferty Associates, dated May 19, 2011 (''Rafferty Letter''); Jennifer Kaminsky, dated May 19, 2011; Anonymous, dated May 19, 2011 (''Anonymous Letter''); Todd Allen, dated May 19, 2011 (''Allen Letter''); Brian Rivel, President, Rivel Research Group, dated May 20, 2011 (''Rivel Letter''); Jerry Falkner, May 22, 2011 (''Falkner Letter''); Enzo Villani, President, MZ North America, dated June 6, 2011 (''MZ Letter''); John Fairir, dated June 7, 2011 (''Fairir Letter''); Michael Pepe, CEO, PrecisionIR Group, dated June 7, 2011 (''PrecisionIR Letter''); Michael O'Connell, Director IR Solutions, SNL Financial, dated June 10, 2011 (''SNL Letter''); Dominic Jones, President, IR Web Reporting International, Inc., dated June 15, 2011 (''IR Web Reporting Letter''); Darrell Heaps, CEO, Q4 Web System, dated June 16, 2011 (''Q4 Letter''); Dominic Jones, President, IR Web Reporting International, Inc., dated June 29, 2011 (''IR Web Reporting Letter 2''); e-mails to Robert Cook, Director, Division of Trading and Markets and David Shillman, Associate Director, Division of Trading and Markets, from Patrick Healy, CEO, Issuer Advisory Group, LLC, dated June 26, 2011 and June 28, 2011 (both e-mails indicating that the Issuer Advisory Group would be filing a comment letter to the proposed rule change); and letter from Patrick Healy, CEO, Issuer Advisory Group, LLC, dated June 30, 2011 (''Issuer Advisory Letter'').

[5] *See* Letter to Elizabeth M. Murphy, Secretary, Commission, from Janet L. McGinness, Senior Vice President—Legal and Corporate Secretary, NYSE,

Continued

in which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change, to August 21, 2011.[6] This order grants approval of the proposed rule change.

II. Description of the Proposal

In its filing, NYSE is proposing to amend the Manual by adding a new Section 907.00 that sets forth a practice of offering certain complimentary products and services to currently and newly listed issuers. NYSE offers the complimentary products and services as described below to respond to competitive pressures in the market for listings to attract new listings and retain existing listings.[7] These products and services are developed or delivered by NYSE or by a third-party for use by NYSE listed companies. Some of these products are commercially available by such third-party vendors. According to NYSE, all listed issuers receive the same complimentary products and services through the NYSE Market Access Center, while certain tiers of listed issuers receive additional products and services. As discussed in more detail below, the additional services an issuer receives is based, for currently listed issuers, on total shares of common stock or American Depository Receipts (''ADRs'') issued and outstanding and, for newly listed issuers, on total global market value based on a public offering price.

A. NYSE Market Access Center

NYSE developed a market information analytics platform that is available for free to all NYSE listed issuers, called the NYSE Market Access Center. In the rule filing, NYSE states that the NYSE's Market Access Center was created to ''provide issuers with better market insight and information across all exchange and trading venues.''[8] The NYSE Market Access Center includes products and services that were either a) developed by NYSE using proprietary data and/or intellectual property or b) built by a third-party expressly for NYSE-listed companies. According to NYSE, within this platform, all issuers have access to tools and information related to market intelligence, education, investor outreach, media visibility, corporate governance, and advocacy initiatives.[9] Additionally, the NYSE Market Access Center provides all issuers with access to discounted products and services from the same third-party vendors. All issuers listed on the Exchange have access to the NYSE Market Access Center on the same basis. At the time of its filing with the Commission, NYSE noted that the products and services currently available through the NYSE Market Access Center have a commercial value of approximately $50,000 annually.[10]

B. Tiered Products and Services Offered to Certain Companies

In addition to the NYSE Market Access Center, NYSE offers products and services to certain currently listed and newly listed issuers on a tiered basis. Currently listed issuers are categorized into two tiers, Tier One and Tier Two. Under NYSE's proposal, Tier One issuers are U.S. issuers that have 270 million or more total shares of common stock issued and outstanding in all share classes, including and in addition to Treasury shares, and Foreign Private Issuers that have 270 million or more in ADRs issued and outstanding, each calculated annually as of December 31 of the preceding year.[11] Tier Two issuers are categorized as those U.S. issuers that have 160 million to 269,999,999 total shares of common stock issued and outstanding in all share classes, including and in addition to Treasury shares, and Foreign Private Issuers that have 160 million to 269,999,999 in ADRs issued and outstanding, each calculated annually as of December 31 of the preceding year.[12] In addition to the NYSE Market Access Center products and services, Tier One issuers receive market surveillance products and services, which NYSE states have a commercial value of $45,000 annually, and web-hosting products and services, which NYSE states have a commercial value of approximately $12,000 to $16,000 annually. Tier Two issuers can choose to receive either web-hosting products and services at the values noted above, or market analytics products and services, with a commercial value according to NYSE of $20,000 annually.

Newly listed issuers similarly are categorized into two tiers, Tier A and Tier B.[13] Tier A includes issuers with a global market value of $400 million or more based on the public offering price. Tier B includes issuers with a global market value of less than $400 million based on the public offering price. In addition to the NYSE Market Access Center products and services, Tier A issuers receive either market surveillance products and services for a period of 12 calendar months from the date of listing or market analytics products and services for a period of 24 calendar months from the date of listing, at the issuer's election. The commercial value for these services is the same as those described above for Tier One or Tier Two issuers. Additionally, Tier A companies receive web-hosting, the value of which is noted above, and news distribution products and services, with a commercial value of $10,000 annually, for a period of 24 calendar months from the date of listing. Tier B companies receive web-hosting and news distribution products and services for a period of 24 calendar months from the date of listing. At the expiration of the 24-month period, Tier A or Tier B issuers that meet the qualifications of Tier One or Tier Two based on total shares or total ADRs issued and outstanding receive either Tier One or Tier Two products and services.[14]

III. Summary of Comments and NYSE Response to Comments

Fourteen commenters raised objections to the proposal.[15] Generally, commenters expressed concern that the NYSE's practice of offering complimentary services harms competing suppliers of those services or adversely affects competition in affected markets.[16] Specifically, several commenters expressed concern about

dated June 27, 2011 (''NYSE Response Letter''). NYSE's Response Letter is in response to those comments submitted prior to June 27, 2011. *See* note 4, *supra* for a list of those letters.

[6] *See* Securities Exchange Act Release No. 64809 (July 5, 2011), 76 FR 40758 (July 11, 2011).

[7] *See* e-mail from Theodore Lazo, General Counsel, NYSE to Sharon Lawson, Senior Special Counsel, Division of Trading and Markets and Arisa Tinaves, Special Counsel, Division of Trading and Markets on August 2, 2011.

[8] *See* Notice, *supra* note 3.

[9] In the Notice, the Exchange provided examples of the products and services offered by the NYSE Market Access Center and noted that a description of all offerings is available on the Exchange's Web site. *See* Notice, *supra* note 3.

[10] *See supra* note 7.

[11] All share classes issued include, for example, where a company has two classes of common stock, such as Class A and Class B common shares.

[12] *See* Notice, *supra* note 3.

[13] ''Newly listed issuers'' means U.S. issuers conducting an initial public offering (''IPO''), issuers emerging from bankruptcy, spinoffs (where a company lists new shares in the absence of a public offering), and carve-outs (where a company carves out a business line or division, which then conducts a separate IPO). Newly listed issuers do not include issuers that transfer their listings from another national securities exchange; rather, transferring issuers are eligible for the services available to currently listed issuers. *See* proposed Rule 907.00 in the Manual.

[14] The Exchange provided a description of all products and services offered to the Tiers. *See* Notice, *supra* note 3.

[15] *See supra* note 4.

[16] *See* Rafferty Letter, Allen Letter, Rivel Letter, Falkner Letter, MZ Letter, Fairir Letter, PrecisionIR Letter, SNL Letter, and IR Web Reporting Letter. *See also,* Issuer Advisory Letter (stating that the proposed rule change restricts competition for listings).

adverse effects arising from the ''strategic partnership'' with Thomson-Reuters and Ipreo. The concern is that offering complimentary services disadvantages smaller businesses providing investor relations services.[17] One commenter noted that the NYSE's complimentary offering of these services makes it ''too difficult to compete'' with Thomson-Reuters and Ipreo.''[18] Commenters also believed that the proposal, by endorsing certain vendors, would discourage new vendors from entering markets for vendor services or stifle innovation.[19]

Commenters believed that the proposal would require issuers to use the specific vendor offered by NYSE or create the impression that listed companies must use the preferred vendor.[20] Additionally, three commenters believed that although issuers are not required to use the services and providers offered by NYSE, providers of competing products are still disadvantaged because they would have to convince issuers to pay for a similar service that the issuers are able to receive for no cost from the Exchange.[21] However, one vendor who commented stated that in the last several months, its service has replaced an NYSE complimentary service, specifically web-hosting, for a number of NYSE issuers.[22] Additionally, another commenter stated that numerous issuers have continued to use their existing preferred service providers at an additional cost to the issuers, instead of taking advantage of the complimentary products and services provided by NYSE.[23]

Four commenters suggested that instead of offering complimentary products and services of certain vendors, NYSE should instead offer issuers a subsidy or credit, which would allow them to use any service provider.[24] One commenter argued that such credit would benefit the Exchange by allowing it to continue to provide such products and services to issuers, but through a vendor of the issuers' own choosing.[25] This commenter believed that such an approach would ultimately benefit competition by leveling the playing field and allowing all vendors, both large and small to compete.[26]

Another commenter recommended disapproving the proposed rule change and having the exchanges consider free listings or alternatively, having the Commission require increased disclosure regarding listing benefit packages provided to issuers, which would address transparency concerns.[27] Additionally, the commenter suggested that the Commission appoint an independent task force comprised of issuers to recommend a model that would permit the exchanges to provide services while not limiting value-added service offerings.[28] The commenter argued that NYSE's proposal would result in the equivalent of a maximum service cap and that the Commission's approval of the proposal will be used by the Exchange as a justification for limiting their service offerings.[29]

One commenter noted that the proposal is not clear on the fee arrangements between the Exchange and the product and service vendors and questioned whether issuers pay for services over and above the services provided by NYSE and if the vendors share revenues with the Exchange or if the services are competitively priced.[30] The commenter also asked if NYSE receives payment from its preferred providers.[31]

Lastly, this commenter raised the issue of whether a for-profit exchange should be in the investor relations services business at all.[32] According to the commenter, there is a conflict of interest between the exchange's role as a service provider or endorser of service providers and its role as a self-regulatory organization that sets and enforces disclosure requirements for its listed companies.[33]

In the NYSE Response Letter, NYSE responded to the issues raised by the commenters.[34] The NYSE Response Letter clarified that no issuer is forced or required to utilize the complimentary products or services as a condition of listing and consequently, can continue to use alternative products and services of their choice.[35]

Further, the Exchange represented that it provides the third-party products and services to listed companies through non-exclusive arrangements with vendors. Accordingly, the Exchange is willing to consider entering into such arrangements with other third-party vendors that provide ''high-quality'' products and services. NYSE further stated that it does not endorse, nor require the use of, any particular vendor or any particular products and services.[36]

In response to the NYSE Response Letter, one commenter questioned the Exchange's willingness to enter into arrangements with other third-party vendors, stating that upon performing its own research, the commenter was unable to ''find any information provided by NYSE outlining the process that vendors must follow to have their services added or reviewed.''[37] Further, the commenter questioned whether the Exchange's current vendor that offers web-hosting and wire services is of ''high quality'', asserting that the vendor lacked distribution to a popular website for investors to which all of its competitors provide distribution services.[38]

Finally, in response to the conflict of interest issue that was raised, the Exchange disagreed that there is any conflict of interest with respect to its offerings of products and services because such product and services are offered on a complimentary basis and the arrangements with the vendors are non-exclusive. NYSE also reiterated that issuers are not required to accept or use the products or services to satisfy their obligations under the Exchange's listing standards.[39]

IV. Discussion and Commission's Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of Section 6 of the Act.[40]

[17] *See* Allen Letter, Falkner Letter, Fairir Letter, and Rivel Letter. *See also,* Anonymous Letter (noting that there are already obstacles for smaller businesses).

[18] *See* Fairir Letter (arguing that NYSE is trying to justify its high listing cost).

[19] *See* GLX Letter, MZ Letter, Fairir Letter, PrecisionIR Letter, IR Web Reporting Letter, and Q4 Letter. *See also,* Falkner Letter (noting the smaller providers provide innovative and often times better value).

[20] *See* Rafferty Letter, Rivel Letter, Fairir Letter, PrecisionIR Letter, and IR Web Reporting Letter. *See also,* SNL Letter (noting that the proposal could reasonably be viewed as an endorsement by the NYSE and Commission of specific vendors) and IR Web Reporting Letter 2 (noting that issuers may conclude that certain vendors will enable issuers to comply with the Exchange's listing requirement given the NYSE's endorsement).

[21] *See* Fairir Letter, Precision IR Letter, and IR Web Reporting Letter.

[22] *See* Q4 Letter.

[23] *See* Issuer Advisory Letter.

[24] *See* MZ Letter, Fairir Letter, IR Web Reporting Letter, Q4 Letter, and IR Web Reporting Letter 2. *See also,* Issuer Advisory Letter (noting that the NYSE's proposal restricts issuers by forcing them to select from a narrow list of providers).

[25] *See* MZ Letter. *See also,* IR Web Reporting Letter (noting that a subsidy or credit would serve the NYSE's objective of attracting listings).

[26] *See* MZ Letter.

[27] *See* Issuer Advisory Letter.

[28] *Id.*

[29] *Id.*

[30] *See* IR Web Reporting Letter.

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] *See supra* note 5.

[35] *See* NYSE Response Letter.

[36] *Id.*

[37] *See* IR Web Reporting Letter 2.

[38] *Id.*

[39] *See* NYSE Response Letter.

[40] 15 U.S.C. 78f. In approving this proposed rule change, the Commission has considered the

Continued

Specifically, the Commission finds that the proposal is consistent with Sections 6(b)(4),[41] 6(b)(5),[42] and 6(b)(8)[43] in that the proposal is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among exchange members and issuers and other persons using its facilities and among other things, that the Exchange's rule is designed to promote just and equitable principles of trade, and is not designed to permit unfair discrimination between issuers, and that the rules of the Exchange do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Commission believes that the proposed rule change, which would permit the NYSE to provide complimentary products and services to all listed companies and additional products and services to certain companies based on (i) total shares or total ADRs issued and outstanding for currently listed issuers or (ii) global market value based on a public offering price for newly listed issuers, is appropriate and consistent with the Act. The Commission also believes that by describing in the Manual the products and services available to issuers and the values of the products and services, the Exchange is adding greater transparency to its rules and the fees applicable to issuers.

The Commission notes that the NYSE has represented that the various tiers are designed so that qualifying issuers with increased trading volumes and market activity have enhanced access to products and services that the listed companies would use in the absence of the complimentary services arrangement. The NYSE has further represented that all issuers receive some level of free services and that the requirements to qualify for a higher level of free services and products are transparent and set forth clearly in the language being adopted in new Section 907.00 of the Manual. This language also includes the commercial value of the free services in each tier. While not all issuers receive the same level of services, NYSE has stated that trading volume and market activity are related to the level of services that the listed companies would use in the absence of the complimentary services arrangements.[44] Further, the criteria for satisfying the tiers are the same for all issuers. Accordingly, based on the factors noted above, the Commission believes that the proposed rule changes to the Manual are consistent with the requirements of the Act and, in particular, that the products and services and their commercial value are equitably allocated among issuers consistent with Section 6(b)(4) of the Act, and the rule does not unfairly discriminate between issuers consistent with Section 6(b)(5) of the Act.

The NYSE Response Letter clarified and responded to many of the questions and concerns raised by commenters. Specifically, NYSE represented that issuers are not forced or required to utilize the complimentary products and services as a condition of listing. Furthermore, the third-party products and services are provided through non-exclusive arrangements with vendors and the Exchange does not expressly endorse any particular vendor or any product or services provided by any particular vendor. In fact, one vendor noted that it has replaced the NYSE's complimentary web-hosting vendor with its web system for a number of NYSE listed issuers.[45] Another commenter stated that issuers use other service providers despite incurring additional costs.[46]

The Commission recognizes, however, that the proposed rule change may affect the purchase decisions of some listed issuers. The effect of offering the services of some vendors on a complimentary basis is to provide issuers with the services of those vendors at a price that is lower in relative terms than what other vendors charge. A reduction in a vendor's relative price will generally cause some issuers to substitute their business toward that vendor. Accordingly, the Commission believes that the NYSE's offering of selected vendors' products and services on a complimentary basis will, by lowering their relative price, likely cause some listed issuers to substitute their business away from other vendors and toward the selected vendors. The Commission believes, however, that the impact of this substitution would be mitigated for the reasons discussed below.

The Commission believes that the NYSE is responding to competitive pressures in the market for listing in making this proposal. Specifically, the NYSE is offering complimentary products and services to attract new listings, retain currently-listed issuers, and respond to competitive pressures.[47] The Commission understands that the NYSE faces competition in the market for listing services, and that it competes in part by improving the quality of the services that it offers listed companies. By offering products and services on a complimentary basis and ensuring that it is offering the services most valued by its listed issuers, the NYSE will improve the quality of the services that listed companies receive. Accordingly, the Commission believes that NYSE's proposal reflects the current competitive environment for exchange listings among national securities exchanges, and is appropriate and consistent with Section 6(b)(8) in furtherance of the purposes of the Act.[48]

The Commission also recognizes that to ensure quality to its listed issuers, the NYSE represented that it selects only vendors with the capacity to service all their eligible listed companies without sacrificing quality.[49] Thus, some small service vendors may be placed at a disadvantage. Nonetheless, the Commission does not believe that the proposal harms the market for the complimentary products and services in a way that constitutes an inappropriate burden on competition or an inequitable allocation of fees, or fails to promote just and equitable principles of trade, in a manner inconsistent with the Act. As noted above, issuers are not forced or required to utilize the complimentary products and services and some issuers have selected competing products and services. The NYSE's consideration of quality and the needs of its listed issuers in selecting the vendors and its willingness to change vendors is consistent with competition for vendor services. The Commission also understands that the NYSE selected its current service providers substantially based on the service providers that many NYSE listed issuers were using at the time of the selection.[50] The approval of the rule proposal, will, however, help ensure that individual issuers are not given specially negotiated packages for products and services to list or remain

proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[41] 15 U.S.C. 78f(b)(4).

[42] 15 U.S.C. 78f(b)(5).

[43] 15 U.S.C. 78f(b)(8).

[44] *See* Notice, *supra* note 3.

[45] *See* Q4 Letter.

[46] *See* Issuer Advisory Letter.

[47] *See supra* note 7.

[48] 15 U.S.C. 78f(b)(8).

[49] *See* e-mail from Theodore Lazo, General Counsel, NYSE Regulation to Sharon Lawson, Senior Special Counsel, Division of Trading and Markets on August 5, 2011. *See also,* telephone conversation between Joseph Mecane, Executive Vice President, NYSE, Theresa Molloy, Vice President, NYSE, Holly Kulka, Senior Vice President, NYSE, Theodore Lazo, General Counsel, NYSE Regulation and Sharon Lawson, Senior Special Counsel and Arisa Tinaves, Special Counsel, Division of Trading and Markets, Commission and Amy K. Edwards, Assistant Director and Cindy Alexander, Assistant Chief Economist, Division of Risk, Strategy, and Financial Information, Commission.

[50] *Id.*

listed which would raise unfair discrimination issues under the Act.

While some commenters have argued that the Commission's approval of the NYSE's proposal will mean the Commission has implicitly approved the particular service providers NYSE currently uses, the Commission disagrees. The Commission, in approving the Exchange's proposal, is not endorsing, specifically or implicitly, any party with which the NYSE has chosen to do business.

The Commission has carefully considered the comment letters. Although some of the alternative proposals by the commenters might also satisfy the standards under Sections 6(b) and 19(b) of the Act[51] depending on the facts and circumstances, those proposals are not before us, and the Commission believes that the NYSE's proposal is consistent with these standards and, therefore, should be approved. Other commenters raised certain issues beyond the scope of the Commission's review of this rule proposal, such as the fee arrangements between the NYSE and the providers of the services described in this order. The Commission has carefully considered these comments but believes that the proposal before the Commission satisfies the requirements for approval under Sections 6(b) and 19(b) of the Act[52] for the reasons discussed above.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[53] that the proposed rule change (SR–NYSE–2011–20) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[54]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–21035 Filed 8–17–11; 8:45 am]

BILLING CODE 8011–01–P

[51] 15 U.S.C. 78f(b) and 15 U.S.C. 78s(b).

[52] *Id.*

[53] 15 U.S.C. 78s(b)(2).

[54] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65125; File No. SR–NASDAQ–2011–105]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change To Establish an Acceptable Trade Range for Quotes and Orders Entered on the NASDAQ Options Market

August 12, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 2, 2011, The NASDAQ Stock Market LLC (''NASDAQ'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

NASDAQ proposes to establish an Acceptable Trade Range for quotes and orders entered on the NASDAQ Options Market (''NOM''). Similar mechanisms are used successfully on other exchanges to protect investors and members by limiting volatility and obvious errors.

The text of the proposed rule change is available at *http://NASDAQ.cchwallstreet.com/*, at NASDAQ's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASDAQ included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASDAQ 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

Background. In the current high-speed electronic market environment, various trading centers grapple with issues associated with thinly traded securities such as price dislocations, wide quotes, and erroneous executions that can result in trade cancellations. Though these situations are not overly prevalent, they can produce confusion and frustration among market participants. As a custodian and operator of several U.S. exchanges, NASDAQ believes that it is always prudent and appropriate to consider system enhancements that will preclude potential future issues with or unforeseen gaps in the existing structure of its trading systems.

Accordingly, NASDAQ is proposing to adopt a mechanism that will prevent the NOM trading system (''System'') from experiencing dramatic price swings. This circumstance can exist if, for example, a market order or aggressively priced limit order is entered that is larger than the total volume of contracts quoted at the top-of-book across all U.S. options exchanges. Currently, without any protections in place, this could result in options executing at prices that have little or no relation to the theoretical price of the option.

For example, in a thinly traded option:

Away Exchange Quotes:

Exchange	Bid size	Bid price	Offer price	Offer size
PHLX	10	$1.00	$1.05	10
NYSE Arca	10	1.00	1.05	10
NYSE Amex	10	1.00	1.10	10
BOX	10	1.00	1.15	10

NOM Price Levels:

Exchange	Bid size	Bid price	Offer price	Offer size
NOM	10	$1.00	$1.05	10

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Exchange	Bid size	Bid price	Offer price	Offer size
NOM			1.10	10
NOM			1.40	10
NOM			5.00	10

If NOM receives a routable market order to buy 80 contracts, the System will respond as described below:

—10 contracts will be executed at $1.05 against NOM
—10 contracts will be executed at $1.05 against PHLX
—10 contracts will be executed at $1.05 against NYSE Arca.
—10 contracts will be executed at $1.10 against NOM
—10 contracts will be executed at $1.10 against NYSE AMEX
—10 contracts will be executed at $1.15 against BOX

After these executions, there are no other known valid away exchange quotes. The NBBO is therefore comprised of the remaining interest on the NOM book, specifically 10 contracts at $1.40 and 10 contracts at $5.00. In the absence of an Acceptable Trade Range mechanism, the order would execute against the remaining interest at $1.40 and $5.00, resulting in potential harm to investors.

To bolster the normal resilience and market behavior that persistently produces robust reference prices, NOM is proposing to create a level of protection that prevents the market from moving beyond set thresholds. The thresholds consist of a reference price plus (minus) set dollar amounts based on the nature of the option and the premium of the option. The exchange is not introducing a new concept. In fact, The NASDAQ Stock Market, NASDAQ OMX PSX, and NASDAQ OMX BX all place a limit on the prices at which market orders will be allowed to execute.[3]

System Operation. The proposed Acceptable Trade Range would work as follows: Prior to executing orders received by the exchange, an Acceptable Trade Range is calculated to determine the range of prices at which orders may be executed. When an order is initially received, the threshold is calculated by adding (for buy orders) or subtracting (for sell orders) a value,[4] as discussed below, to the National Best Offer for buy orders or the National Best Bid for sell orders to determine the range of prices that are valid for execution. A buy (sell) order will be allowed to execute up (down) to and including the maximum (minimum) price within the Acceptable Trade Range. The Acceptable Trade Range threshold becomes the reference price for the next Acceptable Trade Range calculation. If an order cannot be completely executed within the Acceptable Trade Range, and the limit price of the order is greater (for buy orders) or less (for sell orders) than the Acceptable Trade Range threshold, the unexecuted portion of the original order will be posted at the Acceptable Trade Range threshold. The order will remain posted for a brief period, not to exceed one second, to allow the market to refresh and to determine whether or not more liquidity will become available (on NOM or any other exchange if the order is designated as routable) within the posted price of the order before moving on to a new Threshold Price. The Acceptable Trade Range threshold, at which the order is posted, then becomes the new reference price[5] and a new threshold is calculated. Once the brief pause has expired, if the order has not been fully executed, it will be allowed to execute up to and including the new Acceptable Trade Range Threshold Price.

During the brief pause, NOM will display the Acceptable Trade Range Threshold Price on one side of the market and the best available price on the opposite side of the market using a ''non-firm'' indicator.[6] This allows the order setting the Acceptable Trade Range Threshold Price to retain price/time priority in the NOM book and also prevents any later-entered order from accessing liquidity ahead of it. If NOM were to display trading interest available on the opposite side of the market, that trading interest would be automatically accessible to later-entered orders during the period when the order triggering the Acceptable Trade Range is paused. Following the Posting Period, the Exchange will return to a normal trading state and disseminate its best bid and offer.

NASDAQ believes that disseminating a non-firm quotation message as described above is consistent with its obligations under the SEC Quote Rule.[7] The fact that NASDAQ is experiencing volatility that is strong enough to trigger the Acceptable Trade Range mechanism qualifies as an unusual market condition. NASDAQ expects such situations to be rare, and as described below it will set the parameters of the mechanism at levels that will ensure that it is triggered quite infrequently. In addition, the Acceptable Trade Range mechanism will cause the market to pause for no more than one second, a briefer pause than occurs in other markets that are experiencing and attempting to dampen volatility.[8] Importantly, the brief pause only occurs after the Exchange has already executed transactions—potentially at multiple price levels—rather than pausing before executing any transactions in the hopes of attracting initial liquidity.

Importantly, the Acceptable Trade Range is neutral with respect to away markets. The order may route to other destinations to access liquidity priced within the Acceptable Trade Range provided the order is designated as routable. If the order still remains unexecuted, this process will repeat until the order is executed, cancelled, or posted at its limit price. If after an order is routed to the full size of an away exchange and additional size remains available, the remaining contracts will be posted on NOM at a price that

[3] NASDAQ believes that the proposed Acceptable Trade Range mechanism is superior to the market collar orders currently used in equity markets because the Acceptable Trade Range will apply to all orders rather than just unpriced orders. Additionally, rather than immediately cancelling the order, the market would continue to work the order for execution. *See* NASDAQ Stock Market rule 4751(f)(13), NASDAQ OMX BX 4751(f)(10), and NASDAQ OMX PSX 3301(f)(9).

[4] The value that is to be added to the reference price will be set by the exchange and posted on the exchange *Web site: http://www.nasdasqtrader.com.*

[5] If a new NBB is received that is greater than a buy order posted at the Acceptable Trade Range threshold, or a new NBO is received that is lower than a sell order posted at the Acceptable Trade Range threshold, the new NBB (for buy orders) or NBO (for sell orders) will be the new reference price.

[6] Non-firm quote indication values are described on page 18 of the specifications disseminated by the Options Price Regulatory Authority. *See http://www.opradata.com/specs/participant_interface_specification.pdf.*

[7] 17 CFR 242.602.

[8] For example, the NASDAQ Acceptable Trade Range mechanism will pause for a briefer period than the Liquidity Replenishment Point or ''LRP'' employed by the New York Stock Exchange. The LRP resembles the Acceptable Trade Range in that it also is designed to dampen volatility under similar circumstances, it pauses the market in the affected security, and it disseminates to the network processor a non-firm quote condition during the resulting pause. *See* NYSE Rules 1000(a)(iv) and 60(e)(ii). Unlike the Acceptable Trade Range mechanism, the LRP can exceed one second in duration.

assumes the away market has executed the routed order. This practice of routing and then posting is consistent with the national market system plan governing trading and routing of options orders and the NOM policies and procedures that implement that plan.[9]

For example, assume that the Acceptable Trade Range is set for $0.05 and the following quotations are posted in all markets:

Away Exchange Quotes:

Exchange	Bid size	Bid price	Offer price	Offer size
ISE	10	$0.75	$0.90	10
AMEX	10	0.75	0.92	10
PHLX	10	0.75	0.94	10

NOM Price Levels:

Exchange	Bid size	Bid price	Offer price	Offer size
NOM	10	$0.75	$0.90	10
NOM			0.95	10
NOM			0.97	10
NOM			1.00	20

NOM receives a routable order to buy 70 contracts at $1.10. The Acceptable Trade Range is $0.05 and the reference price is the National Best Offer—$0.90. The Acceptable Trade Range threshold is then $0.90 + $0.05 = $0.95. The order is allowed to execute up to and including $0.95. The System then pauses for a brief period not to exceed one second to allow the market (including other exchanges) to refresh and to determine whether additional liquidity will become available within the order's posted price. If additional liquidity becomes available on NOM or any away market, that liquidity will be accessed and executed.

- 10 contracts will be executed at $0.90 against NOM
- 10 contracts will be executed at $0.90 against ISE
- 10 contracts will be executed at $0.92 against AMEX
- 10 contracts will be executed at $0.94 against PHLX
- 10 contracts will be executed at $0.95 against NOM
- Then, after executing at multiple price levels, the order is posted at $0.95 for a brief period not to exceed one second to determine whether additional liquidity will become available.
- A new Acceptable Trade Range Threshold Price of $1.00 is determined (new reference price of $0.95 + $0.05 = $1.00)
- If, during the brief pause not to exceed 1 second, no liquidity becomes available within the order's posted price of $0.95, the System will then execute 10 contracts at $0.97, and 10 contracts at $1.00 [10]

Similarly, if a new order is received when a previous order has reached the Acceptable Trade Range threshold, the Threshold Price will be used as the reference price for the new Acceptable Trade Range threshold. Both orders would then be allowed to execute up (down) to the new Threshold Price.

For example:

Away Exchange Quotes:

Exchange	Bid size	Bid price	Offer price	Offer size
ISE	10	$0.75	$0.90	10
AMEX	10	$0.75	$0.92	10
PHLX	10	$0.75	$0.94	10

NOM Price Levels:

Exchange	Bid size	Bid price	Offer price	Offer size
NOM	10	$0.75	$0.90	10
NOM			$0.95	10
NOM			$1.05	20

- NOM receives a routable order to buy 60 contracts at $1.10. The Acceptable Trade Range is $0.05 and the reference price is the National Best Offer—$0.90. The Acceptable Trade Range threshold is then $0.90 + $0.05 = $0.95. The order is allowed to execute up to and including $0.95.
- 10 contracts will be executed at $0.90 against NOM
- 10 contracts will be executed at $0.90 against ISE

[9] *See* Options Order Protection and Locked/Crossed Markets Plan; Securities Exchange Act Release No. 60405 (July 30, 2009), 74 FR 39362 (August 6, 2009); NOM Rules Chapter VI, Section 7(b)(3)(C). Section 5(b)(v) of the Plan provides an exception from trade through prevention when: ''[t]he transaction that constituted the Trade-Through was effected by a Participant that simultaneously routed an Intermarket Sweep Order to execute against the full displayed size of any Protected Quotation that was traded through;'' [sic]

[10] The brief pause described above will not disadvantage customers seeking the best price in any market. For example, if in the example above an NYSE ARCA quote of $0.75 x $0.96 with size of 10 x 10 is received, a routable order would first route to NYSE ARCA at $0.96, then execute against NOM at $0.97.

• 10 contracts will be executed at $0.92 against AMEX
• 10 contracts will be executed at $0.94 against PHLX
• 10 contracts will be executed at $0.95 against NOM
• Then, after executing at multiple price levels, the order is posted at $0.95 for a brief period not to exceed one second to determine whether additional liquidity will become available.
• A new Acceptable Trade Range Threshold Price of $1.00 is determined (new reference price of $0.95 + $0.05 = $1.00)
• If, during the brief period not to exceed one second, a second order is received to buy 10 contracts at $1.25, the two orders would then post at the new Acceptable Trade Range Threshold price of $1.00 for a brief period not to exceed one second to determine whether additional liquidity will become available.
• A new Acceptable Trade Range threshold of $1.05 will be calculated.
• If no additional liquidity becomes available within the posted price of the orders ($1.00) during the brief period not to exceed one, the orders would execute 10 contracts each against the order on the NOM book at $1.05

Setting Acceptable Range Values. The options class premium will be the dominant factor in determining the Acceptable Trade Range. Generally, options with lower premiums tend to be more liquid and have tighter bid/ask spreads; options with higher premiums have wider spreads and less liquidity. Accordingly, a table consisting of several steps based on the premium of the option will be used to determine how far the market for a given option will be allowed to move. This table or tables would be listed on the NASDAQTrader.com Web site and any periodic updates to the table would be announced via an Options Trader Alert.

For example, looking at some SPY January 2011 Call options on December 27th of 2010:

Bid/Offer of SPY Jan 126 Call (at or near-the-money): $1.78 × $1.79 (several hundred contracts on bid and offer)

Bid/Offer of SPY Jan 80 Call (deep in-the-money): $45.61 × $45.87 (20 contracts on each side)

The deep in-the-money calls (Jan 80 calls) have a wider spread ($45.87–$45.61 = $0.26) compared to a spread of $0.01 for the at-the-money calls (Jan 126 calls). Therefore, it is appropriate to have different thresholds for the two options. For instance, it may make sense to have a $0.05 threshold for the at-the-money strikes (Premium < $2) and a $0.50 threshold for the deep in-the-money strikes (Premium > $10).

To consider another example, the January 2011 CSCO put options on December 27th of 2010:

Bid/Offer of CSCO 20 Jan Put (at or near-the-money): $0.11 × $0.12 (300×550)

Bid/Offer of CSCO 35 Jan Put (deep in-the-money): $14.35 × $15.20 (48×18)

Even though CSCO has a much lower share price than SPY, and is a different type of security (it is a common stock of a technology company whereas SPY is an ETF based on the S&P 500 Index), the pattern is the same. The option with the lower premium has a very narrow spread of $0.01 with significant size displayed whereas the higher premium option has a wide spread ($0.85) and less size displayed.

The Acceptable Trade Range settings will be tied to the option premium. However, other factors will be considered when determining the exact settings. For example, Acceptable Ranges may change if market-wide volatility is as high as it was during the financial crisis in 2008 and 2009, or if overall liquidity is low based on historical trends. These different market conditions may present the need to adjust the threshold amounts from time to time to ensure a well-functioning market. Without adjustments, the market may become too constrained or conversely, prone to wide price swings. As stated above, the Exchange would publish the Acceptable Trade Range table or tables on the NASDAQTrader.com Web site. The Exchange does not foresee updating the table(s) often or intraday. The Exchange will provide sufficient advanced notice of changes to the Acceptable Trade Range table to its membership via Options Trader Alerts.

The Acceptable Trade Range settings would generally be the same across all options traded on NOM, although NASDAQ proposes to maintain flexibility to set them separately based on characteristics of the underlying security. For instance, Google is a stock with a high share price ($602.38 closing price on December 27th). Google options therefore may require special settings due to the risk involved in actively quoting options on such a high-priced stock. Option spreads on Google are wider and the size available at the best bid and offer is smaller. Google could potentially need a wider threshold setting compared to other lower-priced stocks. There are other options that fit into this category (e.g. AAPL) which makes it necessary to have threshold settings that have flexibility based on the underlying security. Additionally, it is generally observed that options subject to the Penny Pilot program quote with tighter spreads than options not subject to the Penny Pilot. Currently, NASDAQ expects to set Acceptable Trade Ranges for three categories of options: Standard Penny Pilot, Special Penny Pilot (IWM, QQQQ, SPY), and Non-Penny Pilot.[11]

2. Statutory Basis

NASDAQ believes the proposed rule change is consistent with the provisions of Section 6 of the Act,[12] in general and with Section 6(b)(5) of the Act,[13] in particular, which requires that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest. The proposed rule change is consistent with these requirements in that it will reduce the negative impacts of sudden, unanticipated volatility in individual NOM options, and serve to preserve an orderly market in a transparent and uniform manner, enhance the price-discovery process, increase overall market confidence, and promote fair and orderly markets and the protection of investors.

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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and

[11] NASDAQ notes that the Acceptable Range Test in place at NASDAQ OMX PHLX—PHLX Rule 1082(a)(ii)(B)(3)(f)—currently provides for this flexibility.

[12] 15 U.S.C. 78f.

[13] 15 U.S.C. 78f(b)(5).

publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2011–105 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–2011–105. This file number should be included on the subject line if e-mail 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 on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of NASDAQ. 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–2011–105 and should be submitted on or before September 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–21034 Filed 8–17–11; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65132]

Order Temporarily Exempting the Floor Broker Operations of Broker-Dealers With Market Access That Handle Orders on a Manual Basis From the Automated Controls Requirement of Rule 15c3–5(c)(1)(ii) and Rule 15c3–5(c)(2) Under the Securities Exchange Act of 1934

August 15, 2011.

I. Introduction

Pursuant to Rule 15c3–5(f) under the Securities Exchange Act of 1934 (''Exchange Act''),[1] the Securities and Exchange Commission (''Commission''), by order, may exempt from the provisions of Rule 15c3–5 (''Rule''), either unconditionally or on specified terms and conditions, any broker or dealer, if the Commission determines that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.[2] As discussed below, the Commission temporarily is exempting the floor broker operations of broker-dealers with market access that handle orders on a manual basis (''Floor Brokers'') from the automated controls requirement of Rules 15c3–5(c)(1)(ii)[3] and (c)(2)[4] until November 30, 2011.[5]

II. Background

On November 3, 2010, the Commission adopted Rule 15c3–5 under the Exchange Act.[6] Among other things, Rule 15c3–5 requires each broker-dealer with access to trading securities[7] directly on an exchange or ATS, including a broker-dealer providing sponsored or direct market access to customers or other persons, and each broker-dealer operator of an ATS that provides access to trading securities directly on its ATS to a person other than a broker-dealer, to establish, document, and maintain a system of risk management controls and supervisory procedures that, among other things, is reasonably designed to (1) Systematically limit the financial exposure of the broker-dealer that could arise as a result of market access,[8] and (2) ensure compliance with all regulatory requirements that are applicable in connection with market access.[9] The required financial risk management controls and supervisory procedures must be reasonably designed to prevent the entry of orders that exceed appropriate pre-set credit or capital thresholds,[10] or that appear to be erroneous.[11] The regulatory risk management controls and supervisory procedures must also be reasonably designed to prevent the entry of orders unless there has been compliance with all regulatory requirements that must be satisfied on a pre-order entry basis,[12] prevent the entry of orders that the broker-dealers or customer is restricted from trading,[13] restrict market access technology and systems to authorized persons,[14] and assure appropriate surveillance personnel receive immediate post-trade execution reports.[15]

The Commission has received a request from NYSE Amex LLC (''NYSE Amex''), NYSE Arca, Inc. (''NYSE Arca''), and New York Stock Exchange LLC (''NYSE'') (collectively, ''NYSE Euronext'') to extend the compliance date for the automated controls requirement pursuant to Rules 15c3–5(c)(1)(ii) and (c)(2) for Floor Brokers until November 30, 2011.[16] Specifically,

[1] *See* 17 CFR 240.15c3–5(f).

[2] *See also* Exchange Act Section 36(a)(1), 15 U.S.C. 78mm(a)(1) (providing general authority for Commission to grant exemptions from provisions of Exchange Act and rules thereunder, provided the Commission makes certain required findings).

[3] *See* 17 CFR 240.15c3–5(c)(1)(ii).

[4] *See* 17 CFR 240.15c3–5(c)(2).

[5] On June 27, 2011, the Commission extended the compliance date, until November 30, 2011, for all of the requirements of Rule 15c3–5 for fixed income securities, and the requirements of Rule 15c3–5(c)(1)(i) for all securities. *See* Securities Exchange Act Release No. 64748 (June 27, 2011), 76 FR 38293 (June 30, 2011).

[6] *See* Exchange Act Release No. 63241 (Nov. 3, 2010), 75 FR 69792 (Nov. 15, 2010) (''Rule 15c3–5 Adopting Release'').

[7] Rule 15c3–5 applies to trading in all securities on an exchange or ATS. *Id.* at 69765.

[8] *See* 17 CFR 240.15c3–5(c)(1).

[9] *See* 17 CFR 240.15c3–5(c)(2).

[10] *See* 17 CFR 240.15c3–5(c)(1)(i).

[11] *See* 17 CFR 240.15c3–5(c)(1)(ii).

[12] *See* 17 CFR 240.15c3–5(c)(2)(i).

[13] *See* 17 CFR 240.15c3–5(c)(2)(ii).

[14] *See* 17 CFR 240.15c3–5(c)(2)(iii).

[15] *See* 17 CFR 240.15c3–5(c)(2)(iv).

[16] *See* letter from Janet McGinness, Senior Vice President—Legal and Corporate Secretary, NYSE Euronext, on behalf of NYSE Amex, NYSE Arca, and NYSE, to Elizabeth Murphy, Secretary,

Continued

NYSE Euronext indicated that more time is needed to complete the implementation of the automated controls required pursuant to Rules 15c3–5(c)(1)(ii) and (c)(2) for orders handled on a manual basis because the floor broker operations of broker-dealers with market access historically have used manual systematic controls for their risk management and regulatory purposes with respect to manual orders, and they will need additional time to complete the development and implementation of automated controls for such manual orders.[17] NYSE Euronext explained that certain Floor Brokers initially believed that their existing combination of automated and manual controls would be sufficient for compliance with Rule 15c3–5,[18] and only recently became aware that the required pre-trade controls under the Rule must be systemic and automated for compliance purposes.[19] NYSE Euronext also explained that additional time would provide the NYSE Euronext with an opportunity to update Floor Broker-related systems and thereby facilitate compliance with the Rule by Floor Brokers.[20]

III. Discussion

The Commission is temporarily exempting Floor Brokers from the automated controls requirement of Rules 15c3–5(c)(1)(ii)[21] and (c)(2)[22] until November 30, 2011. The Commission believes that providing additional time for such Floor Brokers to complete the development and implementation of automated controls pursuant to Rules 15c3–5(c)(1)(ii) and (c)(2) for orders handled on a manual basis, where manual systematic controls historically were used for risk management and regulatory purposes, is reasonable. In addition, the Commission believes that temporarily exempting Floor Brokers from the automated controls requirement of Rules 15c3–5(c)(1)(ii) and (c)(2) until November 30, 2011, should facilitate the orderly and meaningful implementation of the required automated risk management controls for those Floor Brokers that need more time to be in compliance with the Rule.

For the foregoing reasons, the Commission finds that granting the foregoing temporary exemption is necessary and appropriate in the public interest, and is consistent with the protection of investors.

IV. Conclusion

It Is Hereby Ordered, pursuant to Rule 15c3–5(f),[23] that the floor broker operations of broker-dealers with market access that handle orders on a manual basis are temporarily exempted from the automated controls requirement of Rules 15c3–5(c)(1)(ii)[24] and (c)(2)[25] until November 30, 2011.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–21099 Filed 8–17–11; 8:45 am]

BILLING CODE 8011–01–P

Commission, dated June 29, 2011 (''NYSE Euronext Letter'').

[17] *Id.*

[18] *Id.* at 2.

[19] *See* Rule 15c3–5 Adopting Release.

[20] NYSE Euronext Letter at 2.

[21] *See* 17 CFR 240.15c3–5(c)(1)(ii).

[22] *See* 17 CFR 240.15c3–5(c)(2).

[23] *See* 17 CFR 240.15c3–5(f).

[24] *See* 17 CFR 240.15c3–5(c)(1)(ii).

[25] *See* 17 CFR 240.15c3–5(c)(2).

DEPARTMENT OF STATE

[Public Notice 7557]

Culturally Significant Objects Imported for Exhibition Determinations: ''Wonder of the Age: Master Painters of India, 1100–1900''

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 ''Wonder of the Age: Master Painters of India, 1100–1900,'' 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 Metropolitan Museum of Art, New York, New York, from on or about September 28, 2011, until on or about January 8, 2012, 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: August 11, 2011.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2011–21129 Filed 8–17–11; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending July 30, 2011

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under subpart B (formerly subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 *et. seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: DOT–OST–2011–0143.

Date Filed: July 29, 2011.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: August 19, 2011.

Description: Application of TwinAir Calypso Limited, Inc. requesting authority to conduct scheduled passenger operations as a commuter air carrier.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2011–21083 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Office of Commercial Space Transportation (AST); Notice of Availability of the Finding of No Significant Impact (FONSI) for the Federal Aviation Administration (FAA)/AST To Issue, Renew, or Modify Launch Operator Licenses for Atlas V Launch Vehicles Covered Under the Evolved Expendable Launch Vehicle (EELV) Program From Space Launch Complex-3 East (SLC–3E) at Vandenberg Air Force Base (VAFB), California

AGENCY: Federal Aviation Administration, Department of Transportation.

ACTION: Notice of Availability of the FONSI.

SUMMARY: In accordance with the National Environmental Policy Act (NEPA) of 1969, 42 United States Code 4321–4347 (as amended), Council on Environmental Quality (CEQ) NEPA implementing regulations (40 Code of Federal Regulations [CFR] Parts 1500–1508), and FAA Order 1050.1E, Change 1, the FAA is announcing the availability of a FONSI for the FAA/AST action to issue, renew, or modify Launch Operator Licenses for Atlas V launch operations from SLC–3E at VAFB. The FONSI is based on the analysis and findings of the 2003 United States Air Force (USAF) Final Environmental Assessment for the Atlas V System at SLC–3E (2003 EA).

In 1998, the USAF issued the 1998 Final Environmental Impact Statement for the EELV Program (1998 EIS) to evaluate the potential environmental impacts of the development, deployment, and operation of EELV systems (later known as the Atlas V and Delta IV launch vehicle families). In 2000, the USAF prepared the Supplemental Environmental Impact Statement for the EELV Program (2000 SEIS) to evaluate the potential environmental impacts of adding up to five solid-propellant strap-on rocket motors to the Atlas V launch vehicle and larger solid-propellant strap-on rocket motors on the Delta IV vehicle. The FAA participated as a cooperating agency in preparation of both the 1998 FEIS and 2000 SEIS.

In 2003, changes in USAF programs resulted in a need for SLC–3E at VAFB to be used for Atlas V launches rather than SLC–3W as originally planned, and therefore the USAF prepared the 2003 EA. The EA supplemented and updated the previous NEPA evaluation of implementing the Atlas V program as analyzed in the 1998 FEIS and 2000 SEIS. The 2003 EA analyzed the environmental impacts associated with the proposed action of modifying existing facilities and roadways and launching the Atlas V up to four times annually from SLC–3E at VAFB. The 2003 EA tiered its analyses from the 1998 FEIS and 2000 SEIS, and therefore both documents were incorporated by reference into the 2003 EA. The FAA did not participate as a cooperating agency with the USAF in preparation of the 2003 EA. Under the FAA's Proposed Action as stated in the FONSI, FAA/AST could issue, renew, or modify Launch Operator Licenses for Atlas V launch operations from SLC–3E at VAFB. A Launch Operator License would authorize launches of Atlas V vehicles over the five-year term of the license.

In accordance with the requirements of FAA Order 1050.1E, Change 1, paragraph 410, the FAA has independently evaluated the information contained in the 2003 EA and has verified the continued validity of the analysis contained in the EA. The FAA has determined that the discussion of Atlas V launch operations in the 2003 EA sufficiently addresses the concerns of the FAA and complies with FAA requirements for implementing NEPA as stated in FAA Order 1050.1E, Change 1. The FAA has determined that there is no new information or analysis that would require preparation of a new or supplemental EA or EIS according to the CEQ Regulations (40 CFR 1502.9(c)(1)). Therefore, the FAA issued the FONSI concurring with the analysis of impacts and findings in the 2003 EA and formally adopts the launch operations discussion in the EA in compliance with the requirements of 40 CFR 1506.3 to support the issuance, renewal, or modification of Launch Operator Licenses for Atlas V launch operations from SLC–3E at VAFB. The 2003 EA is incorporated by reference and is summarized as necessary in the FONSI.

The FAA has posted the FONSI on the Internet at *http://www.faa.gov/about/office_org/headquarters_offices/ast/.*

FOR FURTHER INFORMATION CONTACT: Mr. Daniel A. Czelusniak, Environmental Program Lead, Office of Commercial Space Transportation, Federal Aviation Administration, 800 Independence Ave., SW., Room 325, Washington, DC 20591, telephone (202) 267–5924; E-mail *Daniel.Czelusniak@faa.gov.*

Issued in Washington, DC, on August 12, 2011.

Michael McElligott,

Manager, Space Transportation Development Division.

[FR Doc. 2011–21048 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Office of Commercial Space Transportation (AST); Notice of Availability of the Record of Decision (ROD) for the Federal Aviation Administration (FAA)/AST To Issue, Renew, or Modify Launch Operator Licenses for Launch Vehicles Covered Under the Evolved Expendable Launch Vehicle (EELV) Program, Which Include Atlas V and Delta IV Vehicles, From Cape Canaveral Air Force Station (CCAFS), Florida and Vandenberg Air Force Base (VAFB), California

AGENCY: Federal Aviation Administration, DOT.

ACTIONS: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act (NEPA) of 1969, 42 United States Code U.S.C. 4321–4347 (as amended), Council on Environmental Quality (CEQ) NEPA implementing regulations (40 Code of Federal Regulations [CFR parts 1500–1508]), and FAA Order 1050.1E, Change 1, the FAA is announcing the availability of its ROD for the FAA/AST to issue, renew, or modify launch operator licenses for launch vehicles covered under the EELV Program from CCAFS and VAFB. The ROD was prepared to document FAA/AST's decision to issue, renew, or modify launch operator licenses for launch vehicles covered under the EELV Program from CCAFS and VAFB.

The FAA participated as a cooperating agency with the U.S. Air Force (USAF) in the preparation of the 1998 Final Environmental Impact Statement for the EELV Program (1998 FEIS) and the 2000 Supplemental Environmental Impact Statement for the EELV Program (2000 SEIS). The 1998 FEIS preferred alternative analyzed a maximum of 30 combined FAA/AST-licensed launches and non-FAA/AST licensed launches of Atlas V and Delta IV in one year from VAFB and CCAFS, combined. The 2000 SEIS analyzed the environmental impacts of up to five solid-propellant strap-on rocket motors (SRMs) on the Atlas V medium lift vehicle and larger SRMs on the Delta IV vehicle. In addition, the 2000 SEIS considered a maximum of 33 combined

FAA/AST-licensed launches and non-FAA/AST licensed launches of Atlas V and Delta IV occurring in one year from VAFB and CCAFS, combined. The USAF issued RODs based on the findings of the 1998 FEIS and the 2000 SEIS.

In 2003, changes in USAF programs resulted in a need for SLC–3E at VAFB to be used for Atlas V launches rather than SLC–3W as originally planned. In 2003, the USAF prepared a Final Environmental Assessment for the Atlas V System at SLC–3E (2003 EA). The EA supplemented and updated the previous NEPA evaluation of implementing the Atlas V program as analyzed in the 1998 FEIS and 2000 SEIS. The 2003 EA analyzed the environmental impacts associated with the proposed action of modifying existing facilities and roadways and launching the Atlas V up to four times annually from SLC–3E at VAFB. The FAA did not participate as a cooperating agency with the USAF in preparation of the 2003 EA, but has independently evaluated the information contained in the 2003 EA and has verified the continued validity of the analysis contained in the document. The FAA has therefore, adopted the 2003 EA and issued a Finding of No Significant Impact. The analysis from the 2003 EA and the FAA's findings on that analysis are incorporated by reference in the ROD, and therefore references from the 1998 FEIS and 2000 SEIS to SLC–3W at VAFB have been revised to read ''SLC–3E'' throughout the ROD.

Under the FAA's Proposed Action, FAA/AST could issue, renew, or modify launch operator licenses for Atlas V and Delta IV operations at CCAFS and VAFB. The 1998 FEIS and 2000 SEIS analyzed the full potential scope of the operations that could be covered under a launch operator license for Atlas V and Delta IV at CCAFS and VAFB. The FAA's Proposed Action has been identified as the Preferred Alternative.

Under the No Action Alternative, the FAA would not issue, renew, or modify launch operator licenses for Atlas V or Delta IV expendable launch vehicles at CCAFS and VAFB. Without a license, there could not be any FAA/AST-licensed commercial launches of Atlas V or Delta IV vehicles from CCAFS or VAFB; however, non-FAA/AST licensed or government launches of these vehicles could continue from both locations. The ROD addresses the potential environmental impacts of the FAA's Proposed Action and the FAA's No Action Alternative.

In accordance with the requirements of FAA Order 1050.1E, Change 1, paragraph 515, the FAA has independently evaluated the information contained in the 1998 FEIS and 2000 SEIS and has verified the continued validity of the analysis contained in both documents. Through this re-evaluation, the FAA has determined that the 1998 FEIS and 2000 SEIS sufficiently address the concerns of the FAA and comply with FAA requirements for implementing NEPA as stated in FAA Order 1050.1E, Change 1. The FAA has also determined that there is no new information or analysis that would require preparation of a new or supplemental EIS according to the CEQ Regulations (40 CFR 1502.9(c)(1)). The FAA is therefore adopting the 1998 FEIS and 2000 SEIS, and is using these documents to support its decision as stated in the ROD. The FAA has posted the ROD on the FAA Office of Commercial Space Transportation Web site at *http://www.faa.gov/about/office_org/headquarters_offices/ast/.*

Additional Information: Under the Proposed Action, the FAA/AST could issue, renew, or modify launch operator licenses for Atlas V and Delta IV operations at CCAFS and VAFB. The 1998 FEIS and 2000 SEIS analyzed the full potential scope of the operations that could be covered under a launch operator license for Atlas V and Delta IV at CCAFS and VAFB. The 1998 FEIS analyzed the operation of both medium and heavy lift expendable, orbital ''concept vehicles'' (later known as the Atlas V and Delta IV families of vehicles) from CCAFS and VAFB. Delta IV launches would occur from Space Launch Complex-37 (SLC–37) at CCAFS and from SLC–6 at VAFB; the Atlas V launches would occur from SLC–41 at CCAFS and from SLC–3E at VAFB. Under the preferred alternative in the 1998 FEIS, a maximum of 30 combined FAA/AST-licensed launches and non-FAA/AST licensed launches of Atlas V and Delta IV would occur in one year from VAFB and CCAFS, combined. Under the No Action Alternative, the USAF would not proceed with the development and deployment of the EELV program, and Atlas IIA, Delta II, and Titan IVB launch vehicles would continue to be used to support space launches to meet the requirements of the government.

Under the Proposed Action in the 2000 SEIS, up to five solid-propellant strap-on rocket motors (SRMs) would be added to the Atlas V medium lift vehicle and larger SRMs would be used on the Delta IV vehicle. The Atlas V vehicle would launch from SLC–41 at CCAFS and SLC–3E at VAFB, and the Delta IV vehicle would launch from SLC–37 at CCAFS and SLC–6 at VAFB. While use of SRM-assisted vehicles was considered in the 1998 FEIS, the 2000 SEIS considered a higher proportion of vehicles using SRM-assisted vehicles than the 1998 FEIS. Under the Proposed Action in the 2000 SEIS, a maximum of 33 combined FAA/AST-licensed launches and non-FAA/AST licensed launches of Atlas V and Delta IV would occur in one year from VAFB and CCAFS, combined. Under the No Action Alternative, the EELV program would continue, except that SRMs would not be added to the Atlas V launch vehicles and smaller SRMs would be used on Delta IV launch vehicles.

The FAA has determined the analysis of impacts presented in the 1998 FEIS and 2000 SEIS represents the best available information regarding the potential impacts associated with the FAA's regulatory responsibilities described in the ROD. The 1998 FEIS and 2000 SEIS are therefore incorporated by reference and summarized as necessary in the ROD.

Resource areas were considered to provide a context for understanding and assessing the potential environmental effects of the FAA's Proposed Action, with attention focused on key issues. The resource areas considered in the ROD include air quality; biological resources; cultural resources; geology and soils; land use and section 4(f) resources; noise; physical resources (Water Resources [Surface Water, Ground Water, Floodplains], Hazardous Materials, Pollution Prevention, and Solid Waste); and socioeconomics, environmental justice, and children's environmental health and safety. Potential cumulative impacts of the Proposed Action are also addressed in the ROD.

FOR FURTHER INFORMATION CONTACT: Mr. Daniel A. Czelusniak, Environmental Program Lead, Office of Commercial Space Transportation, Federal Aviation Administration, 800 Independence Ave., SW., Suite 325, Washington, DC 20591, by e-mail at *Daniel.Czelusniak@faa.gov* or by phone at (202) 267–5924.

Issued in Washington, DC, on August 12, 2011.

Michael McElligott,

Manager, Space Transportation Development Division.

[FR Doc. 2011–21045 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Commercial Space Transportation Advisory Committee—Open Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Commercial Space Transportation Advisory Committee open meeting.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App. 2), notice is hereby given of a meeting of the Commercial Space Transportation Advisory Committee (COMSTAC). The meeting will take place on Thursday, October 13, 2011, from 8 a.m. to 5 p.m., and Friday, October 14, 2011, from 8 a.m. to 4:30 p.m., at the National Housing Center, 1201 15th Street NW., Washington, DC, 20005. This will be the 54th meeting of the COMSTAC.

The proposed agenda for October 13 features meetings of the working groups as follows:

—Export Controls (8 a.m.–10 p.m.)
—Space Transportation Operations (10 a.m.–12 a.m.)
—Reusable Launch Vehicles (1 p.m.–3 p.m.)
—Risk Management (3 p.m.–5 p.m.)

The proposed agenda for October 14 features:

—Speakers relevant to the commercial space transportation industry, including invitees from the U.S. Department of State and Department of Defense;
—Invited speaker from the FAA NextGen Office;
—Reports and recommendations from the working groups.

Interested members of the public may submit relevant written statements for the COMSTAC members to consider under the advisory process. Statements may concern the issues and agenda items mentioned above and/or additional issues that may be relevant for the U.S. commercial space transportation industry. Interested parties wishing to submit written statements should contact Susan Lender, DFO, (the Contact Person listed below) in writing (mail or e-mail) by October 5, 2011, so that the information can be made available to COMSTAC members for their review and consideration before the October 13 and 14, 2011 meetings. Written statements should be supplied in the following formats: One hard copy with original signature and/or one electronic copy via e-mail.

Subject to approval, a portion of the October 14th meeting will be closed to the public (starting at approximately 3 p.m.).

An agenda will be posted on the FAA Web site at *http://www.faa.gov/go/ast.* For specific information concerning the times and locations of the COMSTAC working group meetings, contact the Contact Person listed below.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Susan Lender (AST–5), Office of Commercial Space Transportation (AST), 800 Independence Avenue SW., Room 331, Washington, DC 20591, telephone (202) 267–8029; E-mail *susan.lender@faa.gov.* Complete information regarding COMSTAC is available on the FAA Web site at: *http://www.faa.gov/about/office_org/headquarters_offices/ast/advisory_committee/.*

Issued in Washington, DC, August 11, 2011.

George C. Nield,

Associate Administrator for Commercial Space Transportation.

[FR Doc. 2011–21072 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Release From Quitclaim Deed and Federal Grant Assurance Obligations for Phoenix-Mesa Gateway Airport, Mesa, AZ

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of Request to Release Airport Land.

SUMMARY: The Federal Aviation Administration (FAA) proposes to rule and invites public comment on the application for a release of approximately 1,727 square feet of airport property at Phoenix-Mesa Gateway, Mesa, Arizona, from all conditions contained in the Quitclaim Deed and Grant Assurances since the parcel of land is not needed for airport purposes. The property will be sold for its fair market value and the proceeds deposited in the airport account. The reuse of the land for a roadway improvement project by the State of Arizona represents a compatible land use that will not interfere with the airport or its operation, thereby protecting the interests of civil aviation.

DATES: Comments must be received on or before September 19, 2011.

FOR FURTHER INFORMATION CONTACT: Comments on the request may be mailed or delivered to the FAA at the following address: Tony Garcia, Airports Compliance Program Manager, Federal Aviation Administration, Airports Division, **Federal Register** Comment, 15000 Aviation Blvd., Lawndale, CA 90261. In addition, one copy of the comment submitted to the FAA must be mailed or delivered to Mr. Walter Fix, Phoenix-Gateway Airport Authority, 5835 S. Sossaman Road, Mesa, Arizona 85212, *Telephone:* (480) 988–7709.

SUPPLEMENTARY INFORMATION: In accordance with the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR 21), Public Law 10–181 (Apr. 5, 2000; 114 Stat. 61), this notice must be published in the **Federal Register** 30 days before the Secretary may waive any condition imposed on a federally obligated airport by surplus property conveyance deeds or grant agreements.

The following is a brief overview of the request:

Phoenix-Mesa Gateway Authority, Mesa, Arizona requested a release from the conditions contained in the Quitclaim Deed and Grant Assurance obligations for approximately 1,727 square feet of airport land. The property is located on the east side of the airport in the vicinity of Ellsworth Road. The land is presently unused and undeveloped. The land is needed for the construction of State Route 24, Gateway Freeway, which will encroach into airport property. The Phoenix-Mesa Gateway Airport Authority has agreed to the sale of the small parcel to the State of Arizona since the property is not needed for airport purposes. The conveyance will not impede future development of the airport, while SR–24 will improve access to the east side of the airport. The sale price will be based on its appraised market value and the sale proceeds will be deposited in the airport account and used for airport purposes. The use of the property as a public roadway represents a compatible use that will not interfere with airport operations. The airport will be properly compensated, thereby serving the interests of civil aviation.

Issued in Hawthorne, California, on August 10, 2011.

Brian Armstrong,

Manager, Safety and Standards, Airports Division, Western-Pacific Region.

[FR Doc. 2011–21085 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Release of an Easement Restriction at Phoenix-Mesa Gateway Airport, Mesa, AZ

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of Request to Release Airport Land.

SUMMARY: The Federal Aviation Administration (FAA) proposes to rule and invites public comment on the application for a release of a U.S. Air Force easement restriction covering 52.6 acres of property abutting Phoenix-Mesa Gateway, Mesa, Arizona, from all conditions contained in a grant of an easement, since the easement is not needed for civilian airport purposes. In exchange for the easement, the airport will receive 19 acres of land and a new avigation easement. Reuse of the land under the easement will remain compatible and not interfere with the airport or its operation. The interest of civil aviation is properly served by the release.

DATES: Comments must be received on or before September 19, 2011.

FOR FURTHER INFORMATION CONTACT: Comments on the request may be mailed or delivered to the FAA at the following address: Tony Garcia, Airports Compliance Program Manager, Federal Aviation Administration, Airports Division, **Federal Register** Comment, 15000 Aviation Blvd., Lawndale, CA 90261. In addition, one copy of the comment submitted to the FAA must be mailed or delivered to Mr. Walter Fix, Phoenix-Gateway Airport Authority, 5835 S. Sossaman Road, Mesa, Arizona 85212, Telephone: (480) 988–7709.

SUPPLEMENTARY INFORMATION: In accordance with the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR 21), Public Law 10–181 (Apr. 5, 2000; 114 Stat. 61), this notice must be published in the **Federal Register** 30 days before the Secretary may waive any condition imposed on a federally obligated airport by surplus property conveyance deeds or grant agreements.

The following is a brief overview of the request:

Phoenix-Mesa Gateway Airport Authority, Mesa, Arizona requested a release of an easement that was obtained from the U.S. Air Force via an Assignment of Easement on April 14, 1998. The easement covers approximately 52.6 acres of private property. It extends eastward from the airport boundary and is located east of Ellsworth Road and north of Pecos Road. Use of the private property east of the airport is restricted by the easement. Relinquishment of the easement will not harm the airport because it is being replaced with a standard avigation easement. The new easement will provide the airport with a continued right for aircraft to fly in the airspace above the private property. It will also prevent interference with airport operations and the erection of obstructions that pose a hazard to aircraft. As compensation, the private land owner will convey 17.53 acres of land at no cost to the Airport Authority that will serve an airport purpose. The land will allow the airport to have a complete runway protection zone for runway end 30R on airport property. Presently, a portion of the RPZ extends beyond the airport boundary to the private property located east of Ellsworth Road. The Airport Authority has agreed to the exchange because the restrictive easement is not needed and will be replaced with an avigation easement. The airport will be additionally compensated with a donation of land that has an immediate airport purpose. The use of the property under the new easement will continue to be used compatibly with the airport and not cause interference with airport operations. The exchange is equitable and the donation of land to the airport clearly serves the interests of civil aviation.

Issued in Hawthorne, California, on August 10, 2011.

Brian Armstrong,

Manager, Safety and Standards, Airports Division, Western-Pacific Region.

[FR Doc. 2011–21082 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Utah

AGENCY: Federal Highway Administration (FHWA), USDOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA that are final within the meaning of 23 U.S.C. 39(l)(1). The actions relate to a proposed highway project, Tooele Midvalley Highway, from I–80 to State Route 36 Tooele County, State of Utah. Those actions grant licenses, 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 that are covered by this notice will be barred unless the claim is filed on or before February 14, 2012. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: *For FHWA:* Mr. Edward Woolford, Environmental Manager, Federal Highway Administration, 2520 West 4700 South, Suite 9A, Salt Lake City, Utah 84118–1880; *Telephone:* (801) 955–3524; *e-mail: Edward.Woolford@dot.gov.* The FHWA Utah Division Office's normal business hours are 7:30 a.m. to 4:30 p.m. (Mountain Time). *For the Utah Department of Transportation (UDOT):* Mr. Matt Zundel, 2010 South 2760 West, Salt Lake City, UT 84104; *Telephone:* (801) 887–3421; *e-mail: mzundel@utah.gov.* The UDOT's normal business hours are Monday through Thursday, 7:30 a.m. to 5:30 p.m. (M. Time).

SUPPLEMENTARY INFORMATION: On Friday, January 14, 2011, the FHWA published the Notice of Availability in the **Federal Register** in Volume 76, No. 10, page 2680, for the following highway project in the State of Utah: Tooele County Midvalley Highway Project, To Address Traffic Congestion on UT–36 and at the I–80 Lake Point interchange through the Year 2030. The proposed action includes capacity improvements to the north-south transportation system in the Tooele Valley that provide additional north-south transportation capacity, reduce anticipated congestion on SR–36, and reduce anticipated congestion at the Lake Point interchange with I–80. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Impact Statement (FEIS) for the project, approved on January 3, 2011, and in the FHWA Record of Decision (ROD) issued on July 27, 2011, and in other documents in the FHWA project files. The FEIS, ROD, and other project records are available by contacting the FHWA or the UDOT at the addresses provided above. The FHWA FEIS and ROD can be viewed and downloaded from the project Web site at *http://www.midvalleyhighway.com* or viewed at public libraries in the project area. This notice applies to all Federal agencies' final actions taken after the issuance date of the FHWA **Federal**

Register notice described above. The laws under which actions were taken include, but are not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303].

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

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.*].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Executive Orders:* E.O. 11990, Protection of Wetlands; E.O. 11988, Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 13175, Consultation and Coordination With Indian Tribal Governments; 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: August 10, 2011.

James Christian,

Division Administrator, Salt Lake City.

[FR Doc. 2011–21018 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2011–0067]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated June 29, 2011, Penn Valley Railroad LLC has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR Section 223.15. FRA assigned the petition Docket Number FRA–2011–0067.

Penn Valley Railroad LLC is requesting consideration of a waiver from 49 CFR § 223.15, Safety Glazing Standards, in regard to Coach PRR 1776. The coach is equipped with a type of automotive safety glass and is serviced and maintained by Penn Valley Railroad LLC. There have not been any injuries on this coach due to broken glass. Penn Valley Railroad LLC is requesting the glazing waiver because of the extremely high cost to replace the glazing and the low risk to safety of continuing to operate with the current safety glass.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *http://www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received by October 3, 2011 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and 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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or at *http://www.dot.gov/privacy.html.*

Issued in Washington, DC, on August 12, 2011.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2011–21095 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2010–0034]

Petition for Waiver of Compliance

In accordance with part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated July 15, 2011, Port Authority Trans-Hudson Corporation (PATH) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 236. FRA has previously assigned all PATH Positive Train Control (PTC)-related documentation Docket Number FRA–2010–0034, and is adding this waiver request to that docket.

PATH seeks a waiver from compliance with PTC system requirements found at 49 CFR Section 236.1006, *Equipping locomotives operating in PTC territory.* Specifically, this petition is made in connection with the implementation of PATH's Automatic Train Control (ATC) project and the plan to use unequipped PA–4 cars as maintenance-of-way (MOW) work equipment. PATH is currently in the process of implementing an ATC system using communications-based train control (CBTC) technology throughout the PATH rail network, as described in the Positive Train Control Implementation and Development Plans previously submitted for FRA approval. As part of that program, PATH will be equipping all A-cars (cab control cars) of the new PA–5 fleet with onboard ATC equipment. By December 31, 2015, PATH's passenger carrying fleet will consist of only multiple-unit train consists made of PA–5 cars, and as such, PATH's operation will be in compliance with the new PTC rule. An important element of the new ATC system implementation at PATH will be the incorporation of a track-circuit-based Secondary Train Detection System (STDS) incorporating wayside signals and automatic train stops (trip stops). The STDS will provide for safe

operation of both PA–5 trains with failed ATC equipment, and MOW work equipment that will not be fitted with onboard ATC equipment.

It is PATH's intention to retire the existing PA–4 fleet from passenger service, but to retain some of these PA–4 cars to function as MOW work equipment. PATH will modify the interiors of some of these vehicles so that they are configured to transport tools and equipment. The PA–4 work vehicles would retain their trip cock equipment, and as such, the STDS would provide enforced braking for these vehicles at stop (red) signals. Further, since the PA–4 cars reliably shunt track circuits, they will be continuously detected by both the STDS and the CBTC system, thereby preventing train-to-train collisions.

PATH's justification for relief is that the proposed use of non-equipped PA–4 vehicles for MOW work equipment does not introduce any new or different safety hazards to the existing operation, and provides additional safety elements not available for other types of MOW equipment. The installation of the ATC and/or CBTC systems and the STDS by December 31, 2015, in conjunction with well-established operating rules and procedures, will in fact provide enhanced safety for such operations.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *http://www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received by October 3, 2011 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and 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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or at *http://www.dot.gov/privacy.html.*

Issued in Washington, DC, on August 12, 2011.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2011–21094 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2011–0104]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel CATATONIC.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2011–0104 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

DATES: Submit comments on or before September 19, 2011.

ADDRESSES: Comments should refer to docket number MARAD–2011–0104. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, E-mail *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel CATATONIC is:

Intended Commercial Use of Vessel: ''Take passengers on half-day or all day sails off Waikiki. Boat will also anchor off Waikiki Beach for snorkeling and swimming. Vessel will depart and arrive back to Kewalo Basin Harbor, which is a commercial boat harbor. We are aiming at taking out family groups and groups of friends.''

Geographic Region: ''Hawaii.''

Privacy Act

Anyone is able to 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 DOT's complete Privacy Act Statement in the **Federal Register**

published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administration.

Dated: August 9, 2011.

Christine Gurland,

Secretary, Maritime Administration.

[FR Doc. 2011–21124 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2011–0109]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel SENSEI.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2011–0109 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

DATES: Submit comments on or before September 19, 2011.

ADDRESSES: Comments should refer to docket number MARAD–2011–0109. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, E-mail *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel SENSEI is:

Intended Commercial Use of Vessel: ''Chartering day cruises to the general public on San Francisco Bay.''

Geographic Region: ''CA.''

Privacy Act

Anyone is able to 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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: August 9, 2011.

Christine Gurland,

Secretary, Maritime Administration.

[FR Doc. 2011–21127 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2011–0106]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel CORSAIRE.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2011–0106 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

DATES: Submit comments on or before September 19, 2011.

ADDRESSES: Comments should refer to docket number MARAD–2011 0106. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, E-mail *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel CORSAIRE is:

Intended Commercial use of Vessel: ''sailing charters, whale watching, dolphin watching.''

Geographic Region: ''Hawaii.''

Privacy Act

Anyone is able to 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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: August 9, 2011.

Christine Gurland,

Secretary, Maritime Administration.

[FR Doc. 2011–21105 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2011–0107]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel TELL TALES.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2011–0107 at *http://www.regulations.gov*. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

DATES: Submit comments on or before September 19, 2011.

ADDRESSES: Comments should refer to docket number MARAD–2011 0107. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov*. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, E-mail *Joann.Spittle@dot.gov*.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel TELL TALES is:

Intended Commercial Use of Vessel: ''day charters up to 12 passengers or charters up to 10 days for up to 6 passengers.''

Geographic Region: ''VA, MD, DE, FL.''

Privacy Act

Anyone is able to 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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administration.

Dated: August 9, 2011.

Christine Gurland,

Secretary, Maritime Administration.

[FR Doc. 2011–21104 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2011–0108]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel EUREKA.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2011 0108 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

DATES: Submit comments on or before September 19, 2011.

ADDRESSES: Comments should refer to docket number MARAD–2011 0108. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents

entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, E-mail *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel EUREKA is:

Intended Commercial Use of Vessel: ''Skippered charters & sailing lessons on San Francisco Bay & California near coastal waters.''

Geographic Region: ''California, Oregon, Washington.''

Privacy Act

Anyone is able to 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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administration.

Dated: August 9, 2011.

Christine Gurland,

Secretary, Maritime Administration.

[FR Doc. 2011–21103 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2011–0105]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel JOINT VENTURE.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2011–0105 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

DATES: Submit comments on or before September 19, 2011.

ADDRESSES: Comments should refer to docket number MARAD–2011–0105. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, E-mail *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel JOINT VENTURE is:

Intended Commercial Use of Vessel: ''Sight seeing charters San Francisco Bay and Sacramento Delta area.''

Geographic Region: ''California.''

Privacy Act

Anyone is able to 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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: August 9, 2011.

Christine Gurland,

Secretary, Maritime Administration.

[FR Doc. 2011–21106 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2011–0103]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel LEONESSA.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2011–0103 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

DATES: Submit comments on or before September 19, 2011.

ADDRESSES: Comments should refer to docket number MARAD–2011–0103. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140,

1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, E-mail *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel LEONESSA is:

Intended Commercial Use of Vessel: ''Limited sailing charters, 6 persons maximum.''

Geographic Region: ''California only.''

Privacy Act

Anyone is able to 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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: August 9, 2011.

Christine Gurland,

Secretary, Maritime Administration.

[FR Doc. 2011–21125 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2011–0081; Notice 1]

BMW of North America, LLC, a subsidiary of BMW AG, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Receipt of Petition for Inconsequential Noncompliance.

SUMMARY: BMW of North America, LLC,[1] a subsidiary of BMW AG.[2] (collectively referred to as ''BMW'') has determined that certain model year 2011 Mini Cooper Clubman and Mini Cooper S Clubman model passenger cars manufactured between February 8, 2011 and May 11, 2011, do not fully comply with paragraph S5.2.1 of Federal Motor Vehicle Safety Standard (FMVSS) No. 101, *Controls and Displays* and paragraphs S5.5.2 and S5.5.5 of FMVSS No. 135, *Light Vehicle Brake Systems.* BMW has filed an appropriate report pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports* (dated May 25, 2011).

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), BMW 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.

This notice of receipt of BMW's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Affected are approximately 75 model year 2011 Mini Cooper Clubman and Mini Cooper S Clubman model passenger cars that were manufactured between February 8, 2011 and May 11, 2011.

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 75[3] model year 2011 Mini Cooper Clubman and Mini Cooper S Clubman model passenger cars that BMW no longer controlled at the time it determined that the noncompliance existed.

Paragraph S5.2.1 of FMVSS No. 101 requires in pertinent part:

S5.2.1 Except for the Low Tire Pressure Telltale, each control, telltale and indicator that is listed in column 1 of Table 1 or Table 2 must be identified by the symbol specified for it in column 2 or the word or abbreviation specified for it in column 3 of Table 1 or Table 2. If a symbol is used, each symbol provided pursuant to this paragraph must be substantially similar in form to the symbol as it appears in Table 1 or Table 2. If a symbol is used, each symbol provided pursuant to this paragraph must have the proportional dimensional characteristics of the symbol as it appears in Table 1 or Table 2.

Paragraphs S5.5.2 and S5.5.5 of FMVSS No. 135 requires in pertinent part:

S5.5.2. Function check. (a) All indicators shall be activated as a check function by either: (1) Automatic activation when the ignition (start) switch is turned to the ''on'' (''run'') position when the engine is not running, or when the ignition (''start'') switch is in a position between ''on'' (''run'') and ''start'' that is designated by the manufacturer as a check position, or (2) A single manual action by the driver, such as momentary activation of a test button or switch mounted on the instrument panel in front of and in clear view of the driver, or, in the case of an indicator for application of the parking brake, by applying the parking brake when the ignition is in the ''on'' (''run'') position. (b) In the case of a vehicle that has an interlock device that prevents the engine from being started under one or more conditions, check functions meeting the requirements of S5.5.2(a) need not be operational under any condition in which the engine cannot be started. (c) The manufacturer shall explain the brake check function test procedure in the owner's manual.

S5.5.5. Labeling. (a) Each visual indicator shall display a word or words in accordance with the requirements of Standard No. 101 (49 CFR 571.101) and this section, which shall be legible to the driver under all daytime and nighttime conditions when activated. Unless otherwise specified, the words shall have letters not less than 3.2 mm (1/8 inch) high and the letters and background shall be of contrasting colors, one of which is red. Words or symbols in addition to those required by Standard No. 101 and this section may be provided for purposes of clarity.

(b) Vehicles manufactured with a split service brake system may use a common brake warning indicator to indicate two or more of the functions described in S5.5.1(a) through S5.5.1(g). If a common indicator is used, it shall display the word ''Brake.''

BMW explained that the noncompliance is that the telltales used for Brake Warning, Park Brake Warning and Antilock Braking System (ABS) failure warnings are displayed using International Organization for Standardization (ISO) symbols instead

[1] BMW of North America, LLC is a U.S. company that manufactures and imports motor vehicles.

[2] BMW AG, is a German company that manufactures motor vehicles.

[3] BMW's petition, which was filed under 49 CFR Part 556, requests an agency decision to exempt BMW as a vehicle manufacturer from the notification and recall responsibilities of 49 CFR Part 573 for 75 of the affected vehicles. However, the agency cannot relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after BMW notified them that the subject noncompliance existed. Those vehicles must be brought into conformance, exported, or destroyed.

of the telltale symbols required by FMVSS Nos. 101 and 135.

BMW stated its belief that although the instrument cluster telltale symbols are displayed using ISO symbols the noncompliance is inconsequential to motor vehicle safety for the following reasons:

(1) If a problem is encountered in which a brake system warning or malfunction indicator symbol is displayed, it is believed that the driver will be able to understand the warning symbol and take any necessary actions required.

(2) The instrument cluster is mounted behind the steering wheel in direct sight of the driver, making any warning symbol or indicator visible.

(3) There is a ''message center'' within the tachometer which is also used to inform the driver that a problem exists and can be used to better clarify why the warning symbol is illuminated.

(4) Due to similarities between the symbols required by FMVSS Nos. 101 and 135 and ISO symbols, eventually the driver will come to associate the wheel depiction symbol with the brake system.

(5) In such an event where the driver is unable to identify the warning symbol the driver would be able to consult the owner's manual which depicts as well as explains each of the warning/malfunction indicator symbols.

(6) BMW has received no customer complaints regarding the issue of non compliant telltales.

BMW also explains NHTSA has previously granted similar petitions.

In summation, BMW believes that the described noncompliance of its vehicles is inconsequential to motor vehicle safety, and 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.

Comments: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted by any of the following methods:

a. By mail addressed to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

b. By hand delivery to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.

c. Electronically: by logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/.* Follow the online instructions for submitting comments. Comments may also be faxed to 1–202–493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000, (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

DATES: Comment closing date: September 19, 2011.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at CFR 1.50 and 501.8)

Issued on: August 12, 2011.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2011–21087 Filed 8–17–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 55 (Sub-No. 708X)]

CSX Transportation, Inc.—Abandonment Exemption—in Beaver County, PA

CSX Transportation, Inc. (CSXT) has filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments* to abandon an approximately 2.39-mile rail line on its Northern Region, Pittsburg Subdivision, between milepost PLK 0.0 and milepost PLK 2.39, in Koppel, Beaver County, Pa. The line traverses United States Postal Service Zip Code 16136 and includes no stations.

CSXT has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) no overhead traffic has operated on the line so none needs to be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on September 17, 2011, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may

Continued

file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by August 29, 2011. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by September 7, 2011,[3] with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to CSXT's representative: Louis E. Gitomer, Law Offices of Louis E. Gitomer, LLC, 600 Baltimore Ave., Suite 301, Towson, MD 21204.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

CSXT has filed environmental and historic reports that address the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by August 23, 2011. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling OEA at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service at 1–800–877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), CSXT shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by CSXT's filing of a notice of consummation by August 18, 2012, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: August 12, 2011.

By the Board.

Rachel D. Campbell,

Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–20986 Filed 8–17–11; 8:45 am]

BILLING CODE 4915–01–P

take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which is currently set at $1,500. *See* 49 CFR 1002.2(f)(25).

[3] CSXT notes that it does not believe that the line is appropriate for other public purposes but may be subject to reversionary interests.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 55 (Sub-No. 711X)]

CSX Transportation, Inc.—Abandonment Exemption—In Oswego County, NY

CSX Transportation, Inc. (CSXT) filed a verified notice of exemption under 49 CFR pt. 1152 subpart F–*Exempt Abandonments* to abandon 2 formerly connected rail lines in CSXT's Northern Region, Albany Division, Fulton Subdivision. The lines are described as follows: (1) 6,814 feet between milepost QMF 25.67, adjacent to County Road 57, and the end of the track between Ontario and Erie Streets; and (2) 5,938 feet between milepost QMF 22.8 and the end of the track at Division Street, in Fulton, Oswego County, NY. The line traverses United States Postal Service Zip Code 13069.

CSXT has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line to be rerouted; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on September 17, 2011, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by August 29, 2011. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by September 7, 2011, with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to CSXT's representative: Louis E. Gitomer, 600 Baltimore Avenue, Suite 301, Towson, MD 21204.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

CSXT has filed environmental and historic reports, which address the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by August 23, 2011. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling OEA, at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), CSXT shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by CSXT's filing of a notice of consummation by August 18, 2012, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which is currently set at $1,500. *See* 49 CFR 1002.2(f)(25).

Board decisions and notices are available on our Web site at ''*http://www.stb.dot.gov.*''

Decided: August 12, 2011.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–21047 Filed 8–17–11; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35537]

Genesee & Wyoming Inc.; Acquisition of Control Exemption; Arizona Eastern Railway Company

Genesee & Wyoming Inc. (GWI), a noncarrier, has filed a verified notice of exemption to acquire control of Arizona Eastern Railway Company (AZER), a Class III rail carrier. GWI intends to consummate the transaction on September 1, 2011, the effective date of the exemption (30 days after the exemption was filed).

GWI directly or indirectly controls one Class II rail carrier, Buffalo & Pittsburgh Railroad, Inc., and 57 Class III rail carriers operating in 23 states. For a complete list of these Class III carriers, and the states within which they operate, see GWI's notice of exemption filed on August 2, 2011. The notice is available on the Board's Web site at ''*http://www.stb.dot.gov.*''

AZER currently owns and operates approximately 200 route miles of rail line between Bowie and Miami, Ariz. and between Lordsburg, N.M. and Clifton, Ariz. AZER is a wholly owned subsidiary of Permian Basin Railways, Inc. (Permian Basin), which in turn is a wholly owned subsidiary of Iowa Pacific Holdings, LLC, a noncarrier holding company. As a result of the proposed transaction, GWI will obtain control of AZER through the purchase of all of AZER's stock from Permian Basin.[1]

Applicants represent that: (1) The rail lines to be acquired by GWI do not connect with any other railroad in the corporate family;[2] (2) the transaction is not part of a series of anticipated transactions that would connect AZER's rail lines with any other railroad in the GWI corporate family; and (3) the transaction does not involve a Class I rail carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).[3]

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Because the transaction involves the control of at least one Class II and one or more Class III rail carriers, the transaction is subject to the labor protection requirements of 49 U.S.C. 11326(b).

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Stay petitions must be filed no later than August 25, 2011 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35537, must be filed with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Thomas J. Litwiler, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 920, Chicago, IL 60606.

Board decisions and notices are available on our Web site at ''*http://www.stb.dot.gov.*''

Decided: August 12, 2011.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–21049 Filed 8–17–11; 8:45 am]

BILLING CODE 4915–01–P

[1] GWI states that if it acquires the stock prior to the September 1, 2011 effective date of the exemption, it would place the stock into an irrevocable, independent voting trust pursuant to 49 CFR 1013, pending the effectiveness of the exemption. GWI states that it would notify the Board of any such occurrence and would submit a copy of the agreement governing the voting trust for AZER's stock.

[2] AZER's lines are located in Arizona and New Mexico. GWI's carriers do not currently operate in the states of Arizona or New Mexico.

[3] A redacted Stock Purchase Agreement was filed with the notice of exemption. The Applicants concurrently filed a motion for protective order pursuant to 49 CFR 1104.14(b) to allow the filing under seal of the unredacted Stock Purchase Agreement. That motion will be addressed in a separate decision.

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

August 15, 2011.

The Department of the Treasury will submit the following public information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. A copy of the submissions may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding these information collections should be addressed to the OMB reviewer listed and to the Treasury PRA Clearance Officer, Department of the Treasury, 1750 Pennsylvania Avenue, NW., Suite 11010, Washington, DC 20220.

DATES: Written comments should be received on or before September 19, 2011 to be assured of consideration.

Alcohol and Tabacco Tax and Trade Bureau (TTB)

OMB Number: 1513–0018.

Type of Review: Revision of a currently approved collection.

Title: Application for Basic Permit under the Federal Alcohol Administration Act.

Form: TTB F 5100.24.

Abstract: TTB 5100.24 will be completed by persons intending to engage in a business involving beverage alcohol operations at a distilled spirits plant, bonded winery, or wholesaling/importing business. The information collected allows TTB to identify the applicant and the location of the business, and to determine whether the applicant qualifies for a permit.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 5,656.

OMB Number: 1513–0019.

Type of Review: Extension without change of a currently approved collection.

Title: Application for Amended Basic Permit under the Federal Alcohol Administration Act.

Forms: TTB F 5100.18.

Abstract: TTB F 5100.18 is completed by permittees who change their operations in a manner that requires a new permit or receive a new notice. The information allows TTB to identify the permittee, the changes to the permit or business, and to determine whether the applicant still qualifies for a basic permit.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 600.

OMB Number: 1513–0023.

Type of Review: Revision of a currently approved collection.

Title: Environmental Information; and Supplemental Information on Water Quality Consideration under 33 U.S.C. 1341(a).

Forms: TTB F 5000.28 and 5000.30.

Abstract: TTB F 5000.29 is used to determine whether an activity will have a significant effect on the environment

and to determine if a formal environmental impact statement or an environmental permit is necessary for a proposed operation. TTB F 5000.30 is used to make a determination as to whether a certification or waiver by the applicable State water quality agency is required under section 21 of the Federal Water Pollution Control Act (33 U.S.C. 1341(a)). Manufacturers that discharge a solid or liquid effluent into navigable waters submit this form.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 3,900.

OMB Number: 1513–0054.

Type of Review: Extension without change of a currently approved collection.

Title: Offer in Compromise of liability incurred under the provisions of Title 26 U.S.C. enforced and administered by TTB; Collection Information Statement (CIS) for Individuals; CIS for Businesses.

Forms: TTB F 5600.17, 5600.18, and 5640.1.

Abstract: TTB F 5640.1 is used by persons who wish to compromise criminal and/or civil penalties for violations of the IRC. If accepted, the offer in compromise is a settlement between the government and the party in violation in lieu of legal proceedings or prosecution. If the party is unable to pay the offer in full, TTB F 5600.17 and 5600.18 are use to gather financial information to develop an installment agreement to allow the party to pay without incurring a financial hardship.

Respondents: Private Sector: Businesses or other for-profits; Individuals and households.

Estimated Total Burden Hours: 140.

OMB Number: 1513–0073.

Type of Review: Extension without change of a currently approved collection.

Title: Manufacturers of Nonbeverage Products—Records to Support Claims for Drawback, TTB REC 5530/2.

Abstract: Records required to be maintained by manufacturers of nonbeverage products are used to prevent diversion of drawback spirits to beverage use. The records are necessary to maintain accountability over these spirits. The records make it possible to trace spirits using audit techniques, thus enabling TTB officers to verify the amount of spirits used in nonbeverage products and subsequently claimed as eligible for drawback of tax. The record retention requirement for this information collection is 3 years.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 10,521.

OMB Number: 1513–0075.

Type of Review: Extension without change of a currently approved collection.

Title: Proprietors or Claimants Exporting Liquors, TTB REC 5900/1.

Abstract: Distilled spirits, wine, and beer may be exported from bonded premises without payment of excise taxes, or, they may be exported if their taxes have been paid and the exporters may claim drawback of the taxes paid. The recordkeeping requirement makes it possible to trace movement of distilled spirits, wine, and beer, thus enabling TTB officers to verify the amount of these liquors eligible for exportation without payment of tax or exportation subject to drawback.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 7,200.

Clearance Officer: Gerald Isenberg, Alcohol and Tobacco Tax and Trade Bureau, Room 200 East, 1310 G Street, NW., Washington, DC 20005; (202) 453–2165.

OMB Reviewer: Shagufta Ahmed, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; (202) 395–7873.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2011–21044 Filed 8–17–11; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

August 15, 2011.

The Department of the Treasury will submit the following public information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. A copy of the submissions may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding these information collections should be addressed to the OMB reviewer listed and to the Treasury PRA Clearance Officer, Department of the Treasury, 1750 Pennsylvania Avenue, NW., Suite 11010, Washington, DC 20220.

DATES: Written comments should be received on or before September 19, 2011 to be assured of consideration.

Bureau of the Public Debt (BPD)

OMB Number: 1535–0059.

Type of Review: Extension without change of a currently approved collection.

Title: Special Form of Assignment for U.S. Registered Definitive Securities and U.S. Bearer Securities for Conversion to BECCS or CUBES.

Form: PD F 1832 E.

Abstract: Used to certify assignments of U.S. registered definitive securities.

Affected Public: Individuals or Households.

Estimated Total Burden Hours: 1,250.

OMB Number: 1535–0113.

Type of Review: Extension without change of a currently approved collection.

Title: Disclaimer and Consent with Respect to United States Savings Bond/Notes.

Form: PD F 1849 E.

Abstract: Used to obtain a disclaimer and consent as the result of an error in registration or otherwise the payment, refund of the purchase price, or reissue as requested by one person would appear to affect the right, title or interest of some other person.

Affected Public: Individuals or Households.

Estimated Total Burden Hours: 700.

Bureau Clearance Officer: Bruce Sharp, Bureau of the Public Debt, 200 Third Street, Parkersburg, West Virginia 26106; (304) 480–8112.

OMB Reviewer: Shagufta Ahmed, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; (202) 395–7873.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2011–21050 Filed 8–17–11; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). The IRS is soliciting comments concerning information collection requirements related to the obligation of material advisors to prepare and maintain lists with respect to reportable transactions.

DATES: Written comments should be received on or before October 17, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Joel Goldberger, at (202) 927–9368, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Joel.P.Goldberger@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: AJCA Modifications to the Section 6112 Regulations.

OMB Number: 1545–1686.

Regulation Project Number: (T.D. 9352).

Abstract: This document contains final regulations under section 6112 of the Internal Revenue Code that provide the rules relating to the obligation of material advisors to prepare and maintain lists with respect to reportable transactions. These regulations affect material advisors responsible for keeping lists under section 6112.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households.

Estimated Number of Respondents: 500.

Estimated Time per Respondent: 100 hours.

Estimated Total Annual Burden Hours: 50,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 1, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–20982 Filed 8–17–11; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413 and 476

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 476

[CMS–1518–F; CMS–1430–F]

RIN 0938–AQ24; RIN 0938–AQ92

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rules.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems and to 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. We also are setting forth the update to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits.

We are updating the payment policy and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and implementing certain statutory changes made by the Affordable Care Act. In addition, we are finalizing an interim final rule with comment period that implements section 203 of the Medicare and Medicaid Extenders Act of 2010 relating to the treatment of teaching hospitals that are members of the same Medicare graduate medical education affiliated groups for the purpose of determining possible full-time equivalent (FTE) resident cap reductions.

DATES: *Effective dates:* These final rules are effective on October 1, 2011, except for the provisions of § 412.230(d)(5), which are effective September 1, 2011. Effective July 29, 2011, the interim rule published March 14, 2011, at 76 FR 13515, is confirmed as final without change.

Applicability dates: The update to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits is applicable beginning on or after October 1, 2011. The payment policy and the annual payment rates for inpatient hospital services provided by IPPS hospitals and by long-term care hospitals (LTCHs) and for implementing certain statutory changes made by the Affordable Care Act and other legislation are applicable to discharges occurring on or after October 1, 2011 unless otherwise specified in this final rule.

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.

Bridget Dickensheets, (410) 786–8670, Rebasing and Revising of the Market Basket for LTCHs Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

James Poyer, (410) 786–2261, Inpatient Quality Reporting—Program Administration, Validation, and Reconsideration Issues.

Shaheen Halim, (410) 786–0641, 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, Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Mary Pratt, (410) 786–6867, LTCH Quality Data Reporting Issues.

Kim Spaulding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

SUPPLEMENTARY INFORMATION:

Electronic Access

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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 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 will no longer be published as part of the annual IPPS and LTCH PPS proposed and final rules. Instead, these tables will be available only through the Internet. The IPPS tables for this final rule are available only through the Internet 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 2012 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2012 final rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/LongTermCareHospitalPPS/LTCHPPSRN/list.asp* under the list item for Regulation Number CMS–1518–F. For complete details on the availability of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this final rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Nisha Bhat at (410) 786–4487.

Acronyms

3M 3M Health Information System
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
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
ARRA American Recovery and Reinvestment Act of 2009, Public Law 111–5
ASC Ambulatory surgical center
ASCA Administrative Simplification Compliance Act of 2002, Public Law 107–105
ASITN American Society of Interventional and Therapeutic Neuroradiology
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
CBSAs Core-based statistical areas
CC Complication or comorbidity
CCR Cost-to-charge ratio
CDAC [Medicare] Clinical Data Abstraction Center
CDAD *Clostridium difficile*-associated disease
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
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 Hospitals
FDA Food and Drug Administration
FFY Federal fiscal year
FQHC Federally qualified health center
FTE Full-time equivalent
FY Fiscal year
GAAP Generally Accepted Accounting Principles
GAF Geographic Adjustment Factor
GME Graduate medical education
HACs Hospital-acquired conditions
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
IPPS [Acute care hospital] inpatient prospective payment system
IRF Inpatient rehabilitation facility
IQR Inpatient Quality Reporting
LAMCs Large area metropolitan counties
LOS Length of stay
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
MA Medicare Advantage
MAC Medicare Administrative Contractor
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
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 1996, 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
O.R. Operating room
OSCAR Online Survey Certification and Reporting [System]
PMSAs Primary metropolitan statistical areas
POA Present on admission
PPACA Patient Protection and Affordable Care Act, Public Law 111–148
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)
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
SFY State fiscal year
SIC Standard Industrial Classification

SNF Skilled nursing facility
SOCs Standard occupational classifications
SOM State Operations Manual
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
UHDDS Uniform hospital discharge data set

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I. Background

A. 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 pay for the capital-related costs of hospital inpatient stays under a prospective payment system (PPS). 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, 2012, 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. 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, Public Law 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 per discharge.

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) effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of 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). 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 are 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.

B. Provisions of 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) Applicable to FY 2012

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 and 2011 were implemented in the following documents:

On June 2, 2010, we issued in the **Federal Register** a notice (75 FR 31118) that contained the final wage indices, hospital reclassifications, payment rates, impacts, and other related tables, effective for the FY 2010 IPPS and the RY 2010 LTCH PPS, which were required by or directly resulted from implementation of provisions of the Affordable Care Act.

On August 16, 2010, we issued in the **Federal Register** a final rule (75 FR 50042) that implemented provisions of the Affordable Care Act applicable to the IPPS and LTCH/PPS for FY 2011.

In this final rule, we are implementing the following provisions (or portions of the following provisions) of the Affordable Care Act that are applicable to the IPPS and LTCH PPS for FY 2012:

- Section 3001 of Public Law 111–148, which provides for establishment of a hospital value-based purchasing program and applicable measures for value-based incentive payments with respect to discharges occurring during FY 2013.
- Section 3004 of Public Law 111–148, which provides for the submission of quality data for LTCHs beginning in FY 2013 in order to receive the full annual update to the payment rates beginning with FY 2014 and the establishment of quality data measures by FY 2012 for the FY 2014 payment determination.
- Section 3025 of Public Law 111–148, which provides for a hospital readmissions reduction program and related quality data reporting measures.
- Section 3124 of Public Law 111–148, which provides for extension of the Medicare-dependent, small rural hospital (MDH) program through FY 2012.
- Section 3401 of Public Law 111–148, which provides for the incorporation of productivity improvements into the market basket updates for IPPS hospitals and LTCHs.

In addition, we are continuing in FY 2012 to implement the following provisions, which were initiated in FY 2011:

- Section 10324 of Public Law 111–148, which provided 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 2012.
- Sections 3125 and 10314 of Public Law 111–148, which provide for temporary percentage increases in payment adjustments to low-volume hospitals for discharges occurring in FY 2012.
- Section 1109 of Public Law 111–152, which provides for additional payments in FY 2012 for qualifying hospitals in the lowest quartile of per capita Medicare spending.
- Section 5503 of Public Law 111–148, as amended by Public Law 111–152 and section 203 of Public Law 111–309, which provides for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals, and to authorize the ''redistribution'' of the estimated number of FTE resident slots to other qualified hospitals. In addition, section 5503 requires the application of these provisions to IME in the same manner as the FTE resident caps for direct GME.

C. Issuance of a Notice of Proposed Rulemaking

The May 5, 2011 **Federal Register** (76 FR 25788) included the proposed rule that set forth proposed changes to the Medicare IPPS for operating costs and for capital-related costs of acute care hospitals in FY 2012. We also set 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, we set forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2012.

Below is a summary of the major changes that we proposed to make:

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we included—

- Proposed changes to MS–DRG classifications based on our yearly review.
- Proposed application of the documentation and coding adjustment for FY 2012 resulting from implementation of the MS–DRG system.
- A discussion of the Research Triangle Institute, International (RTI) reports and recommendations relating to charge compression.
- 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 quality adjustment in MS–DRG payments for FY 2012.

We discussed the FY 2012 status of new technologies approved for add-on payments for FY 2011 and presented our evaluation and analysis of the FY 2012 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Public Law 108–173, obtained in a town hall meeting).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to the proposed rule, we proposed revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed included the following:

- The proposed FY 2012 wage index update using wage data from cost reporting periods beginning in FY 2008.
- Analysis and implementation of the proposed FY 2012 occupational mix adjustment to the wage index for acute care hospitals, including discussion of the 2010 occupational mix survey.
- A proposal to change the reporting requirements for pension costs for the Medicare wage index.
- 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 2012 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 2012 hospital wage index.
- Determination of the labor-related share for the proposed FY 2012 wage index.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs

In section IV. of the preamble of the proposed rule, we discussed a number of the provisions of the regulations in 42 CFR Parts 412, 413, and 476, including the following:

- The reporting of hospital quality data under the Hospital Inpatient Quality Reporting (IQR) Program as a condition for receiving the full annual payment update increase.
- The proposed implementation of the Hospital Value-Based Purchasing Program measures.
- The proposed establishment of hospital readmission measures for reporting of hospital quality data.
- The proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- The statutorily required IME adjustment factor for FY 2012.
- Proposed payment adjustment for low-volume hospitals.
- Proposal for counting hospice days in the formula for determining the payment adjustment for disproportionate share hospitals.
- Proposal for making additional payments for qualifying hospitals with lowest per enrollee Medicare spending for FY 2012.
- Proposal to clarify ESRD add-on payment requirements based on cost report requirements.
- Proposal relating to changes to the reporting requirements for pension costs for Medicare cost-finding purposes.
- Proposal to implement statutory change to the hospital payment update, including incorporation of a productivity adjustment.
- Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.
- Discussion of August 2010 interim final rule with comment period and further proposed changes relating to the 3-day payment window for payments for services provided to outpatients who are later admitted as inpatients.

4. Proposed FY 2012 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to the proposed rule, we discussed the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2012 and the proposed MS–DRG documentation and coding adjustment for FY 2012.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of the proposed rule, we discussed proposed changes to payments to certain excluded hospitals. In addition, we discussed proposed changes relating to payment for TEFRA services furnished under arrangements and payment for ambulance services furnished by CAH-owned and operated entities.

6. Proposed Changes to the LTCH PPS

In section VII. of the preamble of the proposed rule, we set forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2012, including the annual update of the MS–LTC–DRG classifications and relative weights for use under the LTCH PPS for FY 2012 and the proposed rebasing and revising of the market basket for LTCHs. In addition, we set forth proposals for implementing the quality data reporting program for LTCHs. We also proposed to clarify two policies regarding the calculation of the average length of stay requirement for LTCHs, and proposed a policy to address a LTCH moratorium issue.

7. Determining Proposed Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2012 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We also proposed to establish the threshold amounts for outlier cases. In addition, we addressed the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2012 for certain hospitals excluded from the IPPS.

8. Determining Proposed Prospective Payment Rates for LTCHs

In the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2012 prospective standard Federal rate. We also proposed to establish the proposed 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.

9. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected acute care hospitals and LTCHs.

10. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided our recommendations of the appropriate percentage changes for FY 2012 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The standard Federal rate for hospital inpatient services furnished by LTCHs.

11. 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 1 of each year, in which MedPAC reviews

and makes recommendations on Medicare payment policies. MedPAC's March 2011 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 addressed these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2011 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*.

D. Public Comments Received in Response to the FY 2012 IPPS/LTCH PPS Proposed Rule

We received approximately 385 timely pieces of correspondence containing multiple comments on the FY 2012 IPPS/LTCH PPS proposed rule. We note that some of these public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed with policy responses in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those comments are set forth in the various sections of this final rule under the appropriate heading.

E. Finalization of Interim Final Rule With Comment Period on Revisions to the Reductions and Increases to Hospitals' FTE Resident Caps for Graduate Medical Education Payment Purposes

On March 14, 2011, we issued in the **Federal Register** (76 FR 13515) an interim final rule with comment period to implement section 203 of the Medicare and Medicaid Extenders Act of 2010 (MMEA), Public Law 111–309, relating to the treatment of teaching hospitals that are members of the same Medicare graduate medical education (GME) affiliated groups for the purpose of determining possible full-time equivalent (FTE) resident cap reductions. We received nine timely pieces of correspondence in response this interim final rule with comment period. In section IV.R. of this document, we are summarizing and responding to these public comments and are finalizing the policies contained in the interim final rule with comment period without modification.

II. Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as 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

1. General

As discussed in the preamble to the FY 2008 IPPS final rule with comment period (72 FR 47138), we focused our efforts in FY 2008 on making significant reforms to the IPPS consistent with the recommendations made by MedPAC in its ''Report to the Congress, Physician-Owned Specialty Hospitals'' in March 2005. MedPAC recommended that the Secretary refine the entire DRG system by taking severity of illness into account and applying hospital-specific relative value (HSRV) weights to DRGs.[1] We began this reform process by adopting cost-based weights over a 3-year transition period beginning in FY 2007 and making interim changes to the DRG system for FY 2007 by creating 20 new CMS DRGs and modifying 32 other DRGs across 13 different clinical areas involving nearly 1.7 million cases. As described in more detail below, these refinements were intermediate steps towards comprehensive reform of both the relative weights and the DRG system as we undertook further study. For FY 2008, we adopted 745 new Medicare Severity DRGs (MS–DRGs) to replace the CMS DRGs. We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a full detailed discussion of how the MS–DRG system, based on severity levels of illness, was established (72 FR 47141).

Currently, cases are classified into MS–DRGs for payment under the IPPS based on the following information reported by the hospital: The principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay. (We refer readers to section II.G.11.c. of this final rule for a discussion of our efforts to increase our internal systems capacity to process diagnosis and procedures on hospital claims to 25 diagnosis codes and 25 procedure codes prior to the use of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10 PCS) for inpatient hospital procedure coding, effective October 1, 2013.) In a small number of MS–DRGs, classification is also based on the age, sex, and discharge status of the patient. The diagnosis and procedure information is reported by the hospital using codes from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) prior to October 1, 2013. We refer readers to section II.G.11.b. of this final rule for a reference to the replacement of ICD–9–CM, Volumes 1 and 2, including the Official ICD–9–CM Guidelines for Coding and Reporting, Volume 3, with the ICD–10–CM and ICD–10–PCS, including the Official ICD–10–CM and ICD–10–PCS Guidelines for Coding and Reporting, effective October 1, 2013 (FY 2014).

The process of developing the MS–DRGs was begun by dividing all possible principal diagnoses into mutually exclusive principal diagnosis areas, referred to as Major Diagnostic Categories (MDCs). The MDCs were formulated by physician panels to ensure that the DRGs would be clinically coherent. The diagnoses in each MDC correspond to a single organ system or etiology and, in general, are associated with a particular medical specialty. Thus, in order to maintain the requirement of clinical coherence, no final MS–DRG could contain patients in different MDCs. For example, MDC 6 is Diseases and Disorders of the Digestive System. This approach is used because clinical care is generally organized in

[1] Medicare Payment Advisory Commission: *Report to the Congress, Physician-Owned Specialty Hospitals*, March 2005, page viii.

accordance with the organ system affected. However, some MDCs are not constructed on this basis because they involve multiple organ systems (for example, MDC 22 (Burns)). For FY 2012, cases will be assigned to one of 751 MS–DRGs in 25 MDCs. The table below lists the 25 MDCs.

MAJOR DIAGNOSTIC CATEGORIES

[MDCs]

1	Diseases and Disorders of the Nervous System.
2	Diseases and Disorders of the Eye.
3	Diseases and Disorders of the Ear, Nose, Mouth, and Throat.
4	Diseases and Disorders of the Respiratory System.
5	Diseases and Disorders of the Circulatory System.
6	Diseases and Disorders of the Digestive System.
7	Diseases and Disorders of the Hepatobiliary System and Pancreas.
8	Diseases and Disorders of the Musculoskeletal System and Connective Tissue.
9	Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast.
10	Endocrine, Nutritional and Metabolic Diseases and Disorders.
11	Diseases and Disorders of the Kidney and Urinary Tract.
12	Diseases and Disorders of the Male Reproductive System.
13	Diseases and Disorders of the Female Reproductive System.
14	Pregnancy, Childbirth, and the Puerperium.
15	Newborns and Other Neonates with Conditions Originating in the Perinatal Period.
16	Diseases and Disorders of the Blood and Blood Forming Organs and Immunological Disorders.
17	Myeloproliferative Diseases and Disorders and Poorly Differentiated Neoplasms.
18	Infectious and Parasitic Diseases (Systemic or Unspecified Sites).
19	Mental Diseases and Disorders.
20	Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders.
21	Injuries, Poisonings, and Toxic Effects of Drugs.
22	Burns.
23	Factors Influencing Health Status and Other Contacts with Health Services.
24	Multiple Significant Trauma.
25	Human Immunodeficiency Virus Infections.

In general, cases are assigned to an MDC based on the patient's principal diagnosis before assignment to an MS–DRG. However, under the most recent version of the Medicare GROUPER (Version 28.0), there are 13 MS–DRGs to which cases are directly assigned on the basis of ICD–9–CM procedure codes. These MS–DRGs are for heart transplant or implant of heart assist systems; liver and/or intestinal transplants; bone marrow transplants; lung transplants; simultaneous pancreas/kidney transplants; pancreas transplants; and tracheostomies. Cases are assigned to these MS–DRGs before they are classified to an MDC. The table below lists the 13 current pre-MDCs.

PRE-MAJOR DIAGNOSTIC CATEGORIES

[Pre-MDCs]

MS–DRG 001	Heart Transplant or Implant of Heart Assist System with MCC.
MS–DRG 002	Heart Transplant or Implant of Heart Assist System without MCC.
MS–DRG 003	ECMO or Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except for Face, Mouth, and Neck Diagnosis with Major O.R.
MS–DRG 004	Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except for Face, Mouth, and Neck Diagnosis with Major O.R.
MS–DRG 005	Liver Transplant with MCC or Intestinal Transplant.
MS–DRG 006	Liver Transplant without MCC.
MS–DRG 007	Lung Transplant.
MS–DRG 008	Simultaneous Pancreas/Kidney Transplant.
MS–DRG 009	Bone Marrow Transplant.
MS–DRG 010	Pancreas Transplant.
MS–DRG 011	Tracheostomy for Face, Mouth, and Neck Diagnoses with MCC.
MS–DRG 012	Tracheostomy for Face, Mouth, and Neck Diagnoses with CC.
MS–DRG 013	Tracheostomy for Face, Mouth, and Neck Diagnoses without CC/MCC.

Once the MDCs were defined, each MDC was evaluated to identify those additional patient characteristics that would have a consistent effect on hospital resource consumption. Because the presence of a surgical procedure that required the use of the operating room would have a significant effect on the type of hospital resources used by a patient, most MDCs were initially divided into surgical DRGs and medical DRGs. Surgical DRGs are based on a hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. Medical DRGs generally are differentiated on the basis of diagnosis and age (0 to 17 years of age or greater than 17 years of age). Some surgical and medical DRGs are further differentiated based on the presence or absence of a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

Generally, nonsurgical procedures and minor surgical procedures that are not usually performed in an operating room are not treated as O.R. procedures. However, there are a few non-O.R. procedures that do affect MS–DRG

assignment for certain principal diagnoses. An example is extracorporeal shock wave lithotripsy for patients with a principal diagnosis of urinary stones. Lithotripsy procedures are not routinely performed in an operating room. Therefore, lithotripsy codes are not classified as O.R. procedures. However, our clinical advisors believe that patients with urinary stones who undergo extracorporeal shock wave lithotripsy should be considered similar to other patients who undergo O.R. procedures. Therefore, we treat this group of patients similar to patients undergoing O.R. procedures.

Once the medical and surgical classes for an MDC were formed, each diagnosis class was evaluated to determine if complications or comorbidities would consistently affect hospital resource consumption. Each diagnosis was categorized into one of three severity levels. These three levels include a major complication or comorbidity (MCC), a complication or comorbidity (CC), or a non-CC. Physician panels classified each diagnosis code based on a highly iterative process involving a combination of statistical results from test data as well as clinical judgment. As stated earlier, we refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a full detailed discussion of how the MS–DRG system was established based on severity levels of illness (72 FR 47141).

A patient's diagnosis, procedure, discharge status, and demographic information is entered into the Medicare claims processing systems and subjected to a series of automated screens called the Medicare Code Editor (MCE). The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

After patient information is screened through the MCE and further development of the claim is conducted, the cases are classified into the appropriate MS–DRG by the Medicare GROUPER software program. The GROUPER program was developed as a means of classifying each case into an MS–DRG on the basis of the diagnosis and procedure codes and, for a limited number of MS–DRGs, demographic information (that is, sex, age, and discharge status).

After cases are screened through the MCE and assigned to an MS–DRG by the GROUPER, the PRICER software calculates a base MS–DRG payment. The PRICER calculates the payment for each case covered by the IPPS based on the MS–DRG relative weight and additional factors associated with each hospital, such as IME and DSH payment adjustments. These additional factors increase the payment amount to hospitals above the base MS–DRG payment.

The records for all Medicare hospital inpatient discharges are maintained in the Medicare Provider Analysis and Review (MedPAR) file. The data in this file are used to evaluate possible MS–DRG classification changes and to recalibrate the MS–DRG weights. However, in the FY 2000 IPPS final rule (64 FR 41499 and 41500), we discussed a process for considering non-MedPAR data in the recalibration process. We stated that for use of non-MedPAR data to be feasible for purposes of DRG recalibration and reclassification, the data must, among other things: (1) Be independently verified; (2) reflect a complete set of cases (or a representative sample of cases); and (3) enable us to calculate appropriate DRG relative weights and ensure that cases are classified to the ''correct'' DRG, and to one DRG only, in the recalibration process. Further, in order for us to consider using particular non-MedPAR data, we must have sufficient time to evaluate and test the data. The time necessary to do so depend upon the nature and quality of the non-MedPAR data submitted. Generally, however, a significant sample of the non-MedPAR data should be submitted by mid-October for consideration in conjunction with the next year's proposed rule. This date allows us time to test the data and make a preliminary assessment as to the feasibility of using the data. Subsequently, a complete non-MedPAR database should be submitted by early December for consideration in conjunction with the next year's proposed rule.

As we indicated above, for FY 2008, we made significant improvements in the DRG system to recognize severity of illness and resource usage by adopting MS–DRGs that were reflected in the FY 2008 GROUPER, Version 25.0, and were effective for discharges occurring on or after October 1, 2007. Our MS–DRG analysis for the FY 2012 proposed rule was based on data from the September 2010 update of the FY 2010 MedPAR file, which contained hospital bills received through September 30, 2010, for discharges occurring through September 30, 2010. For this FY 2012 final rule, our MS–DRG analysis is based on data from the March 2011 update of the FY 2010 MedPAR file, which contained hospital bills received through March 31, 2011, for discharges occurring through September 30, 2010.

2. Yearly Review for Making MS–DRG Changes

Many of the changes to the MS–DRG classifications we make annually are the result of specific issues brought to our attention by interested parties. We encourage individuals with comments about MS–DRG classifications to submit these comments no later than early December of each year so they can be carefully considered for possible inclusion in the annual proposed rule and, if included, may be subjected to public review and comment. Therefore, similar to the timetable for interested parties to submit non-MedPAR data for consideration in the MS–DRG recalibration process, comments about MS–DRG classification issues should be submitted no later than early December in order to be considered and possibly included in the next annual proposed rule updating the IPPS.

The actual process of forming the MS–DRGs was, and will likely continue to be, highly iterative, involving a combination of statistical results from test data combined with clinical judgment. In the FY 2008 IPPS final rule (72 FR 47140 through 47189), we described in detail the process we used to develop the MS–DRGs that we adopted for FY 2008. In addition, in deciding whether to make further modification to the MS–DRGs for particular circumstances brought to our attention, we considered whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS–DRG. We evaluated patient care costs using average charges and lengths of stay as proxies for costs and relied on the judgment of our medical advisors to decide whether patients are clinically distinct or similar to other patients in the MS–DRG. In evaluating resource costs, we considered both the absolute and percentage differences in average charges between the cases we selected for review and the remainder of cases in the MS–DRG. We also considered variation in charges within these groups; that is, whether observed average differences were consistent across patients or attributable to cases that were extreme in terms of charges or length of stay, or both. Further, we considered the number of patients who will have a given set of characteristics and generally preferred not to create a new MS–DRG unless it would include a substantial number of cases.

C. Adoption of the MS–DRGs in FY 2008

In the FY 2006, FY 2007, and FY 2008 IPPS final rules, we discussed a number

of recommendations made by MedPAC regarding revisions to the DRG system used under the IPPS (70 FR 47473 through 47482; 71 FR 47881 through 47939; and 72 FR 47140 through 47189). As we noted in the FY 2006 IPPS final rule, we had insufficient time to complete a thorough evaluation of these recommendations for full implementation in FY 2006. However, we did adopt severity-weighted cardiac DRGs in FY 2006 to address public comments on this issue and the specific concerns of MedPAC regarding cardiac surgery DRGs. We also indicated that we planned to further consider all of MedPAC's recommendations and thoroughly analyze options and their impacts on the various types of hospitals in the FY 2007 IPPS proposed rule.

For FY 2007, we began this process. In the FY 2007 IPPS proposed rule, we proposed to adopt Consolidated Severity DRGs (CS DRGs) for FY 2008 (if not earlier). Based on public comments received on the FY 2007 IPPS proposed rule, we decided not to adopt the CS DRGs. In the FY 2007 IPPS final rule (71 FR 47906 through 47912), we discussed several concerns raised by public commenters regarding the proposal to adopt CS DRGs. We acknowledged the many public comments suggesting the logic of Medicare's DRG system should continue to remain in the public domain as it has since the inception of the PPS. We also acknowledged concerns about the impact on hospitals and software vendors of moving to a proprietary system. Several commenters suggested that CMS refine the existing DRG classification system to preserve the many policy decisions that were made over the last 20 years and were already incorporated into the DRG system, such as complexity of services and new device technologies. Consistent with the concerns expressed in the public comments, this option had the advantage of using the existing DRGs as a starting point (which was already familiar to the public) and retained the benefit of many DRG decisions that were made in recent years. We stated our belief that the suggested approach of incorporating severity measures into the existing DRG system was a viable option that would be evaluated.

Therefore, we decided to make interim changes to the existing DRGs for FY 2007 by creating 20 new DRGs involving 13 different clinical areas that would significantly improve the CMS DRG system's recognition of severity of illness. We also modified 32 DRGs to better capture differences in severity. The new and revised DRGs were selected from 40 existing CMS DRGs that contained 1,666,476 cases and represented a number of body systems. In creating these 20 new DRGs, we deleted 8 existing DRGs and modified 32 existing DRGs. We indicated that these interim steps for FY 2007 were being taken as a prelude to more comprehensive changes to better account for severity in the DRG system by FY 2008.

In the FY 2007 IPPS final rule (71 FR 47898), we indicated our intent to pursue further DRG reform through two initiatives. First, we announced that we were in the process of engaging a contractor to assist us with evaluating alternative DRG systems that were raised as potential alternatives to the CMS DRGs in the public comments. Second, we indicated our intent to review over 13,000 ICD–9–CM diagnosis codes as part of making further refinements to the current CMS DRGs to better recognize severity of illness based on the work that CMS (then HCFA) did in the mid-1990's in connection with adopting severity DRGs. We describe below the progress we have made on these two initiatives and our actions for FYs 2008, 2009, 2010, and 2011, and our proposed and final actions for FY 2012 based on our continued analysis of reform of the DRG system. We note that the adoption of the MS–DRGs to better recognize severity of illness has implications for the outlier threshold, the application of the postacute care transfer policy, the measurement of real case-mix versus apparent case-mix, and the IME and DSH payment adjustments. We discuss these implications for FY 2012 in other sections of this preamble and in the Addendum to this final rule.

In the FY 2007 IPPS proposed rule, we discussed MedPAC's recommendations to move to a cost-based HSRV weighting methodology using HSRVs beginning with the FY 2007 IPPS proposed rule for determining the DRG relative weights. Although we proposed to adopt the HSRV weighting methodology for FY 2007, we decided not to adopt the proposed methodology in the final rule after considering the public comments we received on the proposal. Instead, in the FY 2007 IPPS final rule, we adopted a cost-based weighting methodology without the HSRV portion of the proposed methodology. The cost-based weights were adopted over a 3-year transition period in ⅓ increments between FY 2007 and FY 2009. In addition, in the FY 2007 IPPS final rule, we indicated our intent to further study the HSRV-based methodology as well as other issues brought to our attention related to the cost-based weighting methodology adopted in the FY 2007 final rule. There was significant concern in the public comments that our cost-based weighting methodology does not adequately account for charge compression—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. Further, public commenters expressed concern about potential inconsistencies between how costs and charges are reported on the Medicare cost reports and charges on the Medicare claims. In the FY 2007 IPPS final rule, we used costs and charges from the cost reports to determine departmental level cost-to-charge ratios (CCRs) which we then applied to charges on the Medicare claims to determine the cost-based weights. The commenters were concerned about potential distortions to the cost-based weights that would result from inconsistent reporting between the cost reports and the Medicare claims. After publication of the FY 2007 IPPS final rule, we entered into a contract with RTI International (RTI) to study both charge compression and the extent, if any, to which our methodology for calculating DRG relative weights is affected by inconsistencies between how hospitals report costs and charges on the cost reports and how hospitals report charges on individual claims. Further, as part of its study of alternative DRG systems, the RAND Corporation analyzed the HSRV cost-weighting methodology. We refer readers to section II.E. of the preamble of this final rule for a discussion of the issue of charge compression and the cost-weighting methodology for FY 2012.

We believe that revisions to the DRG system to better recognize severity of illness and changes to the relative weights based on costs rather than charges are improving the accuracy of the payment rates in the IPPS. We agree with MedPAC that these refinements should be pursued. Although we continue to caution that any prospective payment system based on grouping cases will always present some opportunities for providers to specialize in cases they believe have higher margins, we believe that the changes we have adopted and the continuing reforms we are proposing to make in this proposed rule for FY 2012 will improve payment accuracy and reduce financial incentives to create specialty hospitals.

We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a full discussion of how the MS–DRG system was established based

on severity levels of illness (72 FR 47141).

D. FY 2012 MS–DRG Documentation and Coding Adjustment, Including the Applicability to the Hospital-Specific Rates and the Puerto Rico-Specific Standardized Amount

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90

As we discussed earlier in this preamble, 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, which include 4 additional MS–DRGs that we are adopting for FY 2012.) 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. Section 7(a) of Public Law 110–90 did not adjust the FY 2010 −1.8 percent documentation and coding adjustment promulgated in the FY 2008 IPPS final rule with comment period. To comply with section 7(a) of Public Law 110–90, we promulgated a final rule on November 27, 2007 (72 FR 66886) that modified the IPPS documentation and coding adjustment for FY 2008 to −0.6 percent, and revised the FY 2008 payment rates, factors, and thresholds accordingly. These revisions were effective on October 1, 2007.

For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent instead of the −1.8 percent adjustment established in the FY 2008 IPPS final rule with comment period. As discussed in the FY 2009 IPPS final rule (73 FR 48447) and required by statute, we applied a documentation and coding adjustment of −0.9 percent to the FY 2009 IPPS national standardized amount. The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, as amended 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. Prospective Adjustment to the Average Standardized Amounts 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.

3. Recoupment or Repayment Adjustments in FYs 2010 Through 2012 Required by 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 make these recoupment or repayment adjustments for discharges occurring during FYs 2010, 2011, and 2012.

4. 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 indicated in the FY 2009 IPPS final rule (73 FR 48450) that we planned a thorough retrospective evaluation of our claims data. We stated that the results of this evaluation would be used by our actuaries to determine any necessary payment adjustments to the standardized amounts under section 1886(d) of the Act to ensure the budget neutrality of the MS–DRGs implementation for FY 2008 and FY 2009, as required by law. In the FY 2009 IPPS proposed rule (73 FR 23541 through 23542), we described our preliminary plan for a retrospective analysis of inpatient hospital claims

data and invited public input on our proposed methodology.

In that proposed rule, we indicated that we intended to measure and corroborate the extent of the overall national average changes in case-mix for FY 2008 and FY 2009. We expected that the two largest parts of this overall national average change would be attributable to underlying changes in actual patient severity of illness and to documentation and coding improvements under the MS–DRG system. In order to separate the two effects, we planned to isolate the effect of shifts in cases *among* base DRGs from the effect of shifts in the types of cases *within* base DRGs.

The MS–DRGs divide the base DRGs into three severity levels (with MCC, with CC, and without CC); the previously used CMS DRGs had only two severity levels (with CC and without CC). Under the CMS DRG system, the majority of hospital discharges had a secondary diagnosis which was on the CC list, which led to the higher severity level. The MS–DRGs significantly changed the code lists of what was classified as an MCC or a CC. Many codes that were previously classified as a CC are no longer included on the MS–DRG CC list because the data and clinical review showed these conditions did not lead to a significant increase in resource use. The addition of a new level of high severity conditions, the MCC list, also provided a new incentive to code more precisely in order to increase the severity level. We anticipated that hospitals would examine the MS–DRG MCC and CC code lists and then work with physicians and coders on documentation and coding practices so that coders could appropriately assign codes from the highest possible severity level. We note that there have been numerous seminars and training sessions on this particular coding issue. The topic of improving documentation practices in order to code conditions on the MCC list was also discussed extensively by participants at the March 11–12, 2009 ICD–9–CM Coordination and Maintenance Committee meeting. Participants discussed their hospitals' efforts to encourage physicians to provide more precise documentation so that coders could appropriately assign codes that would lead to a higher severity level. Because we expected most of the documentation and coding changes under the MS–DRG system would occur in the secondary diagnoses, we believed that the shifts among base DRGs were less likely to be the result of the MS–DRG system and the shifts within base DRGs were more likely to be the result of the MS–DRG system. We also anticipated evaluating data to identify the specific MS–DRGs and diagnoses that contributed significantly to the documentation and coding payment effect and to quantify their impact. This step entailed analysis of the secondary diagnoses driving the shifts in severity within specific base DRGs.

In the FY 2009 IPPS proposed rule, we solicited public comments on the analysis plans described above, as well as suggestions on other possible approaches for performing a retrospective analysis to identify the amount of case-mix changes that occurred in FY 2008 and FY 2009 that did not reflect real increases in patient severity of illness.

A few commenters, including MedPAC, expressed support for the analytic approach described in the FY 2009 IPPS proposed rule. A number of other commenters expressed concerns about certain aspects of the approach and/or suggested alternate analyses or study designs. In addition, one commenter recommended that any determination or retrospective evaluation by the actuaries of the impact of the MS–DRGs on case-mix be open to public scrutiny prior to the implementation of the payment adjustments beginning in FY 2010.

We took these comments into consideration as we developed our proposed analysis plan, and in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24092 through 24101), we solicited public comment on our methodology and analysis. For the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, we performed a retrospective evaluation of the FY 2008 data for claims paid through December 2008. Based on this evaluation, our actuaries determined that implementation of the MS–DRG system resulted in a 2.5 percent change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we updated this analysis with FY 2008 data for claims paid through March 2009, and we noted that the estimates for all IPPS remained essentially the same to those in the proposed rule (42 FR 43770, 43775). Also, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43768 through 43772), we responded to comments on our methodology for the retrospective evaluation of FY 2008 claims data. We refer readers to that final rule for a detailed description of our analysis and prior responses to comments.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50068), we performed the same analysis for FY 2009 claims data using the same methodology as we did for FY 2008 claims. We note that, in the FY 2011 IPPS/LTCH PPS proposed rule, we performed this analysis using FY 2009 claims paid through December 2009. In the FY 2011 IPPS/LTCH PPS final rule, we updated the analysis with FY 2009 claims paid through March 2010, as we discussed in the proposed rule. We note that, for all IPPS hospitals, other than those in Puerto Rico, the estimates were unchanged from those in the proposed rule. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50068) for a detailed description of our analysis and prior responses to comments. The results of the analysis for the FY 2011 proposed and final rules provided additional support for our conclusion that the proposed 5.4 percent estimate accurately reflected the FY 2009 increases in documentation and coding under the MS–DRG system.

As in prior years, the FY 2008 and FY 2009 MedPAR files are available to the public to allow independent analysis of the FY 2008 and FY 2009 documentation and coding effect. Interested individuals may still order these files through the Web site at: *http://www.cms.hhs.gov/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.

5. Prospective Adjustment for FY 2010 and Subsequent Years Authorized by Section 7(b)(1)(A) of Public Law 110–90 and Section 1886(d)(3)(vi) of the Act

Based on our evaluation of FY 2008 Medicare claims data that were most current at the time of the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, the estimated 2.5 percent change in FY 2008 case-mix due to changes in

documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 exceeded the −0.6 percent prospective documentation and coding adjustment applied under section 7(a) of Public Law 110–90 by 1.9 percentage points. In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24096), we solicited public comment on our proposal to make a −1.9 percent prospective adjustment to the standardized amounts under section 1886(d) of the Act to address the effects of documentation and coding changes unrelated to changes in real case-mix in FY 2008. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, in response to public comments, we indicated that we fully understood that our proposed adjustment of −1.9 percent would reduce the increase in payments that affected hospitals would have received in FY 2009 in the absence of the adjustment, and we determined that it would be appropriate to postpone adopting documentation and coding adjustments as authorized under section 7(a) of Public Law 110–90 and section 1886(d)(3)(A)(vi) of the Act until a full analysis of case-mix changes could be completed. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43767 through 43777) 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. 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 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 we have some discretion as to the manner in which we apply the prospective adjustment of −3.9 percent. We indicated that applying the full prospective adjustment of −3.9 percent for FY 2011, in combination with the proposed recoupment adjustment of −2.9 percent in FY 2011 (discussed below) would require an aggregate adjustment of −6.8 percent. As we discuss elsewhere in this section II.D., and more 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. As we also discuss below in this section II.D., we are required to implement the remaining adjustment in section 7(b)(1)(B) of Public Law 110–90 no later than the FY 2012 rulemaking period, and accordingly, in the FY 2011 IPPS/LTCH PPS proposed rule, we proposed a recoupment adjustment under section 7(b)(1)(B) of −2.9 percent for FY 2011 (75 FR 23870 and 23871). Therefore, we stated that we believed it was appropriate to not implement any or all of the −3.9 percent prospective adjustment in FY 2011. 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) for FY 2011. We note that, as a result, payments in FY 2011 (and in each future year until we implement the requisite adjustment) would be 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90. Our actuaries estimate that this 3.9 percentage point increase will result in an aggregate payment of approximately $4 billion. We also noted that payments in FY 2010 were also expected to be 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90, which our actuaries estimated increased aggregate payments by approximately $4 billion in FY 2010.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25803 and 25804), we indicated that because further delay of this prospective adjustment will result in a continued accrual of unrecoverable overpayments, it was imperative that we proposed a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we proposed a −3.15 percent prospective adjustment to the standardized amount to partially eliminate the full effect of the documentation and coding changes on future payments. Due to the offsetting nature of the remaining recoupment adjustment under section 7(b)(1)(B) of Public Law 110–90 (described below in section II.D.6. of this preamble), and after considering other payment adjustments to FY 2012 rates proposed elsewhere within the proposed rule, we indicated that we believe the proposed −3.15 percent adjustment would allow for a significant reduction in potential unrecoverable overpayments, yet would maintain a comparable adjustment level between FY 2011 and FY 2012, reflecting the applicable percentage increase with a documentation and coding adjustment. We stated that we recognize that an additional adjustment of −0.75 (3.9 minus 3.15) percent would be required in future rule making to complete the necessary −3.9 adjustment to meet CMS' statutory requirement under section 7(b)(1)(A) of Public Law 110–90. In the proposed rule, we indicated that we were not at that time proposing a timeline to implement the remainder of this prospective adjustment.

6. Recoupment or Repayment Adjustment for FY 2010 Authorized by Section 7(b)(1)(B) of Public Law 110–90

As discussed in section II.D.1. 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.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule with comment period (74 FR 43773), we estimated a 2.5 percent change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008, exceeding the −0.6 percent prospective documentation and coding adjustment applied under section 7(a) of Public Law 110–90 by 1.9 percentage points. We stated that our actuaries had estimated that this 1.9 percentage point increase resulted in an increase in aggregate payments of approximately $2.2 billion in FY 2008. We did not propose to make an adjustment to the FY 2010 average standardized amounts to offset, in whole or in part, the estimated increase in aggregate payments for discharges occurring in FY 2008, but stated in the proposed rule that we intended to address this issue in future rulemaking. In the FY 2010 IPPS/RY 2010 LTCH PPS

final rule (74 FR 43774), we stated that because we would not receive all FY 2009 claims data prior to publication of the final rule, we would address any increase or decrease in FY 2009 payments in future rulemaking for FY 2011 and 2012 after we performed a retrospective evaluation of the FY 2009 claims data. In response to public comments in FY 2010, we indicated that we recognized that any adjustment to account for the documentation and coding effect observed in the FY 2008 and FY 2009 claims data may result in significant future payment reductions for providers. However, we indicated that we are required under section 7(b)(1)(B) of Public Law 110–90 to recover the difference of actual documentation and coding effect in FY 2008 and FY 2009 that is greater than the prior adjustments. We agreed with the commenters who requested that CMS delay any adjustment and, for the reasons stated above, indicated that we expected to address this issue in the FY 2011 rulemaking. We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43767 through 43777) for a detailed description of our proposal, responses to comments, and finalized policy.

As we indicated in the FY 2011 IPPS/LTCH PPS final rule, the change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 and FY 2009 exceeded the −0.6 and −0.9 percent prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90 for those 2 years, respectively, by 1.9 percentage points in FY 2008 and 3.9 percentage points in FY 2009. In total, this change exceeded the cumulative prospective adjustments by 5.8 (1.9 plus 3.9) percentage points. Our actuaries estimated that this 5.8 percentage point increase resulted in an increase in aggregate payments of approximately $6.9 billion. In the FY 2011 IPPS/LTCH PPS final rule, we noted that there may be a need to actuarially adjust the recoupment adjustment to accurately reflect accumulated interest. Therefore, we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012, subject to actuarial adjustment to reflect accumulated interest, 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. In the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23871), we stated that we intended to take into account the need to reflect accumulated interest in proposing a recoupment adjustment under section 7(b)(1)(B) of Public Law 110–90 for FY 2012.

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 proposed rule, we proposed to make 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 would allow 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).

Unlike the permanent prospective adjustment to the standardized amounts under section 7(b)(1)(A) of Public Law 110–90 described earlier, the recoupment adjustment to the standardized amounts under section 7(b)(1)(B) of Public Law 110–90 is not cumulative, and, therefore, would be removed for subsequent fiscal years once we have completely offset the increase in aggregate payments for discharges for FY 2008 and FY 2009 expenditures. In keeping with our practice of moderating payment adjustments when necessary, we stated that we anticipated that the proposal of phasing in the recoupment adjustment will have an additional, and significant, moderating effect on implementing the requirements of section 7(b)(1)(B) of Public Law 110–90 for FY 2012.

In the FY 2011 IPPS/LTCH PPS proposed rule, we sought public comment on our proposal to offset part of the total 5.8 percent increase in aggregate payments (including interest) for discharges occurring in FY 2008 and FY 2009 resulting from the adoption of the MS–DRGs in FY 2011, noting that this proposal would result in a −2.9 percent adjustment to the standardized amount. We received numerous comments on our proposal, especially from national and regional hospital associations, hospital systems, and individual hospitals. MedPAC also commented on our proposal. We refer readers to the FY 2011 IPPS/LTCH PPS final rule with comment period (75 FR 50055 through 50073) for a detailed description of our analysis and prior responses to comments, and finalized policy.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50068), we finalized the proposed adjustment to the standardized amount of −2.9 percent, which represented approximately half of the aggregate recoupment adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. We were persuaded by both the MedPAC's analysis, and our own review of the methodologies recommended by various commenters, that the methodology we employed to determine the required recoupment adjustment was sound. Since the statute required that we implement the entire recoupment adjustment no later than FY 2012, we have sought, as we commonly do, to moderate the potential impact on hospitals by phasing in the required adjustment over more than one year. As we stated in prior rulemaking, a major advantage of making the −2.9 percent adjustment to the standardized amount in FY 2011 was that, because the required recoupment adjustment is not cumulative, we anticipated removing the FY 2011 −2.9 percent adjustment from the rates (in other words, making a positive 2.9 percent adjustment to the rates) in FY 2012, at the same time that the law required us to apply the remaining approximately −2.9 percent adjustment required by section 7(b)(1)(B) of Public Law 110–90. These two steps in FY 2012, restoring the FY 2011 −2.9 percent adjustment and then applying the remaining adjustment of approximately −2.9 percent, would effectively cancel each other out. The result of these two steps would be an aggregate adjustment of approximately 0.0 percent. While we stated in the FY 2011 IPPS/LTCH PPS final rule the need to potentially adjust the remaining −2.9 percent estimate to account for accumulated interest, our actuaries have determined that there has been no significant interest accumulation and that no additional adjustment will be required. Therefore, for FY 2012, pursuant to 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 proposed to complete 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. Because these adjustments will, in effect, balance out, there will be no year-to-year change in the standardized amount due to this recoupment adjustment. As this

adjustment will complete the required recoupment for overpayments due to documentation and coding effects on discharges occurring in FYs 2008 and 2009, we anticipate removing the effect of this adjustment by adding 2.9 percent to the standardized amount in FY 2013. We continue to believe that this is a reasonable and fair approach that satisfies the requirements of the statute while substantially moderating the financial impact on hospitals.

Comment: One commenter, MedPAC, reiterated its general support for the methodology used by our actuaries to estimate the magnitude of documentation and coding effect on IPPS payments due to the adoption of the MS–DRG system. In its letter, MedPAC explained that the methodology used by our actuaries ''is akin to comparing two sets of payments: What payments actually were in fiscal year 2009 under the 2009 MS–DRGs and relative weights; and what payments would have been in 2009 if MS–DRGs had not been adopted and CMS had continued to use the prior (2007) CMS DRGs and weights.'' MedPAC noted that by taking the difference between these two sets of payments, the methodology is designed to capture ''the new GROUPER's interaction with how hospitals changed their documentation and coding. After the adoption of MS–DRGs in 2008, hospitals switched from recording general descriptions of patients' chronic conditions—which no longer affect payments under MS–DRGs—to recording the specific acute manifestations of patients' chronic conditions, which trigger higher payments under MS–DRGs. However, the same changes in diagnosis documentation and coding have little or no effect on the CMI measured using the 2007 CMS–DRGs and weights. This is because in that version of the GROUPER, both acute manifestations of chronic conditions and general descriptions of chronic conditions trigger higher payments. In contrast, when hospitals had little incentive to change documentation and coding—in 2007, for example—the two CMIs are approximately equal.''

Consistent with its comments in prior years, MedPAC's comment noted that its analysis of Medicare hospital inpatient claims for 2007–2009 yielded similar estimates of the documentation and coding effect. MedPAC concluded that ''CMS would need to reduce IPPS payments temporarily by 5.8 percent to recover overpayments that occurred in 2008 and 2009. CMS also expected that overpayments equal to 3.9 percent of annual IPPS payments would continue through 2010, 2011, and future years until CMS makes a prospective offsetting adjustment (−3.9 percent) to the IPPS payments rates.''

MedPAC's comment described potential circumstances in which the methodology used both by our actuaries and MedPAC could overestimate the documentation and coding effect, noting that these possible circumstances ''could cause only a small change in the estimated effect of documentation changes.''

MedPAC stated, ''In response to the new MS–DRGs, hospitals had an incentive to report diagnoses that count as CCs in the new system. MedPAC's argument is that hospitals may also have stopped reporting diagnoses that counted as CCs in the old system, but do not count in the new one.'' In short, MedPAC argued that the disappearance of the general chronic condition codes could have caused the CMIs based on the old FY 2007 GROUPER and weights to be understated in FYs 2008 and 2009. Thus, because CMIs based on the 2007 GROUPER and weights are the denominators of the documentation change estimates, understatement would bias the estimates upward. However, understatement would occur only to the extent that hospitals, when coding: (1) Did not replace such general chronic condition codes with corresponding acute manifestation codes and (2) the patient had no other secondary diagnosis code that qualified as a CC in the old GROUPER and are now CCs or MCCs under the MS–DRGs.

MedPAC's analysis concluded that the maximum possible effect of this potential overestimation is 0.36 percent, and ''that total overpayments due to documentation changes in 2008 and 2009 may have ranged from 5.1 to 5.8 percent of IPPS payments ($6.0 to $6.9 billion).''

MedPAC recommended that CMS slow the pace of the payment adjustments so that hospitals would receive a net 1 percent update in FY 2012, as it recommend in its March 2011 Report to Congress. Furthermore, MedPAC stated that legislation should be enacted to require the Secretary of Health and Human Services to adjust payments further to recover all overpayments that have occurred or will occur in FYs 2010, 2011, and 2012 because the prospective adjustment was not completed. MedPAC asserted that:

''To allow payments to increase due to documentation and coding changes would undermine Congressional policy on updates. If Congress wants more money to flow into the hospital sector, a higher update is the appropriate mechanism, not cumulative changes in documentation and coding. Indeed, allowing those changes to increase hospital payments through the back door could eventually discourage needed refinements to the case-mix system in a tight budget era. In other words, if more money inevitably leaks into the system every time case-mix is refined, then there may be pressure to stop refining. That would lead to inequities for both providers and patients.''

Response: We appreciate MedPAC's analysis and continued support of the methodology used to determine the documentation and coding effect, and we agree that this methodology appropriately isolates the documentation and coding effect from real case-mix. With the exception of the possible overstatement described above, we note that MedPAC's analysis yielded results similar to CMS' determination of the documentation and coding effect. Based on our evaluation of FY 2008 and FY 2009 claims, we continue to believe that $6.9 billion dollars in overpayments were made during the period of FY 2008 and 2009. We estimate that a recoupment adjustment totaling 5.8 percent is necessary to recover these overpayments, and that operating IPPS rates are currently overstated by 3.9 percent. We also note that section 7(b)(1)(B) of the TMA requires the agency to recover these overpayments by FY 2012 and that section 7(b)(1)(A) of the TMA requires the agency to adjust rates to ensure that aggregate payments do not continue to be overstated.

With regard to MedPAC's analysis regarding the possible overestimate of the documentation and coding effect, we note that MedPAC characterized the potential effect as ''small'' and provided no corroborating analysis or specific examples of when this scenario may have occurred. We consulted with our medical coding experts and were unable to identify specific examples to support MedPAC's hypothesis. We note that MedPAC stated in its comment letter that the potential for overestimation exists only to the extent that ''hospitals (1) did not replace such general chronic condition codes with corresponding acute manifestation codes and (2) the patient had no other secondary diagnosis code that qualified as a CC in the old grouper.'' We reviewed coding changes that occurred during the transition to MS–DRGs and were able to identify codes that would result in a CC prior to MS–DRGs but would not result in a CC in the MS–DRG system. However, we were unable to identify an instance where this would necessarily result in a lower MS–DRG assignment because more specific codes were

developed to support the more refined MS–DRG system and we would expect hospitals to use the more specific codes. For instance, congestive heart failure was a CC under CMS DRGs, but is not a CC under MS–DRGs. Under MS–DRGs, we started requiring more specific information on the type of heart failure in order to count this as a CC or MCC. Generally, under the MS–DRG system, the ''unspecified'' codes in a category no longer result in CCs.

We did not receive any other public comments regarding MedPAC's statements that we may have overestimated the effect of the documentation and coding by considering cases grouped under the MS–DRG system as having a higher severity due to being coded without appropriate CCs under the pre-MS–DRG system.

At this time, we believe it would not be appropriate to revise our estimates based solely on MedPAC's analysis without knowing of any specific examples of the scenario described above. Without this information, we cannot determine whether there was a sufficient volume of cases to cause a potential documentation and coding overestimate. However, we welcome specific examples from the public to possibly inform future rulemaking.

We acknowledge MedPAC's recommendation to provide hospitals with a net 1 percent update. As noted above, the comment restates MedPAC's recommendation from its March 2011 Report to Congress. We address this issue below in our response to comments by the provider community that expressed concern regarding the impact of various payment adjustments on hospitals.

We also acknowledge MedPAC's request that additional statutory authority be granted to the Secretary of Health and Human Services to recover overpayments made during subsequent fiscal years.

Lastly, we agree with MedPAC that it is important to continue refining the methodology of how case mix is measured to ensure payment accuracy. We note that in this final rule we discuss potential refinements to the MS–DRG relative weight system, and CMS' active engagement in implementing the ICD–10 system. These discussions illustrate the efforts the agency is undertaking to improve the ability to measure case mix precisely and to pay hospitals for inpatient services more accurately.

Comment: Most commenters, including national hospital associations, continued to acknowledge that there were documentation and coding increases in FY 2008 and FY 2009 that were in excess of the statutory 0.6 percent and 0.9 percent adjustments specified in section 7(a) of the TMA. However, as in prior rulemakings on this issue, most commenters again questioned the methodology employed by MedPAC and our actuaries to determine the magnitude of the excess.

We also received Congressional correspondence from numerous members of Congress stating that hospitals had expressed concerns regarding the CMS Actuary's methodology and requesting that CMS ensure that its methodology accurately reflects changes in patient severity prior to finalizing adjustments for documentation and coding in response to hospitals' concerns. Specifically, the correspondence suggested that CMS could consider alternative methodologies for estimating the effect of documentation and coding, including trend-based analysis and chart abstraction.

Several commenters stated that historical case mix trend is inconsistent with our estimate of the effect of the FY 2008 and FY 2009 documentation and coding changes due to the implementation of the MS–DRGs. One commenter stated ''Our analysis, which used multiple years of patient claims, clearly shows that a significant portion of the change CMS found is actually the continuation of historical trends, rather than the effect of documentation and coding changes due to implementation of MS–DRGs. This analysis found a cumulative documentation and coding effect of 3.6 percent for FYs 2008 and 2009, as opposed to the 5.4 percent that CMS found.''

Several commenters submitted an historical case-mix trend analysis last year, which showed a documentation and coding effect of 2.3 percent. An analysis submitted by the same commenters this year showed a cumulative documentation and coding increase through FY 2009 of 3.6 percent. The commenters revised their analysis to respond to CMS comments made in last year's rule. Specifically, the national hospital associations stated that, ''This year we make several modifications to that trend-based analysis to respond to CMS' critiques as enumerated in the FY 2011 inpatient PPS final rule. Given that we have addressed the agency's concerns, we are hopeful that it will give our methodology fresh consideration.'' One hospital association also pointed out that CMS included an assumption regarding real case-mix growth in the adjustment for ''changes in case-mix'' in the capital update framework at § 412.308(c)(1)(ii) and suggested that the estimate made by our actuaries regarding documentation and coding be reduced by this assumption in order to maintain consistency with the capital update framework.

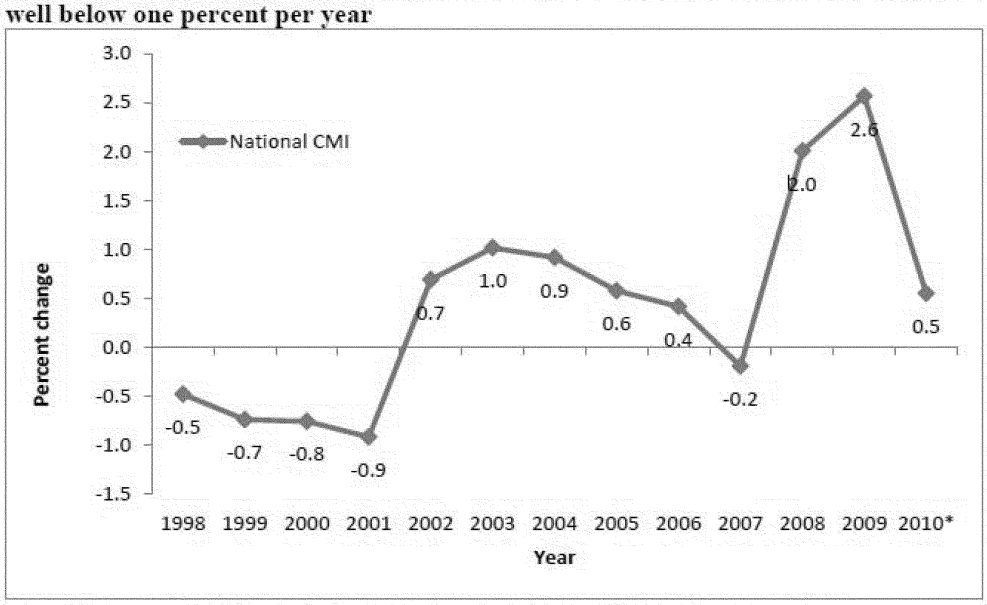
Commenters also examined the methodology used by our actuaries and MedPAC using index number theory. As stated by these commenters, ''the relative case weights in a given grouper are like relative prices in a price index calculation (in fact they are relative prices for the different MS–DRGs) and the quantities of discharges in various MS–DRGs are like the quantities of goods in the price index calculation.'' Commenters claimed that, based on index number theory, the methodology employed by MedPAC and our actuaries can only provide upper and lower bounds of the combined effect of documentation and coding and real case-mix change. MedPAC, however, indicated that knowledge of the 2007 MS–DRG GROUPER, the new MS–DRG GROUPER, historical documentation of patients' diagnoses, and the changes CMS made when it created the MS–DRGs can be used to narrow the range of the potential documentation and coding effect as described above, although they noted that these ''could cause only a small change in the estimated effect of documentation changes.''

As in past years, several commenters indicated that CMS should use medical records data to distinguish documentation and coding changes from real case-mix changes. MedPAC disagreed with the commenters' rationale that the use of medical records data could determine the effect of both documentation and coding, and stated the following: ''Gold-standard coders, however, only see the diagnoses written in the record and therefore are not able to distinguish changes in documentation from real changes in patients' diagnoses. This method of recoding existing documentation only works in situations where hospitals have no incentive to change documentation. That is clearly not the case with the transition to MS–DRGs.''

Response: We disagree that the new analysis presented by the national hospital associations has addressed our concerns with the use of a trend analysis to determine the documentation and coding increase when a more direct measurement of the relevant increase can be obtained using our proposed methodology. In last year's rule, we expressed several concerns with regard to the use of a trend analysis, stating, ''We believe that the determination of an appropriate

historical trend is less straightforward than our methodology, which, as described above, simply removes real case-mix growth from the calculation'' (75 FR 50066). While we pointed out certain analytical flaws in the trend analysis used last year (for a full discussion, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50065 through 50066)), we did not state the correction of those flaws would yield a better documentation and coding estimate than the direct estimate obtained under our proposed methodology. In fact, we noted that ''changes in case-mix do not necessarily follow a consistent pattern over time.'' MedPAC provided analysis in its comment letter which supported CMS' position. MedPAC's analysis demonstrated that CMI growth was modest at best, never exceeding plus or minus 1 percent the decade prior to the introduction of MS–DRGs, and in some years was negative.

Figure 1: Before implementation of MS-DRGs, the change in reported case mix was usually well below one percent per year

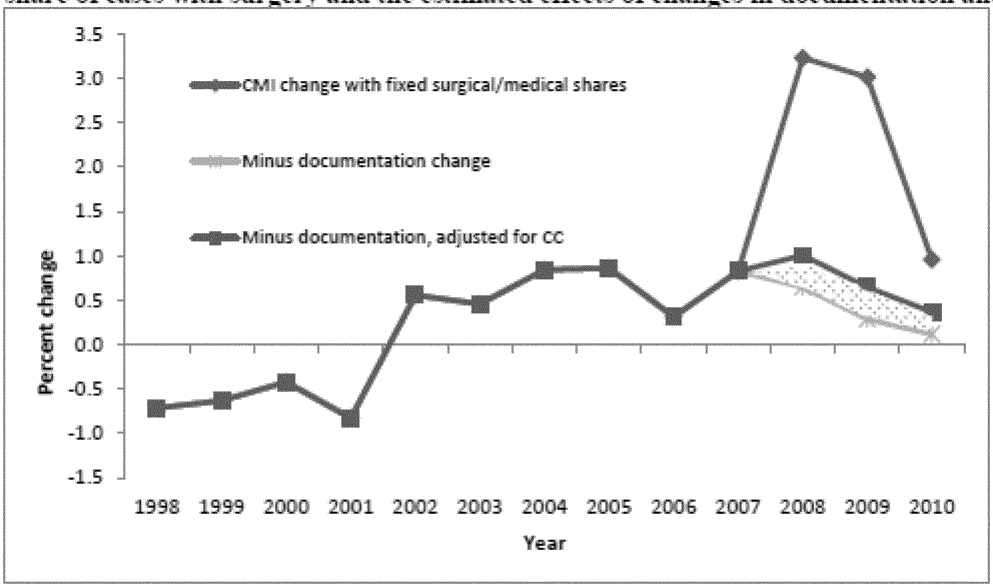


Note: * indicates preliminary data from the proposed rule MedPAR file for fiscal year 2010.
Source: MedPAC analysis of IPPS hospital inpatient claims in the final rule MedPAR files for fiscal years 1997-2009 and the proposed rule MedPAR file for fiscal year 2010, from CMS. CMIs are based on the DRG grouper, relative weights, and transfer policies in effect for each fiscal year. Claims for hospitals designated as critical access hospitals as of 12/31/2010 were excluded from the CMIs for all years.

The national hospital associations' most significant response to our critique of their previous analysis in the FY 2011 IPPS/LTCH PPS final rule was to expand the time period upon which its trend analysis is based to include years where there were sustained negative changes in actual CMI. This raised their estimate of documentation and coding from 2.3 percent to 3.6 percent. We believe that this increase demonstrates the variability in the estimates that can be obtained using trend analyses. We also stated in last year's final rule that ''despite our position that our methodology more directly measures the relevant increase, we did examine the alternative approach favored by commenters for calculating the documentation and classification increase. As a general statement, the approach of examining historical trends to estimate what case-mix would have been in the absence of the adoption of the MS–DRGs should not necessarily yield significantly different results from the analysis done by our actuaries and the MedPAC, if an appropriate historical trend can be determined.''

We reiterate our concerns with the use of historical trends to determine documentation and coding this year, and we do not believe that the modifications to the commenters' analysis address all of these concerns. In particular, we agree with MedPAC that ''absent changes in documentation and coding and the shift away from inpatient surgeries, real changes in the CMI in 2008 through 2010 would be completely consistent with historical CMI changes since 2001.'' In performing its analysis, MedPAC adjusted for changes in the share of cases with surgery, share of cases with CCs, and the estimated effects of changes in documentation and coding. MedPAC summarized the results of its analysis in the following graph.

Figure 2: Annual changes in the CMI look quite ordinary after we adjust for changes in the share of cases with surgery and the estimated effects of changes in documentation and coding



Source: MedPAC analysis of IPPS hospital inpatient claims in the final rule MedPAR files for fiscal years 1997-2009 and the proposed rule MedPAR file for fiscal year 2010, from CMS. CMIs are based on the DRG grouper, relative weights, and transfer policies in effect for each fiscal year. Trends are based on CMIs calculated with fixed medical/surgical shares of 70.5 and 29.5 percent (the averages for the whole period). Percent changes for the other two series reflect the documentation change and CC adjustments described earlier for each year 2008-2010.

In summary, with respect to trend analysis, we continue to believe that the determination of an appropriate historical trend is less straightforward than our proposed methodology, which simply removes real case-mix growth from the calculation. In addition, the estimates obtained using our proposed methodology are consistent with the historical case-mix growth, as demonstrated by MedPAC.

We also disagree with commenters who stated that the methodology employed by MedPAC and our actuaries can only provide upper and lower bounds of the combined effect of documentation and coding and real case-mix change and cannot separate documentation and coding effects from real case-mix change. While MedPAC recognized that the potential for a range of estimates may exist, MedPAC disagreed with the conclusion that index number theory, as described above, should be used to determine this range. MedPAC stated that ''in this instance at least, the estimated range between the lower and upper bounds based on this approach is so wide that the estimates are useless for policy making.'' We agree with MedPAC that the wide range resulting from an index number theory approach renders such an approach useless in this context.

In response to commenters' support for using hospital records to distinguish documentation and coding effect from real case-mix changes, we agree with MedPAC's rationale that such an analysis would fail to capture changes in documentation. MedPAC stated: ''In our view, this approach does not work. The reason is that hospitals had an incentive to persuade attending physicians to be more specific in describing patients' acute manifestations of chronic conditions in their medical records. Some hospitals hired documentation specialists with the goal of changing physicians' medical record documentation, not simply to do a better job of coding what they wrote in the record (Hahey 2008). Gold-standard coders, however, only see the diagnoses written in the record and therefore are not able to distinguish changes in documentation from real changes in patients' diagnoses. This method of recoding existing documentation only works in situations where hospitals have no incentive to change documentation. That is clearly not the case with the transition to MS–DRGs. Thus, a very important part of the effect of changes in documentation and coding cannot be detected by the proposed method.''

We also note that as one part of our initial documentation and coding analysis, we attempted to examine coding changes based on hospital chart data from the Medicare Clinical Data Abstraction Center (CDAC). However, as we described in the FY 2010 IPPS/LTCH PPS final rule, it was not possible to perform this analysis due to aberrant CDAC data. We stated, ''While we attempted to use the CDAC data to distinguish real increase in case-mix growth from documentation and coding in the overall case-mix number, we found aberrant data and significant variation across the FY 1999–FY 2007 analysis period. It was not possible to distinguish changes in documentation and coding from changes in real case-mix in the CDAC data. Therefore, we concluded that the CDAC data would not support analysis of real case-mix growth that could be used in our retrospective evaluation of the FY 2008 claims data.'' (74 FR 43769)

Finally, we disagree with the commenters' suggestion that the assumptions in the capital update framework should be applied in our actuaries' estimate of documentation and coding, because the capital update framework is intended for projection purposes and would be inappropriate to use as a proxy for historical trends.

After careful consideration of all of the public comments we received, including alternatives suggested by commenters, we remain confident in the accuracy of our methodology and its appropriateness in determining the required adjustment amounts.

Comment: Numerous commenters expressed concern regarding the potentially severe negative fiscal impact that would be experienced by providers if the proposed documentation and coding improvement adjustment were to

be implemented. As noted above, MedPAC recommended that CMS reduce its proposed −3.15 percent adjustment to be consistent with a net update factor of +1.0 percent, as it recommended in its March 2011 Report to Congress.

As noted previously, we also received Congressional correspondence from numerous members of Congress that requested CMS to reconsider what would be an appropriate adjustment to hospital payments and also requested that CMS reexamine its methodology. This correspondence noted that hospitals would experience payment reductions if the proposed rule were finalized without modification and further stated that hospitals needed ''adequate Medicare reimbursement to ensure that patients and communities receive the care they need.''

Response: We recognize the concerns regarding possible financial disruption that may be caused by the proposed documentation and coding improvement payment adjustment. We note, however, that these payment adjustments are necessary to correct past overpayments due solely to documentation and coding improvements. We have already delayed implementation of the required prospective adjustment amount, and we proposed only a portion of the remaining required adjustment to allow hospitals time to adjust to future payment differences and to moderate the effect of this adjustment in any given year. We are required under section 7(b)(1)(B) of the TMA to complete the remaining one-time −2.9 percent recoupment adjustment for FY 2008 and FY 2009 overpayments in FY 2012, and we believe the impact of completing this adjustment to be reasonable considering it will be completely offset by removing the FY 2011 recoupment adjustment by placing a +2.9 percent adjustment back to the standardized amount. In FY 2013, a positive +2.9 percent adjustment will be made, completing the recoupment process.

In the proposed rule, we stated it was imperative that CMS make a significant prospective adjustment amount in FY 2012 to prevent the accumulation of unrecoverable overpayments. As stated in previous responses to comments, we remain confident in the accuracy of the overall methodology and its appropriateness in determining the required adjustment amount. However, after consideration of the public comments, and in keeping with our longstanding policy to mitigate, when possible, the effects of significant downward adjustments on hospitals, we are finalizing a prospective adjustment of −2.0 percent, which is a reduction from our proposed adjustment of −3.15 percent. We note that this adjustment will result in a total update of +1.0 percent, in accordance with MedPAC's recommendation in its March 2011 Report to Congress for hospitals that report quality data consistent with the requirements of the Hospital IQR Program. Specifically, as discussed elsewhere in this final rule, the applicable percentage increase for FY 2012 is +1.9 percent (based on a market basket of +3.0 percent, a multifactor productivity adjustment of −1.0 percentage point, and a statutory adjustment of −0.1 percentage point in accordance with section 3401 of the Affordable Care Act). When combined with the +1.1 adjustment in light of *Cape Cod v. Sebelius,* 630 F.3d 203 (D.C. Cir. 2011) discussed elsewhere in this final rule, the applicable percentage increase of +1.9 percent and this proposed prospective adjustment of −2.0 percent results in a net total update of +1.0 percent, prior to additional adjustments for budget neutrality and other policy adjustments. We believe that this level of adjustment will help to minimize year to year volatility in payment rates due to the required documentation and coding adjustment. As we stated in the proposed rule, our analysis found that a prospective adjustment of −3.9 percent continues to be necessary. Because we are making a −2.0 percent prospective adjustment for FY 2012, a remaining prospective of adjustment of −1.9 percent will be necessary. While we are not at this time stating when we will make the remaining required −1.9 percent prospective adjustment, we consider it feasible to make all or most of the adjustment in FY 2013, when a +2.9 percent adjustment will be factored into rates to offset the one-time FY 2012 recoupment adjustment.

The table below summarizes the adjustments for FY 2012 for documentation and coding for IPPS hospitals.

FY 2012 MS–DRG DOCUMENTATION AND CODING ADJUSTMENT

	Required prospective adjustment for FYs 2008–2009	Remaining required recoupment adjustment for FYs 2008–2009	Total remaining adjustment	Prospective adjustment for FY 2012	Recoupment adjustment to FY 2012 payments	Remaining prospective adjustment
Level of Adjustments	−3.9%	−2.9%	−6.8%	−2.0%	−2.9%	−1.9%

7. Background on the Application of the Documentation and Coding Adjustment to the Hospital-Specific Rates

Under section 1886(d)(5)(D)(i) of the Act, 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. Under section 1886(d)(5)(G) of the Act, MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate based on the greatest of the FY 1982, FY 1987, or FY 2002 costs per discharge. In the FY 2008 IPPS final rule with comment period (72 FR 47152 through 47188), we established a policy of applying the documentation and coding adjustment to the hospital-specific rates. In that final rule with comment period, we indicated that because SCHs and MDHs use the same DRG system as all other hospitals, we believe they should be equally subject to the budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. In establishing this policy, we relied on section 1886(d)(3)(A)(vi) of the Act, which provides us with the authority to adjust ''the standardized amount'' to eliminate the effect of changes in coding or classification that do not reflect real change in case-mix.

However, in the final rule that appeared in the **Federal Register** on November 27, 2007 (72 FR 66886), we

rescinded the application of the documentation and coding adjustment to the hospital-specific rates retroactive to October 1, 2007. In that final rule, we indicated that, while we still believe it would be appropriate to apply the documentation and coding adjustment to the hospital-specific rates, upon further review, we decided that the application of the documentation and coding adjustment to the hospital-specific rates is not consistent with the plain meaning of section 1886(d)(3)(A)(vi) of the Act, which only mentions adjusting ''the standardized amount'' under section 1886(d) of the Act and does not mention adjusting the hospital-specific rates.

In the FY 2009 IPPS proposed rule (73 FR 23540), we indicated that we continued to have concerns about this issue. Because hospitals paid based on the hospital-specific rate use the same MS–DRG system as other hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. In section 1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid based on the standardized amount should not receive additional payments based on the effect of documentation and coding changes that do not reflect real changes in case-mix. Similarly, we believe that hospitals paid based on the hospital-specific rates should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patient severity of illness. While we continue to believe that section 1886(d)(3)(A)(vi) of the Act does not provide explicit authority for application of the documentation and coding adjustment to the hospital-specific rates, we believe that we have the authority to apply the documentation and coding adjustment to the hospital-specific rates using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. The special exceptions and adjustment provision authorizes us to provide ''for such other exceptions and adjustments to [IPPS] payment amounts * * * as the Secretary deems appropriate.'' In the FY 2009 IPPS final rule (73 FR 48448 through 48449), we indicated that, for the FY 2010 rulemaking, we planned to examine our FY 2008 claims data for hospitals paid based on the hospital-specific rate. We further indicated that if we found evidence of significant increases in case-mix for patients treated in these hospitals that do not reflect real changes in case-mix, we would consider proposing application of the documentation and coding adjustments to the FY 2010 hospital-specific rates under our authority in section 1886(d)(5)(I)(i) of the Act.

In response to public comments received on the FY 2009 IPPS proposed rule, we stated in the FY 2009 IPPS final rule that we would consider whether such a proposal was warranted for FY 2010. To gather information to evaluate these considerations, we indicated that we planned to perform analyses on FY 2008 claims data to examine whether there has been a significant increase in case-mix for hospitals paid based on the hospital-specific rate. If we found that application of the documentation and coding adjustment to the hospital-specific rates for FY 2010 was warranted, we indicated that we would propose to make such an adjustment in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule.

8. Documentation and Coding Adjustment to the Hospital-Specific Rates for FY 2011 and Subsequent Fiscal Years

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule and final rule (74 FR 24098 through 24100 and 74 FR 43775 through 43776, respectively), we discussed our retrospective evaluation of the FY 2008 claims data for SCHs and MDHs using the same methodology described earlier for other IPPS hospitals. We found that, independently for both SCHs and MDHs, the change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 slightly exceeded the proposed 2.5 percent result discussed earlier for other IPPS hospitals, but did not significantly differ from that result. We refer readers to those rules for a more complete discussion.

Therefore, consistent with our statements in prior IPPS rules, we proposed to use our authority under section 1886(d)(5)(I)(i) of the Act to prospectively adjust the hospital-specific rates by the proposed −2.5 percent in FY 2010 to account for our estimated documentation and coding effect in FY 2008 that does not reflect real changes in case-mix. We proposed to leave this adjustment in place for subsequent fiscal years in order to ensure that changes in documentation and coding resulting from the adoption of the MS–DRGs do not lead to an increase in aggregate payments for SCHs and MDHs not reflective of an increase in real case-mix. The proposed −2.5 percent adjustment to the hospital-specific rates exceeded the −1.9 percent adjustment to the national standardized amount under section 7(b)(1)(A) of Public Law 110–90 because, unlike the national standardized rates, the FY 2008 hospital-specific rates were not previously reduced in order to account for anticipated changes in documentation and coding that do not reflect real changes in case-mix resulting from the adoption of the MS–DRGs.

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24100), we solicited public comment on this proposal. Consistent with our approach for IPPS hospitals discussed earlier, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we also delayed adoption of a documentation and coding adjustment to the hospital-specific rate until FY 2011. We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule for a more detailed discussion of our proposal, responses to comments, and finalized policy.

As we have noted previously, because SCHs and MDHs use the same MS–DRG system as all other IPPS hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. Therefore, we believe they should be equally subject to a prospective budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. We believe the documentation and coding estimates for all subsection (d) hospitals should be the same. While the findings for the documentation and coding effect for all IPPS hospitals are similar to the effect for SCHs and slightly different to the effect for MDHs, we continue to believe that this is the appropriate policy so as to neither advantage or disadvantage different types of providers. As we discuss in section II.D.4. of this preamble, our best estimate, based on the most recently available data, is that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of the documentation and coding changes on future payments to SCHs and MDHs. Unlike the case of standardized amounts paid to IPPS hospitals, prior to FY 2011, we had not made any previous adjustments to the hospital-specific rates paid to SCHs and MDHs to account for documentation and coding changes. Therefore, the entire −5.4 percent recoupment adjustment needed to be made, as opposed to a −3.9 percent remaining adjustment for IPPS hospitals.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50068 through 50071), we made an adjustment to the standardized

amount for IPPS hospitals of −2.9 percent under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. As we noted in the FY 2011 IPPS/LTCH PPS final rule, in determining the level and pace of adjustments to account for such documentation and coding changes, we believe that it is important to maintain, as much as possible, both consistency and equity among these classes of hospitals. Therefore, we finalized a prospective adjustment of −2.9 percent to the hospital-specific rates paid to SCHs and MDHs. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a more detailed discussion of our proposal, responses to comments, and finalized policy.

As discussed earlier in this section II.D., in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed a net −3.15 percent documentation and coding adjustment for IPPS hospitals in FY 2012 (−3.15 percent prospective adjustment plus a −2.9 percent recoupment adjustment in FY 2012, offset by the removal of the −2.9 percent recoupment adjustment for FY 2010). The proposed IPPS adjustment exceeded the remaining −2.5 percent documentation and coding adjustment for hospitals receiving a hospital-specific rate (that is, the entire −5.4 percent adjustment, minus the −2.9 percent adjustment finalized for FY 2011). As we indicated in the FY 2011 IPPS/LTCH PPS proposed rule and final rule, we are continuing, as much as possible, consistent with section 7(b)(1) of Public Law 110–90 and section 1886(d)(5)(I)(i) of the Act, to take such consistency and equity into account in developing future proposals for implementing documentation and coding adjustments. We believe that any adjustment to the hospital-specific rate due to documentation and coding effect should be as similar as possible to adjustments to the IPPS rate. Accordingly, we proposed a −2.5 percent payment adjustment to the hospital-specific rate. We believe that proposing the entire remaining prospective adjustment of −2.5 percent would allow CMS to maintain, to the extent possible, similarity and consistency in payment rates for different IPPS hospitals paid using the MS–DRG. As discussed below, we took a similar approach in finalizing an adjustment to the Puerto-Rico specific rate in FY 2011.

Comment: Numerous commenters requested that CMS rescind its proposed documentation and coding adjustment for SCHs and MDHs and questioned CMS' statutory authority to apply this adjustment to providers receiving a hospital-specific rate. The commenters argued that because section 1886(d)(3)(A)(vi) of the Act only authorizes application of a documentation and coding adjustment to the standardized amount, Congress' specific instruction as to the applicability of this type of adjustment makes it impermissible for CMS to apply the adjustment to the hospital-specific rates. Furthermore, commenters contend that, due to their critical role in isolated communities, any negative documentation and coding adjustment to SCHs and MDHs would endanger their ability to provide the type of care that Congress specifically sought to protect by establishing their special Medicare payment systems.

Response: We continue to disagree with the commenters that the Secretary's broad authority to make exceptions and adjustment to payment amounts under section 1886(d)(3)(A)(vi) of the Act cannot be applied in this instance. We have discussed the basis for applying such an adjustment in prior rules (in the FY 2009 proposed rule (73 FR 23540), the FY 2009 IPPS final rule (73 FR 48448), and the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24098)) and do not agree that the language in section 1886(d)(3)(A)(vi) of the Act limits our authority under section 1886(d)(5)(I)(i) of the Act to make such an adjustment. We recognize that SCHs and MDHs are entitled, through legislation, to receive the hospital-specific rate in order to compensate for their unique service requirements in the provider community. Similar to our approach with IPPS hospitals, we are implementing a phase-in of the documentation and coding adjustment over an appropriate period, beginning in FY 2011. We will continue to separately analyze SCH and MDH claims data to ensure than any future adjustment is appropriate for these provider types.

Comment: MedPAC responded to our request for comments regarding the level of adjustment for special categories of hospitals, such as hospitals paid under the hospital-specific payment rate, by pointing out hospitals have the same financial incentives for documentation and coding improvements and the same ability to benefit from the resulting change in case-mix, and by recommending that ''all IPPS hospitals should be treated the same.'' At the same time, MedPAC also stated that ''delaying prevention of overpayments * * * creates a problem because overpayments will continue to accumulate in 2010 and later years until the effect of documentation and coding improvement is fully offset in the payment rates.'' In setting forward its multi-year recommendation to CMS for complying with the requirements of section 7 of Public Law 110–90, MedPAC emphasized ''minimizing the accumulation of overpayments.''

Response: We appreciate MedPAC's comments and agree that it is appropriate to conclude that hospitals paid under the hospital-specific rate have experienced a 5.4-percent increase documentation and coding in FYs 2008 and 2009, insofar as these hospitals had the same financial incentives to improve documentation and coding in those years as other IPPS hospitals. We further agree with MedPAC that it is appropriate to focus on minimizing the accumulation of overpayments, and we interpret this to mean that MedPAC recommends that CMS move forward as quickly as possible with prospective adjustments at an appropriate level. We appreciate MedPAC's guidance that ''all hospitals be treated the same,'' and stress the importance of consistent treatment of various classes of similarly situated hospitals in our payment policy determinations.

We continue to believe that any adjustment to the hospital-specific rate due to documentation and coding effect should be as similar as possible to adjustments to the standardized amount. Accordingly, because we are finalizing a prospective adjustment to the standardized amount of −2.0 percent for FY 2012, we are also finalizing a prospective adjustment to the hospital-specific rate of −2.0 percent for FY 2012, instead of our proposed adjustment of −2.5 percent. Making this level of adjustment allows CMS to maintain, for FY 2012, consistency in payment rates for different IPPS hospitals paid using the MS–DRG. Because this −2.0 percent adjustment no longer reflects the entire remaining requirement adjustment amount of −2.5 percent, an additional −0.5 percent adjustment to the hospital-specific payment rates will be required in future rulemaking.

9. Application of the Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

a. Background

Puerto Rico hospitals are paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As noted previously, the documentation and coding adjustment we adopted in the FY 2008 IPPS final rule with comment period relied upon our authority under section 1886(d)(3)(A)(vi) of the Act, which provides the Secretary the authority to

adjust ''the standardized amounts computed under this paragraph'' to eliminate the effect of changes in coding or classification that do not reflect real changes in case-mix. Section 1886(d)(3)(A)(vi) of the Act applies to the national standardized amounts computed under section 1886(d)(3) of the Act, but does not apply to the Puerto Rico-specific standardized amount computed under section 1886(d)(9)(C) of the Act. In calculating the FY 2008 payment rates, we made an inadvertent error and applied the FY 2008 −0.6 percent documentation and coding adjustment to the Puerto Rico-specific standardized amount, relying on our authority under section 1886(d)(3)(A)(vi) of the Act. However, section 1886(d)(3)(A)(vi) of the Act authorizes application of a documentation and coding adjustment to the national standardized amount and does not apply to the Puerto Rico specific standardized amount. In the FY 2009 IPPS final rule (73 FR 48449), we corrected this inadvertent error by removing the −0.6 percent documentation and coding adjustment from the FY 2008 Puerto Rico-specific rates (that is, we made a positive 0.6 percent adjustment, increasing the Puerto Rico-specific rates).

While section 1886(d)(3)(A)(vi) of the Act is not applicable to the Puerto Rico-specific standardized amount, we believe that we have the authority to apply the documentation and coding adjustment to the Puerto Rico-specific standardized amount using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. Similar to SCHs and MDHs that are paid based on the hospital-specific rate, we believe that Puerto Rico hospitals that are paid based on the Puerto Rico-specific standardized amount should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patient severity of illness. Consistent with the approach described for SCHs and MDHs, in the FY 2009 IPPS final rule (73 FR 48449), we indicated that we planned to examine our FY 2008 claims data for hospitals in Puerto Rico. We indicated in the FY 2009 IPPS proposed rule (73 FR 23541) that if we found evidence of significant increases in case-mix for patients treated in these hospitals, we would consider proposing to apply documentation and coding adjustments to the FY 2010 Puerto Rico-specific standardized amount under our authority in section 1886(d)(5)(I)(i) of the Act.

b. Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

For the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, we performed a retrospective evaluation of the FY 2008 claims data for Puerto Rico hospitals using the same methodology described earlier for IPPS hospitals paid under the national standardized amounts under section 1886(d) of the Act. We found that, for Puerto Rico hospitals, the increase in payments for discharges occurring during FY 2008 due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 was approximately 1.1 percent. However, as we noted earlier for IPPS hospitals and hospitals receiving hospital-specific rates, if the estimated documentation and coding effect determined based on a full analysis of FY 2009 claims data was more or less than our then current estimates, it would change, possibly lessen, the anticipated cumulative adjustments that we had estimated we would have to make for the FY 2008 and FY 2009 combined adjustment. Therefore, we believed that it would be more prudent to delay implementation of the documentation and coding adjustment to allow for a more complete analysis of FY 2009 claims data for Puerto Rico hospitals.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43777), we indicated that, given these documentation and coding increases, consistent with our statements in prior IPPS rules, we would use our authority under section 1886(d)(5)(I)(i) of the Act to adjust the Puerto Rico-specific rate and solicited public comment on the proposed −1.1 percent prospective adjustment. However, in parallel to our decision to postpone adjustments to the Federal standardized amount, we also indicated that we were adopting a similar policy for the Puerto Rico-specific rate for FY 2010 and would consider the phase-in of this adjustment over an appropriate time period through future rulemaking. We noted that, as with the hospital-specific rates, the Puerto Rico-specific standardized amount had not previously been adjusted based on estimated changes in documentation and coding associated with the adoption of the MS–DRGs.

Consistent with our approach for IPPS hospitals for FY 2010, we indicated that we would address in the FY 2011 rulemaking cycle any change in FY 2009 case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009.

As we have noted above, similar to SCHs and MDHs, hospitals in Puerto Rico use the same MS–DRG system as all other hospitals and we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. Therefore, we believe they should be equally subject to the prospective budget neutrality adjustment that we intend to apply to prospective payment rates for IPPS hospitals, including SCHs and MDHs, in order to eliminate the full effect of the documentation and coding changes associated with implementation of the MS–DRG system.

As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), using the same methodology we applied to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals, our best estimate, based on the then most recently available data (FY 2009 claims paid through March 2010), was that, for documentation and coding that occurred over FY 2008 and FY 2009, a cumulative adjustment of −2.6 percent was required to eliminate the full effect of the documentation and coding changes on future payments from the Puerto Rico-specific rate. As we stated above, we believe it important to maintain both consistency and equity among all hospitals paid on the basis of the same MS–DRG system. At the same time, however, we recognize that the estimated cumulative impact on aggregate payment rates resulting from implementation of the MS–DRG system was smaller for Puerto Rico hospitals as compared to IPPS hospitals and SCHs and MDHs. Therefore, in the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23876), we proposed an adjustment to eliminate the full effect of the documentation and coding changes on the portion of future payments to Puerto Rico hospitals based on the Puerto Rico-specific rate. We stated that we believed that a full prospective adjustment was the most appropriate means to take into full account the effect of documentation and coding changes on payments, while maintaining equity as much as possible between hospitals paid on the basis of different prospective rates. We noted that our updated data analysis in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50072 through 50073) showed that this adjustment would be −2.6 percent. The previous estimate in the proposed rule was a −2.4 percent adjustment.

One reason we proposed the full prospective adjustment for the Puerto Rico-specific rate in FY 2011 was to

maintain equity as much as possible in the documentation and coding adjustments applied to various hospital rates in FY 2011. Because our proposal was to make an adjustment that represents the full adjustment that is warranted for the Puerto Rico-specific rate, we indicated that we did not anticipate proposing any additional adjustments to this rate for documentation and coding effects.

Therefore, because the Puerto Rico-specific rate received a full prospective adjustment of −2.6 percent in FY 2011, we proposed no further adjustment in the proposed rule for FY 2012.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

In the FY 2009 IPPS final rule (73 FR 48450), we continued to implement significant revisions to Medicare's inpatient hospital rates by completing our 3-year transition from charge-based relative weights to cost-based relative weights. Beginning in FY 2007, we implemented relative weights based on cost report data instead of based on charge information. We had initially proposed to develop cost-based relative weights using the hospital-specific relative value cost center (HSRVcc) methodology as recommended by MedPAC. However, after considering concerns expressed in the public comments we received on the proposal, we modified MedPAC's methodology to exclude the hospital-specific relative weight feature. Instead, we developed national CCRs based on distinct hospital departments and engaged a contractor to evaluate the HSRVcc methodology for future consideration. To mitigate payment instability due to the adoption of cost-based relative weights, we decided to transition cost-based weights over 3 years by blending them with charge-based weights beginning in FY 2007. (We refer readers to the FY 2007 IPPS final rule for details on the HSRVcc methodology and the 3-year transition blend from charge-based relative weights to cost-based relative weights (71 FR 47882 through 47898).)

In FY 2008, we adopted severity-based MS–DRGs, which increased the number of DRGs from 538 to 745. Many commenters raised concerns as to how the transition from charge-based weights to cost-based weights would continue with the introduction of new MS–DRGs. We decided to implement a 2-year transition for the MS–DRGs to coincide with the remainder of the transition to cost-based relative weights. In FY 2008, 50 percent of the relative weight for each DRG was based on the CMS DRG relative weight and 50 percent was based on the MS–DRG relative weight.

In FY 2009, the third and final year of the transition from charge-based weights to cost-based weights, we calculated the MS–DRG relative weights based on 100 percent of hospital costs. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a more 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.

2. Summary of the RTI Study of Charge Compression and CCR Refinement

As we transitioned to 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 RTI to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the CCRs across services within cost centers. RTI issued an interim draft report in January 2007 with its findings on charge compression (which was posted on the CMS Web site at: *http://www.cms.hhs.gov/reports/downloads/Dalton.pdf*). In that report, RTI found that a number of factors contribute to charge compression and affect the accuracy of the relative weights. RTI's findings demonstrated that charge compression exists in several CCRs, most notably in the Medical Supplies and Equipment CCR.

In its interim draft report, RTI offered a number of recommendations to mitigate the effects of charge compression, including estimating regression-based CCRs to disaggregate the Medical Supplies Charged to Patients, Drugs Charged to Patients, and Radiology cost centers, and adding new cost centers to the Medicare cost report, such as adding a ''Devices, Implants and Prosthetics'' line under ''Medical Supplies Charged to Patients'' and a ''CT Scanning and MRI'' subscripted line under ''Radiology-Diagnostics''. Despite receiving public comments in support of the regression-based CCRs as a means to immediately resolve the problem of charge compression, particularly within the Medical Supplies and Equipment CCR, we did not adopt RTI's recommendation to create additional regression-based CCRs. (For more details on RTI's findings and recommendations, we refer readers to the FY 2009 IPPS final rule (73 FR 48452).) RTI subsequently expanded its analysis of charge compression beyond inpatient services to include a reassessment of the regression-based CCR models using both outpatient and inpatient charge data. This interim report was made available in April 2008 during the public comment period on the FY 2009 IPPS proposed rule and can be found on RTI's Web site at: *http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200804.pdf*. The IPPS-specific chapters, which were separately displayed in the April 2008 interim report, as well as the more recent OPPS chapters, were included in the July 3, 2008 RTI final report entitled, ''Refining Cost-to-Charge Ratios for Calculating APC [Ambulatory Payment Classification] and DRG Relative Payment Weights,'' that became available at the time of the development of the FY 2009 IPPS final rule. The RTI final report can be found on RTI's Web site at: *http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf*.

RTI's final report found that, under the IPPS and the OPPS, accounting improvements to the cost reporting data reduce some of the sources of aggregation bias without having to use regression-based adjustments. In general, with respect to the regression-based adjustments, RTI confirmed the findings of its March 2007 report that regression models are a valid approach for diagnosing potential aggregation bias within selected services for the IPPS and found that regression models are equally valid for setting payments under the OPPS.

RTI also noted that cost-based weights are only one component of a final prospective payment rate. There are other rate adjustments (wage index, IME, and DSH) to payments derived from the revised cost-based weights, and the cumulative effect of these components may not improve the ability of final payment to reflect resource cost. RTI endorsed short-term regression-based adjustments, but also concluded that more refined and accurate accounting data are the preferred long-term solution to mitigate charge compression and related bias in hospital cost-based weights. For a more detailed

summary of RTI's findings, recommendations, and public comments we received on the report, we refer readers to the FY 2009 IPPS final rule (73 FR 48452 through 48453).

3. Summary of Policy Changes Made in FY 2011

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, and because of RAND's finding that regression-based adjustments to the CCRs do not significantly improve payment accuracy, 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 refer readers to the Web site: *http://www.rand.org/pubs/working_papers/WR560/,* and the FY 2009 IPPS/LTCH PPS final rule for details on the RAND report (73 FR 48453 through 48457).) 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 what should be reported in these respective cost centers, we adopted the commenters' recommendation that hospitals should use revenue codes established by AHA's National Uniform Billing Committee to determine what should be reported in the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers. Accordingly, a new subscripted line 55.30 for ''Implantable Devices Charged to Patients'' was created in July 2009 as part of CMS' Transmittal 20 update to the existing cost report Form CMS–2552–96. This new subscripted cost center has been available for use for cost reporting periods beginning on or after May 1, 2009.

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, MRI, 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. As we discussed in the FY 2009 IPPS/LTCH PPS and CY 2009 OPPS/ASC proposed and final rules, RTI found that the costs and charges of CT scans, 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 OPPS relative weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRI, 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 cost from charges on claims data. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a more detailed discussion on the reasons for the creation of standard cost centers for CT scans, MRI, and cardiac catheterization.) The new standard cost centers for MRI, CT scans, 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. CMS issued the new hospital cost report Form CMS–2552–10 on December 30, 2010. The new cost report form can be accessed at the CMS Web site at: *https://www.cms.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS021935&intNumPerPage=10.* Once at this Web site, users should double click on ''Chapter 40.''

4. Discussion for FY 2012

In the FY 2009 IPPS/LTCH PPS 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. Specifically, we stated, ''Because there is approximately a 3-year lag between the availability of cost report data for IPPS and OPPS rate-setting purposes in a given fiscal year, we may be able to derive two distinct CCRs, one for medical supplies and one for devices, for use in calculating the FY 2012 or FY 2013 IPPS relative weights and the CY 2012 or CY 2013 OPPS relative weights'' (73 FR 48468). However, as noted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43782), due to delays in the issuance of the revised cost report CMS 2552–10, a new CCR for Implantable Devices Charged to Patients may not be available until FY 2013. Similarly, when we finalized the decision in the FY 2011 IPPS/LTCH PPS final rule to add new cost centers for MRI, CT scans, 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). That is, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50077), we stated that the data from the standard cost centers for MRI, CT scans, and cardiac catheterization respectively, would not even be available for possible use in calculating the relative weights earlier than 3 years after Form CMS–2552–10 becomes available. We further stated that, at that time, we would analyze the data and determine if it is appropriate to use those data to create distinct CCRs from these cost centers for use in the relative weights for the respective payment systems. We also reassured public commenters that there was no need for immediate concern regarding possible negative payment impacts on MRI and CT scans under the IPPS and the OPPS because the cost report data that would be used for the calculation of the relative weights were at least 3 years from being available. We stated that we will first thoroughly analyze and run impacts on the data and provide the public with the opportunity to comment before distinct CCRs for MRI and CT scans would be finalized for use in the calculation of the relative weights. We also urged all hospitals to properly report their costs and charges for MRI, CT scans, and all other services so that, in several years' time, we will have reliable data from all hospitals on which to base a decision as to whether to incorporate additional CCRs into the relative weight calculation (75 FR 50077).

Accordingly, in preparation for the FY 2012 IPPS/LTCH PPS proposed rule, we assessed the availability of data in the ''Implantable Devices Charged to Patients'' cost center. In order to develop a robust analysis regarding the use of cost data from the ''Implantable Devices Charged to Patients'' cost center, it was necessary to have a critical mass of cost reports filed with data in this cost center. The cost center for ''Implantable Devices Charged to Patients'' is effective for cost reporting periods beginning on or after May 1, 2009. While developing the FY 2012 IPPS/LTCH PPS proposed rule, we checked the availability of FY 2009 cost reports in the December 31, 2010 quarter ending update of HCRIS, which was the latest upload of FY 2009 cost report data that we could use for the proposed rule. We determined that there were only 437 hospitals (out of approximately 3,500 IPPS hospitals)

that completed the ''Implantable Devices Charged to Patients'' cost center. We did not believe that this 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, and the ''MRI, CT Scans, and Cardiac Catheterization'' cost centers, for the FY 2013 IPPS rulemaking cycle and, if appropriate, we would propose to create a distinct CCR at that time.

Comment: Commenters requested that CMS reconsider its position to not use the data from the implantable device cost center to calculate the MS–DRG relative weights for FY 2012. The commenter noted that during the development of the proposed rule, CMS found that only 437 hospitals out of approximately 3,500 IPPS hospitals reported data in the ''Implantable Devices Charged to Patients'' cost center of the Medicare hospital cost report based on the December 2010 update of FY 2009 HCRIS. One commenter found, while reviewing the March 2011 update of FY 2009 HCRIS, that there are approximately 800 hospitals that are reporting cost information in the implantable medical device cost center.

Another commenter stated that, based on the December 2010 update of FY 2009 HCRIS, 804 hospitals reported data on either line 55 (Medical Supplies Charged to Patients) or line 55.30 (Implantable Devices Charged to Patients), and in the March 2011 update of FY 2009 HCRIS, approximately 1,600 hospitals were reporting data on either of those lines. As such, the commenters believed there is now a sufficient amount of data to use the implantable device CCR to calculate the relative weights and improve accuracy of the payment rates. Commenters also noted that if we do not use the implantable device cost center to calculate the FY 2012 relative weights, there will be enough data to develop an implantable device CCR for FY 2013.

One commenter suggested that CMS adopt regression-based CCRs to calculate the FY 2012 MS–DRG relative weights because CMS does not yet have sufficient cost report data to develop the implantable device CCR. This would allow CMS to address charge compression immediately and improve payment accuracy for medical devices and implantables.

Response: In the FY 2012 IPPS/LTCH PPS proposed rule, we indicated that we did not have sufficient cost report data to develop the kind of robust analysis that we assured the public we would provide prior to implementing a new CCR for implantable medical devices. Therefore, we stated that we will reassess the availability of data for FY 2013. We have reviewed the availability of FY 2009 cost reports in the March 31, 2011 quarter ending update of HCRIS, which is the latest upload of FY 2009 cost report data that we currently have available. We have determined that, for cost reporting periods beginning on or after May 1, 2009, the effective date of line 55.30 (Implantable Devices Charged to Patients), there are 961 hospitals (out of approximately 3,500 IPPS hospitals) that have completed the ''Implantable Devices Charged to Patients'' cost center. This represents an increase of 524 compared to the 437 entries that we found when developing the FY 2012 proposed rule. Regardless of the number of hospitals currently reporting data in the ''Implantable Devices Charged to Patients'' cost center, the data that were available at the time we were developing our proposed policies for FY 2012 were insufficient, and we believe it would be inappropriate to finalize a specific CCR for implantable devices charged to patients for FY 2012 without an opportunity for the public to review and comment on our analysis. Rather, we believe that it is appropriate to wait until FY 2013, when we hope to be able to provide a proper impact analysis of the addition of a CCR for implantable devices charged to patients in the relative weights calculation. Accordingly, we are not implementing a regression-based CCR for implantable devices at this time. Therefore, we are not implementing any new CCRs for use in the relative weights calculation for FY 2012.

Comment: Commenters urged CMS to increase education efforts to encourage faster hospital adoption of the use of the implantable medical device cost center. Commenters noted that, at the time of the development of the FY 2012 IPPS/LTCH PPS proposed rule, only 437 hospitals had completed the implantable device cost center, and this demonstrated that CMS needs to undertake additional outreach to hospitals to ensure that they appropriately complete the Medicare hospital cost report.

Response: We agree that it is important that hospitals understand how to accurately report data in the ''Implantable Devices Charged to Patients'' cost center, and we have worked to add more clarity to the cost report instructions. However, we do believe that the December 31, 2010 update of HCRIS reflected relatively few entries for this cost center because the corresponding cost center line was only available for use for cost reporting periods beginning on or after May 1, 2009. This effective date was somewhat awkward in terms of timing and would not have applied to a large number of hospitals whose data would not be evident to CMS until the March 31, 2011 update to HCRIS.

Comment: Commenters suggested that CMS monitor the accuracy of the data reported in the implantable device cost center on the Medicare hospital cost report. Commenters urged CMS to impress the importance upon the Medicare Administrative Contractors (MACs) of establishing a mechanism to audit the implantable device cost center to ensure that the costs and charges are appropriately reported. One commenter suggested that CMS require MACs to require hospitals to explain why they had not reported in the implantable device cost center. In addition, the commenters suggested that CMS reissue instructions, similar to Transmittal 321, dated February 28, 2009, to the MACs with recommendations that MACs develop an audit program for line 55 (Medical Supplies Charged to Patients) and line 55.30 (Implantable Devices Charged to Patients). Commenters noted that potential audit mechanisms include identifying the presence of revenue codes 274, 275, 276 and 624 reported on the PS&R used to settle the cost report, and comparing the CCR based on line 55.30 to the CCR based on line 55. In addition, one commenter suggested that the cost reporting software be modified to create a level 1 error in the case where no data is reported on line 55.30 (Implantable Devices Charged to Patients) to compel hospitals to report that information.

Response: We agree with the commenters that the cost reporting lines, whether they are for Implantable Devices Charged to Patients, MRI, CT scans, cardiac catheterization, or any others, should be subject to greater audit scrutiny from the Medicare contractors. The new Medicare cost report form CMS–2552–10, on line 121 of Worksheet S–2, Part I, asks ''Did this facility incur and report costs for implantable devices charged to a patient? Enter in column 1 ''Y'' for yes or ''N'' for no.'' All hospital types, including non-IPPS hospitals, CAHs, and Maryland inpatient short-term acute hospitals, are required to properly report their costs and charges, and if the answer to this question is Y for any type of hospital, then line 72, column 26, of

Worksheet B, Part I must be greater than 0, with an accurate amount that reflects the hospital's costs for implantable devices charged to patients. In addition, we note that a Level 1 edit on the CMS–2552–10 form already exists that ensures that line 72, column 26, of Worksheet B, Part I (Implantable Devices Charged to Patients on Worksheet A of the CMS–2552–10 form) is greater than 0 if Worksheet S–2, Part I, line 121 is ''Y''. The edit is also set up for the reverse scenario; that is, if there is an amount on Worksheet B, Part I, line 72, column 26, then the response on Worksheet S–2, Part I, line 121 must be ''Y.''

Comment: Some commenters supported not making major refinements to the calculation of MS–DRG relative weights. Commenters valued the consistency, transparency, and predictability of the calculation of the MS–DRG relative weights.

Response: We appreciate the commenters' support for our proposal of not making major refinements to the MS–DRG relative weights in the absence of sufficient data from which to create new CCRs. We also value consistency, transparency, and predictability in the calculation of the MS–DRG relative weights.

Comment: One commenter supported our decision to create standard cost centers for CT, MRI, and cardiac catheterization for hospitals to report their costs and charges on the Medicare hospital cost report. In addition, the commenter supported urgently adopting the use of the CT, MRI, and cardiac catheterization cost centers in calculating the MS–DRG relative weights.

Response: We appreciate the commenter's support. As we stated in the proposed rule, we will reassess the availability of data for the ''Implantable Devices Charged to Patients'' cost center, and the ''MRI, CT Scans, and Cardiac Catheterization'' cost centers, for the FY 2013 IPPS rulemaking cycle, and, if appropriate, we will propose to create distinct CCRs for these cost centers at that time.

Comment: One commenter noted that allogeneic stem cell acquisition charges are reported using revenue code 0819 for ''Other Organ Acquisition.'' However, the commenter added, this revenue code is not part of the 15 national cost center CCRs used in the calculation of the MS–DRG relative weights. In addition, the commenter stated, the Medicare hospital cost report does not specifically identify a cost center for bone marrow acquisition costs. The commenter requested direction on capturing these acquisition costs and how those costs and charges are accounted for in the MS–DRG relative weight calculation.

Response: We appreciate this comment, but note that it is not within the scope of the issues discussed in the FY 2012 IPPS/LTCH PPS proposed rule regarding the calculation of the MS–DRG relative weights. However, we also note that allogeneic bone marrow transplant charges are included in the 15 CCRs, specifically as part of the Blood and Blood Products CCR and that CCR's associated cost centers on the cost report.

Comment: One commenter stated that CMS should specifically exclude sleeve gastrectomy charges derived from the Medicare claims data and sleeve gastrectomy costs from the Medicare hospital cost report data from the MS–DRG weight recalibrations. The commenter noted that CMS excludes Medicare claims for services that are non-covered for Medicare beneficiaries from the MS–DRG relative weight calculation and, therefore, sleeve gastrectomy charges should be excluded. In addition, the commenter recommended that CMS remind providers that Medicare cost reports should exclude charges and costs associated with the sleeve gastrectomy procedure, as it is a noncovered service.

Response: We appreciate this comment, but note that it is not within the scope of the issues discussed in the FY 2012 IPPS/LTCH PPS proposed rule regarding the calculation of the MS–DRG relative weights. We will take this issue into consideration for future rulemaking.

Comment: One commenter suggested that CMS evaluate the MedPAR claims database to ensure that it is not using Medicare managed care claims data to calculate the MS–DRG relative weights, as CMS has proposed to only use fee-for-service claims to calculate the MS–DRG relative weights.

Response: We appreciate this comment, but note that it is not within the scope of the issues discussed in the FY 2012 IPPS/LTCH PPS proposed rule regarding the calculation of the MS–DRG relative weights. However, we note that it is already our policy to exclude managed care claims from the MS–DRG relative weights calculation.

After consideration of the public comments received, we are not implementing any new CCRs for use in the relative weights calculation for FY 2012.

F. Preventable Hospital-Acquired Conditions (HACs), Including Infections

1. Background

a. Statutory Authority

Section 1886(d)(4)(D) of the Act 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. 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. Under the HAC payment policy, all CCs/MCCs on the claim must be HACs in order to generate a lower MS–DRG payment. In addition, Medicare continues to assign a discharge to a higher paying MS–DRG if a selected condition is POA.

The POA indicator reporting requirement and the HAC payment provision apply to IPPS hospitals only. Non-IPPS hospitals, including CAHs, LTCHs, IRFs, IPFs, cancer hospitals, children's hospitals, hospitals in Maryland operating under waivers, rural health clinics, federally qualified health centers, RNHCIs, and Department of Veterans Affairs/Department of Defense hospitals, are exempt from POA reporting and the HAC payment provision. Throughout this section, the

term ''hospital'' refers to an IPPS hospital.

The HAC provision found in section 1886(d)(4)(D) of the Act is part of an array of Medicare tools that we are using to promote increased quality and efficiency of care. Those tools include measuring performance, using payment incentives, publicly reporting performance results, applying national and local coverage policy decisions, enforcing conditions of participation, and providing direct support for providers through Quality Improvement Organization (QIO) activities. The application of these tools, such as this HAC provision, is transforming Medicare from a passive payer to an active purchaser of higher value health care services. We are applying these strategies for inpatient hospital care and across the continuum of care for Medicare beneficiaries.

This effort is highly compatible with the underlying purposes as well as existing structural features of Medicare's IPPS. 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 259 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. However, since we implemented the HAC provisions, if a secondary diagnosis acquired during a hospital stay is a HAC and no other CCs or MCCs are present, the hospital receives a payment under the MS–DRGs as if the HACs were not present. (We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a discussion of DRG reforms (72 FR 47141).)

b. 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, we direct readers to the following publications: 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); and the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23880) and final rule (75 FR 50080). A complete list of the 10 current categories of HACs is included in section II.F.2. of this preamble.

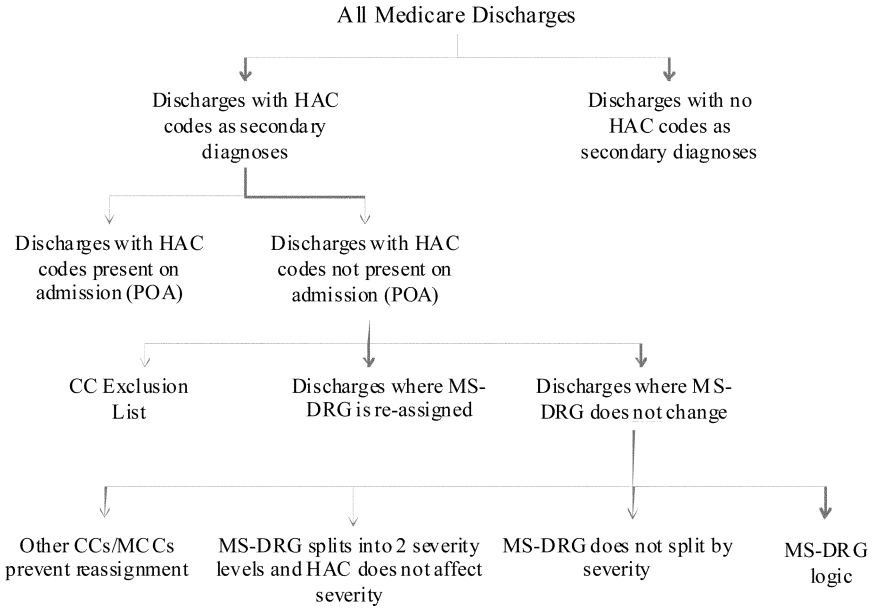
In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50080 through 50101), we did not add any categories of additional HACs or make any changes to policies already established under the authority of section 1886(d)(4)(D) of the Act.

c. Collaborative Process

In establishing the HAC payment policy under section 1886(d)(4)(D) of the Act, our experts have worked closely with public health and infectious disease professionals from across the Department of Health and Human Services, including CDC, the Agency for Healthcare Research and Quality (AHRQ), and the Office of Public Health and Science (OPHS), to identify the candidate preventable HACs, review comments, and select HACs. CMS and CDC also have collaborated on the process for hospitals to submit a POA indicator for each diagnosis listed on IPPS hospital Medicare claims and on the payment implications of the various POA reporting options. In addition, as discussed below, we have used rulemaking and Listening Sessions to obtain public input.

d. Application of HAC Payment Policy to MS–DRG Classifications

As described above, in certain cases, application of the HAC payment policy provisions can result in MS–DRG reassignment to a lower paying MS–DRG. The following diagram portrays the logic of the HAC payment policy provision as adopted in the FY 2008 IPPS final rule with comment period (72 FR 47200) and in the FY 2009 IPPS final rule (73 FR 48471):



e. Public Input Regarding Selected and Potential Candidate HACs

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50080 through 50101), we did not add or remove categories of HACs, nor did we make any changes to previously established policies. However, we continue to encourage public dialogue about refinement of the HAC list.

Given the timeliness of the HAC discussion, particularly when considered within the context of recent legislative health care reform initiatives, we remain eager to engage in an ongoing public dialogue about the various aspects of this policy. We plan to continue to include updates and findings from the Research Triangle Institute, International (RTI) evaluation on CMS' Hospital-Acquired Conditions and Present on Admission Indicator Web site available at: *http://www.cms.hhs.gov/HospitalAcqCond/.*

f. 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 the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23381) (and as noted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50081)), we listed the instructions and change requests that were issued to IPPS hospitals and also to non-IPPS hospitals regarding the submission of POA indicator data for all diagnosis codes on Medicare claims and the processing of non-PPS claims We also indicated that specific instructions on how to select the correct POA indicator for each diagnosis code were included in the *ICD–9–CM Official Guidelines for Coding and Reporting,* available on the CDC Web site at: *http://www.cdc.gov/nchs/data/icd9/icdguide10.pdf.* We reiterate that additional information regarding POA indicator reporting and application of the POA reporting options is available on the CMS Web site at: *http://www.cms.gov/HospitalAcqCond/.*

In preparation for the transition to the ICD–10–CM/PCS code set effective October 1, 2013, further information regarding the use of the POA indictor with the ICD–10–CM/PCS classification as it pertains to the HAC policy will be discussed in future rulemaking. In the meantime, we encourage readers to review the educational materials and draft code sets currently available for ICD–10–CM/PCS at the CMS Web site at: *http://www.cms.gov/ICD10/.* In addition, the draft ICD–10–CM/PCS coding guidelines can be viewed at the CDC Web site at: *http://www.cdc.gov/nchs/data/icd9/10cmguidelines2011.*

Historically, we have not provided coding advice. Rather, we collaborate with the American Hospital Association (AHA) through the *Coding Clinic for ICD–9–CM.* We will continue to collaborate with the AHA to promote the *Coding Clinic for ICD–9–CM* as the source for coding advice about the POA indicator.

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:*

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.*

In the FY 2009 IPPS final rule (73 FR 48486 through 48487), we adopted final payment policies to: (1) pay the CC/MCC MS–DRGs for those HACs coded with ''Y'' and ''W'' indicators; and (2) not pay the CC/MCC MS–DRGs for those

HACs coded with ''N'' and ''U'' indicators.

Beginning on or after January 1, 2011, hospitals are 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. However, for claims that continue to be submitted using the 4010 electronic transmittal standards format, the POA indicator of ''1'' is still necessary because of reporting restrictions from the use of the 4010 electronic transmittal standards format.

Hospitals that began reporting with the 5010 format on and after January 1, 2011, can no longer report a POA indicator of ''1'' for POA exempt codes. The POA field should instead be left blank for codes 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. These instructions, entitled ''5010 Implementation-Changes to Present on Admission (POA) Indicator '1' and the K3 Segment,'' can be located at the following link on the CMS Web site: *http://www.cms.gov/manuals/downloads/Pub100_20.pdf.*

We are continuing our efforts to clarify instructions regarding use of the POA indicator. As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50088), we received public comments in response to the FY 2011 IPPS/LTCH PPS proposed rule that expressed concern about the accuracy of reporting of POA indicators for HACs related to intracranial injury with loss of consciousness. The codes for loss of consciousness are listed in the Falls and Trauma HAC category, within the ''Intracranial Injury'' subcategory. Because loss of consciousness is a component of intracranial injuries rather than a separate condition, we agreed that the POA guidelines that instructed coders to assign an ''N'' indicator if any part of the combination code was not present on admission did not apply to the loss of consciousness codes. As a member of the Editorial Advisory Board for the *Coding Clinic for ICD–9–CM,* we worked with the American Hospital Association (AHA), American Health Information Management Association (AHIMA), and CDC to provide additional clarification on how these conditions should be reported. Additional guidance on how these cases should be reported can be found in AHA's *Coding Clinic for ICD–9–CM,* 2nd Quarter 2010, ''Frequently Asked POA Questions'' section. That publication clarified the POA reporting for patients in whom a single code captures the fact that the patient was admitted as a result of a head injury and then subsequently lost consciousness after the admission. For these cases, we clarified that the POA indicator assigned should be ''Y,'' indicating that the head injury and resulting loss of consciousness occurred prior to (and was present on) admission.

We expect that this clarification will lead to greater consistency and accuracy in POA indicator reporting for these conditions. We look forward to continuing our efforts as part of the AHA's Editorial Advisory Board for *Coding Clinic for ICD–9–CM* to provide guidance on accuracy of coding and the reporting of POA indicators. Hospitals look to this publication to provide detailed guidance on ICD–9–CM coding and POA reporting. We encourage hospitals to send any other questions about ICD–9–CM codes or POA indicator selection to the AHA so that the Editorial Advisory Board can continue its role of providing instruction on the accurate selection and reporting of both ICD–9–CM codes and POA indicators.

2. Additions and Revisions to the HAC Policy for FY 2012

a. Contrast-Induced Acute Kidney Injury

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25813 and 25814), we discussed our analysis for a proposed new condition as a possible candidate for selection for FY 2012 under section 1886(d)(4)(D) of the Act. As described in more detail in section II.F.1.a. of this preamble, each HAC must be: (1) High cost, high volume, or both; (2) 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 (3) could reasonably have been prevented through the application of evidence-based guidelines. We also discussed other considerations relating to the selection of a HAC, including any administrative or operational issues associated with a proposed condition. For example, the condition may only be able to be identified by multiple codes, thereby requiring the development of special GROUPER logic to also exclude similar or related ICD–9–CM codes from being classified as a CC or an MCC. Similarly, a condition acquired during a hospital stay may arise from another condition that the patient had prior to admission, making it difficult to determine whether the condition was reasonably preventable. We invited public comment on clinical, coding, and prevention issues on our proposal to add contrast-induced acute kidney injury as a condition subject to the HAC payment provision for FY 2012 (for discharges occurring on or after October 1, 2011).

Contrast-induced acute kidney injury is a significant complication of the use of iodinated contrast media and accounts for a large number of cases of hospital-acquired acute kidney injury cases. A published study has shown that renal failure associated with contrast administration is correlated with up to 11 percent of cases of renal failure that occur in hospitals (Nash, K., Hafeez, A., *et al:* ''Hospital-Acquired Renal Insufficiency,'' *American Journal on Kidney Disease,* 2002, Vol. 39, No. 5, pp. 930–936). Patients who experience acute kidney injury have an increased risk of inhospital mortality even after adjustments for disease comorbidities (McCullough, J.: ''Contrast-Induced Acute Kidney Injury,'' *Journal of the American College of Cardiology,* 2008, Vol. 51, No. 15, pp. 1419–1428). Data suggest that the risk for mortality extends beyond the period of hospitalization, resulting in 1-year and 5-year mortality rates significantly higher than those patients who have not developed acute kidney injury. In addition, contrast-induced acute kidney injury is associated with an increased incidence of myocardial infarction, bleeding requiring transfusion, and prolonged hospital stays (McCullough, J.: *American Journal of Medicine,* 1997, Vol. 103, pp. 368–375). We note that ''acute kidney injury'' is a new terminology endorsed by the National Kidney Foundation to replace ''acute renal failure.''

There is not a unique code that identifies kidney injury. However, kidney injury can be identified as a subset of discharges with ICD–9–CM diagnosis code 584.9 (Acute kidney failure, unspecified). As we discussed in the FY 2012 IPPS/LTCH PPS proposed rule, our clinical advisors believe that diagnosis code 584.9, in combination with the associated procedure codes listed below, can accurately identify contrast-induced acute kidney injury:

- 88.40 (Arteriography using contrast material, unspecified site)
- 88.41 (Arteriography of cerebral arteries)
- 88.42 (Aortography)
- 88.43 (Arteriography of pulmonary arteries)
- 88.44 (Arteriography of other intrathoracic vessels)
- 88.45 (Arteriography of renal arteries)
- 88.46 (Arteriography of placenta)
- 88.47 (Arteriography of other intra-abdominal arteries)

- 88.48 (Arteriography of femoral and other lower extremity arteries)
- 88.49 (Arteriography of other specified sites)
- 88.50 (Angiocardiography, not otherwise specified)
- 88.51 (Angiocardiography of venae cavae)
- 88.52 (Angiocardiography of right heart structures)
- 88.53 (Angiocardiography of left heart structures)
- 88.54 (Combined right and left heart angiocardiography)
- 88.55 (Coronary arteriography using a single catheter)
- 88.56 (Coronary arteriography using two catheters)
- 88.57 (Other and unspecified coronary arteriography)
- 88.58 (Negative-contrast cardiac roentgenography)
- 88.59 (Intra-operative coronary fluorescence vascular angiography)
- 88.60 (Phlebography using contrast material, unspecified site)
- 88.61 (Phlebography of veins of head and neck using contrast material)
- 88.62 (Phlebography of pulmonary veins using contrast materal)
- 88.63 (Phlebography of other intrathoracic veins using contrast material)
- 88.64 (Phlebography of the portal venous system using contrast material)
- 88.65 (Phlebography of other intra-abdominal veins using contrast material)
- 88.66 (Phlebography of femoral and other lower extremity veins using contrast material)
- 88.67 (Phlebography of other specified sites using contrast material)
- 87.71 (C.A.T. of kidney)
- 87.72 (Other nephrotomogram)
- 87.73 (Intravenous pyelogram)
- 87.74 (Retrograde pyelogram)
- 87.75 (Percutaneous pyelogram)

We proposed to identify contrast-induced acute kidney injury with diagnosis code 584.9 in combination with one or more of the above associated procedure codes.

We also considered identifying contrast-induced acute kidney injury through the use of external injury codes, or E-codes. Code E947.8 (Other drugs and medicinal substances) has an inclusion term ''Contrast media used for diagnostic x-ray procedures'' to identify the use of contrast. However, as we noted in the proposed rule, we do not currently require the reporting of E-codes for the HAC payment provisions under the IPPS. Therefore, we were unable to rely on the identification of contrast-induced acute kidney injury through E-codes on Medicare IPPS HACs claims.

Section 1886(d)(4)(D) of the Act requires that a HAC be a condition that is ''high cost, high volume, or both.'' In FY 2009, there were 38,324 inpatient discharges coded with acute renal failure as specified by ICD–9–CM diagnosis code 584.9 reported as not present on admission (POA status = N) when reported with one of the above procedure codes submitted through Medicare claims. The cases had an average charge of $29,122 for the entire hospital stay. Studies suggest the additional average cost per day for a patient who has acquired contrast-induced acute kidney injury is $2,654. Other data report patients stays increases by 3.75 days once they have acquired the diagnosis (Subramanian, S.: ''Economic Burden of Contrast-Induced Nephropathy: Implications for Prevention Strategies,'' *Journal of Medical Economics,* 2007, Vol. 10, pp. 119–134).

There are widely recognized guidelines for the prevention of acute kidney injury that address the prevention of contrast-induced acute kidney injury, and we believe the condition is reasonably preventable. One of these guidelines can be found at: *http://www.renal.org/Clinical/GuidelinesSection/AcuteKidneyInjury.aspx.*

The condition of contrast-induced acute kidney injury as specified in our proposal is a CC under the MS–DRGs.

We indicated in the proposed rule that we had not identified any additional administrative or operational difficulties with proposing this condition as a HAC. We invited public comment on whether contrast-induced acute kidney injury meets the requirements set forth under section 1886(d)(4)(D) of the Act, as well as other coding and prevention issues associated with our proposal to add this injury as a condition subject to the HAC payment provision for FY 2012 (for discharges occurring on or after October 1, 2011). We also indicated that we were particularly interested in receiving comments on the degree to which contrast-induced acute kidney injury is reasonably preventable through the application of evidence-based guidelines.

Comment: One commenter supported CMS' proposal to add contrast-induced acute kidney injury as a HAC under section 1886(d)(4)(D) of the Act. The commenter applauded the inclusion of contrast-induced acute kidney injury to the HAC policy for FY 2012, and encouraged CMS to continue to expand and refine the HACs and categories.

Response: We appreciate the commenter's support.

Comment: Many commenters discussed their concerns regarding the specificity and sensitivity of the ICD–9–CM codes proposed to identify the proposed new contrast-induced acute kidney injury HAC. The commenters believed that these codes would not solely capture contrast-induced acute kidney injury and would capture other conditions as well. The commenters expressed concern about the specificity of the current ICD–9–CM code 584.9 in reliably identifying cases of acute kidney injury that occurred due to a specific diagnosis instead of acute kidney injury that is believed to occur secondary to being correlated with exposure to contrast. The commenter stated that, for example, a patient admitted to a hospital could experience drug-induced kidney injury that has resolved; later during that hospital stay, the patient has a subsequent angiographic procedure. Under our proposed methodology, the commenter added, this patient would be erroneously identified as having contrast-induced acute kidney injury.

Some commenters suggested that CMS use E-codes, which identify injuries, while others did not support the use of E-codes because they are not consistently coded for Medicare billing purposes. Commenters further noted that the list of ICD–9–CM procedure codes proposed to assist in identifying the use of contrast as the reason for the acute kidney injury occurring are often not reported on hospital claims. The commenters explained that most of the codes do not represent procedures affecting payment, are not required, and, therefore, are not reported.

Other commenters recommended waiting to finalize this proposed candidate condition until the ICD–10 code set is implemented. The commenters suggested that a unique code to identify and describe contrast-induced acute kidney injury could be proposed in ICD–10, and this would eliminate the coding limitations that currently exist for this condition in ICD–9–CM.

Response: We acknowledge the commenters' concerns regarding the current ICD–9–CM coding issues surrounding contrast-induced acute kidney injury, and that our proposal could inadvertently include claims for beneficiaries who experience acute kidney injury that may not be contrast-induced. We note that, as discussed in the FY 2008 IPPS final rule with comment period (72 FR 47216), under 42 CFR 412.60(d), a hospital has 60 days after the date of the notice of the initial

assignment of a discharge to a DRG to request a review of that assignment. The hospital may submit additional information as a part of its request. A hospital that believes a discharge was assigned to the incorrect DRG as a result of application of the payment adjustment for HACs may request review of the DRG assignment by its fiscal intermediary or MAC. However, we also recognize that it is important to be as precise as possible in specifying which codes to use to identify a HAC, and that a lack of precision could increase hospitals' administrative burden in pursuing these appeals.

In addition, we recognize that E-codes do capture injuries and could offer more precision in identifying contrast-induced acute kidney injury than our proposal. We also agree with the commenters who pointed out that E-codes are currently not required for Medicare billing purposes and, therefore, are inconsistently reported on claims. We note further that because these codes are not required for Medicare IPPS payment purposes, MS–DRG assignments do not currently take E-codes into account.

We also appreciate the comments that pointed out that the procedure codes identified in our proposal are often not reported. We note that commenters asserted that these codes were not reported because they did not affect payment. We are concerned that the potential for reduced payment would create a further disincentive to include these procedure codes on Medicare claims. As we stated earlier, we recognize that it is important to be as precise as possible in the interest of payment accuracy in specifying which codes to use to identify a HAC.

We also agree that ICD–10 will offer a greater degree of specificity. Currently, no code exists within ICD–10 that would exclusively capture contrast-induced acute kidney injury. We note that, as discussed in the FY 2012 IPPS/LTCH proposed rule (76 FR 25843), and in section II.G.13.b. of this final rule, a partial code freeze was discussed at multiple meetings of the ICD–9–CM Coordination and Maintenance Committee, and public comment was actively solicited. At the September 15–16, 2010 meeting, an announcement was made that the ICD–9–CM Coordination and Maintenance Committee will implement a partial freeze of the ICD–9–CM and ICD–10 (ICD–10–CM and ICD–10–PCS) codes prior to the implementation of ICD–10 on October 1, 2013. There was considerable support for this partial freeze. The partial freeze will be implemented as follows:

- The last regular, annual updates to both ICD–9–CM and ICD–10 code sets will be made on October 1, 2011.
- On October 1, 2012, there will be only limited code updates to both the ICD–9–CM and ICD–10 code sets to capture new technologies and diseases as required by section 503(a) of Public Law 108–173.
- On October 1, 2013, there will be only limited code updates to ICD–10 code sets to capture new technologies and diagnoses as required by section 503(a) of Public Law 108–173. There will be no updates to ICD–9–CM, as it will no longer be used for reporting.
- On October 1, 2014, regular updates to ICD–10 will begin.

The ICD–9–CM Coordination and Maintenance Committee will continue to meet twice a year during the partial freeze. At these meetings, the public will be asked to comment on whether or not requests for new diagnosis or procedure codes should be created based on the criteria of the need to capture a new technology or disease. Any code requests that do not meet the criteria will be evaluated for implementation within ICD–10 on and after October 1, 2014, once the partial freeze has ended.

In summary, we agree with the commenters' recommendations regarding coding and are deferring decision making regarding the inclusion of contrast-induced acute kidney injury as a HAC until such a time when improved coding is available.

Comment: Several commenters submitted comments pertaining to the sufficiency or strength of the evidence-based guidelines in terms of providing information or direction that would lead to the prevention of contrast-induced acute kidney injury 100 percent of the time. The commenters stated that evidence-based guidelines are based on varying levels of evidence, from expert consensus based on opinion (the ''weakest'' level) to expert consensus based on data produced in randomized controlled trials (the ''strongest'' level). According to the commenters, in many cases, the guidelines do not address all patient populations. Commenters also stated that current evidence-based guidelines for decreasing the incidence of contrast-induced acute kidney injury are limited. The commenters also noted that new guidelines addressing the topic of contrast-induced acute kidney injury are being published in late summer of 2011 by an international organization, Kidney Disease Improving Global Outcomes (KDIGO), after a multiyear development process. They noted that CMS should take these guidelines into consideration when they become available.

Response: We acknowledge that different types of evidence-based guidelines exist. However, we believe that the inclusion of contrast-induced acute kidney injury in the current evidence-based guidelines for Acute Kidney Injury supports the inclusion of contrast-induced acute kidney injury as a condition on the HAC list. We agree that any new evidence-based guidelines for contrast-induced acute kidney injury should be considered when they become available.

Comment: A few commenters expressed concern about the proposal potentially creating an incentive for practitioners to avoid necessary contrast use in patients with high risk of acute kidney disease.

Response: We acknowledge and are sensitive to the theoretical possibility of patient access to care being restricted. We are unaware of significant data supporting this assertion, but we will continue to monitor the situation for potential unintended consequences with regard to this concern.

Comment: Some commenters recommended that CMS not reduce payment for this condition, but to instead develop a quality measure that would track it. The commenters noted that such a measure could track whether the appropriate evidence-based steps to prevent contrast-induced acute kidney injury have been performed and documented.

Response: We appreciate the commenters' recommendation. We note that we did not propose to develop a quality measure for contrast-induced acute kidney injury in the proposed rule. Thus, we consider this comment to be outside of the scope of the provisions discussed in the proposed rule. However, this subject area represents an area of continued interest and opportunity for the agency, and we will take this recommendation into consideration during the development of future rulemaking.

In conclusion, after consideration of the public comments we received, we are deferring the decision making on the addition of contrast-induced acute kidney injury as a HAC until future rulemaking, and such a time when improved coding is available for the reasons described above. We note that the reduction of contrast-induced acute kidney injury represents an area of continued interest for the agency, and we believe that substantial opportunity exists for hospitals to improve quality in this area.

b. Additional New Diagnosis Codes for Existing HACs

As we discussed in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25814), as changes to diagnosis codes and new diagnosis codes are proposed and finalized for the list of CCs and MCCs, we modify the list of selected HACs to reflect these changes. We included in Table 6A of the proposed rule (which was made available via the Internet) the five new ICD–9–CM diagnosis codes that we proposed to add to three of the current HAC categories. We proposed to add two new codes for the Falls and Trauma HAC category, two new codes for the Surgical Site Infection (SSI) Following Certain Bariatric Procedures HAC category, and one new code for the Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category. The two new diagnosis codes that we proposed to add to the Falls and Trauma HAC category were code 808.44 (Multiple closed pelvic fractures without disruption of pelvic circle) and code 808.54 (Multiple open pelvic fractures without disruption of pelvic circle). These codes fall within the range of the fracture code subcategory (800 through 829). The two new diagnosis codes that we proposed to add to the Surgical Site Infection (SSI) Following Certain Bariatric Procedures HAC category were code 539.01 (Infection due to gastric band procedure) and code 539.81 (Infection due to other bariatric procedure). We stated our belief that these diagnosis codes are appropriate for inclusion in the existing category when reported as a secondary diagnosis with the specified principal diagnosis code of morbid obesity (code 278.01) and one of the designated bariatric procedure codes (code 44.38, 44.39, or 44.95). Lastly, the one new diagnosis code that we proposed to add to the Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category was code 415.13 (Saddle embolus of pulmonary artery). Diagnosis code 415.13 would be applicable when reported along with one of the following procedures codes describing certain orthopedic procedures: 00.85 through 00.87, 81.51, 81.52, or 81.54. Shown in the table below are these five new diagnosis codes with their corresponding descriptions and their proposed CC/MCC designations.

ICD–9–CM code	Code descriptor	Proposed CC/MCC designation
539.01	Infection due to gastric band procedure	CC
539.81	Infection due to other bariatric procedure	CC
415.13	Saddle embolus of pulmonary artery	MCC
808.44	Multiple closed pelvic fractures without disruption of pelvic circle	CC
808.54	Multiple open pelvic fractures without disruption of pelvic circle	MCC

We invited public comments on the proposed adoption of these five new ICD–9–CM diagnosis codes as CC/MCCs that are listed above, which, if finalized, would be added to the current Falls and Trauma HAC category, Surgical Site Infection (SSI) Following Certain Bariatric Procedures HAC category and Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category and would be subject to the HAC payment provision for FY 2012.

Comment: Several commenters supported CMS' proposal to adopt the five new ICD–9–CM diagnosis codes with their proposed CC/MCC designations for addition to the current Falls and Trauma HAC category, Surgical Site Infection (SSI) Following Certain Bariatric Procedures HAC category, and Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category and to subject them to the HAC payment provision for FY 2012.

Response: We appreciate the commenters' support.

Comment: One commenter expressed concern regarding the appropriateness of adding ICD–9–CM diagnosis code 415.13 as a condition that, when reported along with the designated procedure codes describing certain orthopedic procedures (00.85 through 00.87, 81.51, 81.52, or 81.54) in the Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category, be subject to the HAC payment provision. The commenter stated that HAC selection should be based on conditions considered to be reasonably preventable with adherence to evidence-based practice guidelines. The commenter further believed that a saddle embolus of the pulmonary artery, when reported with the cited orthopedic procedure codes, is not a condition that is ''reasonably preventable'' and that patients undergoing total knee replacement and total hip replacement in the Medicare population are at the highest risk for developing a DVT/PE.

The commenter also stated that the current structure of the MS–DRG system does not specifically risk-adjust for these conditions in the MS–DRGs related to primary total hip replacement (code 81.51) or primary total knee replacement (code 81.54). The commenter believed that risk adjustment is an indispensible component of an equitable HAC policy. The commenter suggested that CMS account for the patient-specific risk factors that affect preventability and reported that many hospitalized patients have comorbidities and other patient characteristics that put them at an increased risk of complications. The commenter suggested that CMS take these factors into account in creating a policy that is reasonable and equitable, in order to minimize incentives for limiting access for patients who are at higher risk for complications.

This same commenter also expressed support of CMS' efforts to encourage the adoption of evidence-based treatment guidelines that could improve the quality of care for patients. However, while the commenter noted that evidence-based guidelines can reduce events, the commenter asserted that CMS selected one of the patient populations at highest risk for DVT/PE, diverging from the concept of ''reasonably preventable.''

Response: We appreciate the commenter's detailed comments on the proposal to add diagnosis code 415.13 as a condition that, when reported along with the designated procedure codes described above, is subject to the HAC payment provision. In the FY 2008 IPPS final rule with comment period (72 FR 47200 through 47218), we discussed the evidence based guidelines regarding DVT/PE and agreed with commenters that this is reasonably preventable. In the FY 2009 IPPS final rule (73 FR 48481), we addressed commenters' concerns regarding the preventability of DVT/PE and noted that the statute does not require that a condition be ''always preventable''' in order to qualify as an

HAC, but rather that it be ''reasonably preventable,'' which necessarily implies something less than 100 percent.

With regard to the commenter's assertion that risk adjustment is an indispensible component of an equitable HAC policy, we refer readers to the FY 2009 IPPS final rule and the FY 2010 IPPS/RY 2010 LTCH PPS final rule. In the FY 2009 IPPS final rule (73 FR 48487 through 48488), we discussed risk adjustment of payments related to HACs. We addressed this issue again in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43785), where we noted that a risk adjustment methodology may lead to greater precision of HAC payment determinations. As part of the RTI evaluation of the HAC–POA program, the concept of risk adjustment continues to be an important area of interest and study for the agency. We will consider the results of RTI's evaluation when it is complete and, if appropriate, make a proposal and solicit public comment in future rulemaking.

After consideration of the public comments we received, we are finalizing the adoption of the five new ICD–9–CM diagnosis codes described above as CC/MCCs to be added to their respective HAC categories as proposed. Therefore, effective October 1, 2011 (FY 2012), procedure codes 808.44 and 808.54 describing multiple pelvic fractures will be added to the Falls and Trauma HAC category, procedure codes 539.01 and 539.81 describing infections related to gastric procedures will be added to the Surgical Site Infection (SSI) Following Certain Bariatric Procedures HAC category, and procedure code 415.13 describing a type of pulmonary embolus will be added to the Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category. All of these conditions will be subject to the HAC payment provision for FY 2012.

c. Revision to HAC Subcategory Title

After publication of the FY 2011 IPPS/LTCH PPS final rule, we received a comment stating that the subcategory title ''Electric Shock'' that is included in the Falls and Trauma HAC category was misleading. The commenter stated that this subcategory title did not accurately describe the CC/MCC ICD–9–CM diagnoses codes (991 through 994) contained within this subcategory. The commenter requested that CMS develop a new title that would more accurately describe this group of codes.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25814), we stated that we agreed with the commenter that the HAC subcategory title ''Electric Shock'' is potentially misleading because the codes included within these ranges contain a variety of injuries, including the following:

- Category 991 (Effects of Reduced Temperature)
- Category 992 (Effects of Heat and Light)
- Category 993 (Effects of Air Pressure)
- Category 994 (Effects of Other External Causes)

We proposed to change the title of this HAC subcategory from ''Electric Shock'' to ''Other Injuries'' because it includes a variety of injury codes. The subcategory will continue to include the codes within the 991 through 994 code ranges appearing on the CC/MCC list. We did not propose any changes to the list of codes in this subcategory; we simply proposed to rename the subcategory title. We invited public comments on the proposed title change to the HAC subcategory from ''Electric Shock'' to ''Other Injuries'' for FY 2012.

Comment: Several commenters supported CMS' proposal to change the title of this HAC subcategory from ''Electric Shock'' to ''Other Injuries'' because it includes a variety of injury codes. The commenters stated that this title change would better describe the conditions included in the range of codes.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the title of the HAC subcategory from ''Electric Shock'' to ''Other Injuries.'' The subcategory will continue to include the codes within the 991 through 994 code ranges appearing on the CC/MCC list. In addition, we are not making any changes to the list of codes in this subcategory; the subcategory title will simply be renamed effective FY 2012.

d. Conclusion

In the FY 2012 IPPS/LTCH PPS proposed rule, we listed the current HAC categories and the ICD–9–CM codes that identify the conditions and have been finalized through FY 2011. For FY 2012, we proposed that these conditions continue to be subject to the HAC payment provision, along with the creation of a new HAC category for contrast-induced acute kidney injury. (We note that, as discussed in section II.F.2.a. of the preamble of the proposed rule and this final rule, we are not adopting our proposal to add a new HAC category for contrast-induced acute kidney injury for FY 2012.) In addition, we proposed to add five new ICD–9–CM diagnosis codes and to revise the title of the ''Electric Shock'' subcategory in the Falls and Trauma HAC category.

Comment: Several commenters supported maintaining the current HAC categories and the ICD–9–CM codes that identify those conditions. These commenters agreed that the conditions should continue to be subject to the HAC payment provision for FY 2012.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are adopting the following list of HAC categories and the ICD–9–CM codes that identify the conditions that have been finalized through FY 2011 and that we are finalizing in this final rule for FY 2012.

HAC	CC/MCC (ICD–9–CM Code)
Foreign Object Retained After Surgery	998.4 (CC)
	998.7 (CC)
Air Embolism	999.1 (MCC)
Blood Incompatibility	999.60 (CC)
	999.61 (CC)
	999.62 (CC)
	999.63 (CC)
	999.69 (CC)
Pressure Ulcer Stages III & IV	707.23 (MCC)
	707.24 (MCC)
Falls and Trauma:	Codes within these ranges on the CC/MCC list:
—Fracture	800–829
—Dislocation	830–839

HAC	CC/MCC (ICD–9–CM Code)
—Intracranial Injury	850–854
—Crushing Injury	925–929
—Burn	940–949
—Other Injuries	991–994
Catheter-Associated Urinary Tract Infection (UTI)	996.64 (CC) Also excludes the following from acting as a CC/MCC: 112.2 (CC) 590.10 (CC) 590.11 (MCC) 590.2 (MCC) 590.3 (CC) 590.80 (CC) 590.81 (CC) 595.0 (CC) 597.0 (CC) 599.0 (CC)
Vascular Catheter-Associated Infection	999.31 (CC)
Manifestations of Poor Glycemic Control	250.10–250.13 (MCC) 250.20–250.23 (MCC) 251.0 (CC) 249.10–249.11 (MCC) 249.20–249.21 (MCC)
Surgical Site Infections	
Surgical Site Infection, Mediastinitis, Following Coronary Artery Bypass Graft (CABG).	519.2 (MCC) And one of the following procedure codes: 36.10–36.19
Surgical Site Infection Following Certain Orthopedic Procedures	996.67 (CC) 998.59 (CC) And one of the following procedure codes: 81.01–81.08, 81.23–81.24, 81.31–81.38, 81.83, 81.85
Surgical Site Infection Following Bariatric Surgery for Obesity	*Principal Diagnosis*—278.01 539.01 (CC) 539.81 (CC) 998.59 (CC) And one of the following procedure codes: 44.38, 44.39, or 44.95
Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures.	415.11 (MCC) 415.13 (MCC) 415.19 (MCC) 453.40–453.42 (CC) And one of the following procedure codes: 00.85–00.87, 81.51–81.52, or 81.54

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 48474 through 48486) for detailed analyses supporting the selection of each of the HACs selected through FY 2012.

3. RTI Program Evaluation Summary

a. Background

On September 30, 2009, a contract was awarded to Research Triangle Institute, International (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 is an intra-agency project with funding and technical support coming from CMS, OPHS, AHRQ, and CDC. The evaluation will also examine the implementation of the program and evaluate additional conditions for future selection.

RTI's evaluation of the HAC–POA provisions is divided into several parts. In the FY 2011 IPPS/LTCH PPS final rule (50085 through 50101), we summarized the analyses by RTI that had been completed at that time. These RTI analyses of POA indicator reporting, frequencies and net savings associated with current HACs, and frequencies of previously considered candidate HACs reflected MedPAR claims from October 2008 through September 2009.

b. FY 2009 Data Analysis

As we describe in section II.F.1.f. of this preamble, we have provided instructions to IPPS hospitals and non-IPPS hospitals regarding the submission of POA indicator data for all diagnosis codes on Medicare claims and the processing of non-PPS claims (75 FR 23381) and note that specific instructions on how to select the correct POA indicator for each diagnosis code were included in the *ICD–9–CM Official Guidelines for Coding and Reporting,* available on the CDC Web site at: *http://www.cdc.gov/nchs/data/icd9/icdguide10.pdf.* After publication of the FY 2011 IPPS/LTCH PPS final rule, we identified a discrepancy between the claims data that hospitals submitted and the CMS data file used to calculate the HAC measures. Specifically, this error led to incorrect HAC assignments in cases where a hospital reported an external cause of injury (E-code). Since then, we have corrected this error in the data file.

As a result, the RTI analysis of the HAC–POA program that was conducted using FY 2009 claims data was updated using the corrected data file. The corrected data do not appear to have a

material impact on our previous findings for FY 2009. Revised data tables 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/* after publication of the FY 2012 IPPS/LTCH PPS proposed rule.

c. FY 2010 Data Analysis

RTI's analysis of the FY 2010 MedPAR data file for the HAC–POA program evaluation was prepared for publication in the FY 2012 IPPS/LTCH PPS proposed rule. We indicated in the proposed rule that we would provide the results from the study on the CMS Web site at *http://www.cms.gov/HospitalAcqCond/01_Overview.asp* and on the RTI Web site at *http://www.rti.org/reports/cms/* when it became available. We also stated that we anticipated that the examination of FY 2010 MedPAR data would be completed soon after publication of the proposed rule. We invited public comment on RTI's analysis of the FY 2010 MedPAR data for the HAC–POA program.

Since publication of the FY 2012 IPPS/LTCH proposed rule, we determined that it would be beneficial to the public if we provided a summary of the results of RTI's HAC–POA program evaluation of the FY 2010 MedPAR data in this FY 2012 IPPS/LTCH final rule, in addition to making these results available on both the CMS and RTI Web sites mentioned above. Below we present a summary of these results.

d. FY 2010 RTI Analysis on POA Indicator Reporting of Current HACs.

To better understand the impact of HACs on the Medicare program, it is necessary to first examine the incidence of POA indicator reporting across all eligible Medicare discharges. As mentioned previously, only IPPS hospitals are required to submit POA indicator data for all diagnosis codes on Medicare claims. Therefore, all non-IPPS hospitals were excluded, as well as providers in waiver States (Maryland) and territories other than Puerto Rico.

Using MedPAR claims data from October 2009 through September 2010, RTI found a total of approximately 74.38 million secondary diagnoses across approximately 10.2 million discharges. As shown in Chart A below, the majority of all secondary diagnoses (80.94 percent) were reported with a POA indicator of ''Y,'' meaning the condition was POA.

CHART A—POA CODE DISTRIBUTION ACROSS ALL SECONDARY DIAGNOSES

	Number	Percentage
Total Discharges in Final File		10,189,168
Total Number of Secondary Diagnoses Across Total Discharges	74,382,681	100.00
POA Indicator Description:		
Y Condition present on admission	60,206,593	80.94
W Status cannot be clinically determined	13,145	0.02
N Condition not present on admission	5,001,138	6.72
U Documentation not adequate to determine if condition was present on admission	2,223,318	2.99
1 Exempted ICD–9–CM code	6,938,487	9.33

Source: RTI Analysis of MedPAR IPPS Claims, October 2009 through September 2010.

Following the initial analysis of POA indicator reporting for all secondary diagnoses, RTI then evaluated POA indicator reporting for specific HAC-associated secondary diagnoses. The term ''HAC-associated secondary diagnosis'' refers to those diagnoses that are on the selected HAC list and were reported as a secondary diagnosis. Chart B below shows a summary of the HAC categories with the frequency in which each HAC was reported as a secondary diagnosis and the corresponding POA indicators assigned on the claims. It is important to note that, because more than one HAC-associated diagnosis code can be reported per discharge (that is, on a single claim), the frequency of HAC-associated diagnosis codes may be more than the actual number of *discharges* that have a HAC-associated diagnosis code reported as a secondary diagnosis. Below we discuss the frequency of each HAC-associated diagnosis code and the POA indicators assigned to those claims.

RTI analyzed the frequency of each reported HAC-associated secondary diagnosis (across all approximately 10.2 million discharges) and the POA indicator assigned to the claim. Chart B below shows that the most frequently reported conditions were in the Falls and Trauma HAC category, with a total of 189,231 HAC-associated diagnosis codes being reported for that HAC category. Of these 189,231 diagnoses, 5,762 reported a POA indicator of ''N'' and 326 reported a POA indicator of ''U'' for not POA. Similarly, 183,048 diagnoses reported a POA indicator of ''Y'' for POA and 95 diagnoses reported a POA indicator of ''W.'' The lowest frequency appears in the Surgical Site Infection (SSI) Following Bariatric Surgery for Obesity HAC category with only 18 HAC-associated secondary diagnosis codes (and procedure codes) reported, where 17 diagnoses were reported with a POA indicator of ''N'' and 1 diagnosis was reported with a POA indicator of ''Y.''

CHART B—POA STATUS OF CURRENT HACS: OCTOBER 2009 THROUGH SEPTEMBER 2010

Selected HAC	Frequency as a secondary diagnosis	Treated as hospital acquired conditions				Not treated as Hospital acquired conditions			
		POA = N		POA = U		POA = Y		POA = W	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
1. Foreign Object Retained After Surgery (CC)	565	278	49.2	1	0.2	286	50.6	0	0.0
2. Air Embolism (MCC)	42	29	69.0	0	0.0	13	31.0	0	0.0
3. Blood Incompatibility (CC)	35	12	34.3	0	0.0	23	65.7	0	0.0
4. Pressure Ulcer Stages III & IV (MCC)	120,582	1,407	1.2	81	0.1	119,065	98.7	29	0.0

CHART B—POA STATUS OF CURRENT HACS: OCTOBER 2009 THROUGH SEPTEMBER 2010—Continued

Selected HAC	Frequency as a secondary diagnosis	Treated as hospital acquired conditions				Not treated as Hospital acquired conditions			
		POA = N		POA = U		POA = Y		POA = W	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
5. Falls and Trauma (MCC & CC)	189,231	5,762	3.0	326	0.2	183,048	96.7	95	0.1
6. Catheter-Associated UTI (CC)	18,247	3,877	21.2	24	0.1	14,319	78.5	27	0.1
7. Vascular Catheter-Associated Infection (CC)	10,066	4,346	43.2	25	0.2	5,673	56.4	22	0.2
8. Poor Glycemic Control (MCC)	16,468	565	3.4	14	0.1	15,888	96.5	1	0.0
9A. Surgical Site Infection Mediastinitis CABG (CC)	40	36	90.0	0	0.0	4	10.0	0	0.0
9B. Surgical Site Infection Following Certain Orthopedic Procedures (CC)	365	220	60.3	1	0.3	144	39.5	0	0.0
9C. Surgical Site Infection Following Bariatric Surgery for Obesity (CC)	18	17	94.4	0	0.0	1	5.6	0	0.0
10. Pulmonary Embolism & DVT Orthopedic (MCC)	3,820	3,132	82.0	16	0.4	648	17.0	24	0.6
Total*	359,479	19,681	5.5	488	0.1	339,112	94.3	198	0.1

As described in section II.F.1.f. of this preamble, in the FY 2009 IPPS final rule (73 FR 48486 through 48487), we adopted final payment policies to: (1) Pay the CC/MCC MS–DRGs for those HACs coded with ''Y'' and ''W'' indicators; and (2) not pay the CC/MCC MS–DRGs for those HACs coded with ''N'' and ''U'' indicators. We also discussed the comments we received urging CMS to consider changing the policy and to pay for those HACs assigned a POA indicator of ''U'' (documentation is insufficient to determine if the condition was present at the time of admission). We stated we would monitor the extent to which and under what circumstances the ''U'' POA reporting option is used. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43784 and 43785), we also discussed and responded to comments regarding HACs coded with the ''U'' indicator. As shown in Chart B above, RTI's analysis provides data on a total of 488 HAC-associated secondary diagnoses reported with a POA indicator of ''U.'' These 488 diagnoses represented 2.4 percent of the 20,169 diagnoses that were considered not POA (that is, POA indicator of ''N'' or ''U''). Approximately 3 of the 10 conditions reported no diagnoses with POA indicators of ''U'': Air embolism, Blood Incompatibility, and two of the three surgical site infections (Mediastinitis after CABG and SSI after bariatric surgery for obesity). For the two most frequently occurring conditions, the Falls and Trauma HAC category and Stage III and/or IV Pressure Ulcers, diagnoses with a POA indicator of ''U'' represented a small proportion of diagnoses that were considered not POA (that is, POA indicator of ''N'' or ''U''). For the Falls and Trauma HAC category, 5.7 percent of diagnoses (326 cases) considered not POA were reported with a POA indicator of ''U.'' For Stage III and/or IV Pressure Ulcers, 5.4 percent of diagnoses (81 cases) considered not POA were reported with a POA indicator of ''U.'' These two categories also represented the conditions where diagnoses with a POA indicator of ''U'' were the highest proportion of diagnoses considered not POA. We consider the range of 0 to 5.7 percent to indicate that ''U'' is not used with great frequency for these 10 conditions. In the proposed rule, we stated that we did not contemplate a proposal to change our policy under which CMS does not pay at the higher CC/MCC amount when a selected HAC diagnosis code is reported with a POA indicator of ''U.'' The data analysis described above continues to support our policy.

We encourage readers to further review the RTI detailed report which demonstrates the frequency of each individual HAC-associated diagnosis code within the HAC categories. As an example, we note that in the Foreign Object Retained After Surgery HAC category, there are two unique ICD–9–CM diagnosis codes used to identify that condition: diagnosis code 998.4 (Foreign body accidentally left during a procedure) and diagnosis code 998.7 (Acute reaction to foreign substance accidentally left during a procedure). In the detailed RTI report, readers can view that diagnosis code 998.4 was reported 547 times and diagnosis code 998.7 was reported 18 times, across all MS–DRGs, for a total of 565 times. The RTI detailed report is available at the following Web site: *http://www.rti.org/reports/cms/.*

e. FY 2010 RTI Analysis of Frequency of Discharges and POA Indicator Reporting for Current HACs

RTI further analyzed the effect of the HAC provision by studying the frequency with which a HAC-associated diagnosis was reported as a secondary diagnosis with a POA indicator of ''N'' or ''U'' and, of that number, how many resulted in MS–DRG reassignment. In Chart C below, Column A shows the number of discharges for each HAC category where the HAC-associated diagnosis was reported as a secondary diagnosis. Column B shows the percent of discharges reporting a HAC-associated diagnosis code relative to the total discharges ''at risk'' in each HAC category. For HAC categories 1 through 8, both medical and surgical MS–DRGs are included in the total discharges ''at risk'' so this equates to 10,189,168 discharges. The remaining HAC categories are defined by the combination of diagnosis and procedure codes; therefore, only the surgical MS–DRGs that include the designated procedure codes are included in the total discharges ''at risk.'' For HAC 9a, the total discharges ''at risk'' equates to 97,341. For HAC 9b, the total discharges ''at risk'' equates to 118,815 and for HAC 9c, the total discharges ''at risk'' equates to 15,698. Lastly, for HAC 10, the total discharges ''at risk'' equates to 440,571.

Column C shows the number of discharges for each HAC reported with a POA indicator of ''N'' or ''U.'' For example, there were 42 discharges that reported Air Embolism as a secondary diagnosis. The chart shows that, of these 42 reported discharges, 29 discharges (69.05 percent) had a POA indicator of ''N'' or ''U'' and was identified as a HAC discharge. The HAC policy applied to these 29 discharges, and they could, therefore, have had an MS–DRG reassignment. Column E shows the number of discharges where an actual MS–DRG reassignment occurred. For the Air Embolism HAC, Column E shows that the number of discharges that resulted in actual MS–DRG reassignments is 15 (51.72 percent of the 29 discharges with a POA indicator of ''N'' or ''U''). Thus, while there were 29 discharges (69.05 percent of the original

42 that had air embolism reported as a secondary diagnosis) with an air embolism reported with a POA indicator of ''N'' or ''U'' identified as a HAC discharge that could have caused MS–DRG reassignment, 15 discharges (51.72 percent) experienced MS–DRG reassignments. There are a number of reasons why a selected HAC reported with a POA indicator of ''N'' or ''U'' will not result in MS–DRG reassignment. These reasons were illustrated with the diagram in section II.F.1.c. of this preamble and will be discussed in further detail in section II.F.3.e. of this preamble.

Chart C below also shows that, of the 317,644 discharges with a HAC-associated diagnosis as a secondary diagnosis, 3,587 discharges ultimately resulted in MS–DRG reassignment. As we discuss below, there were 15 claims that resulted in MS–DRG reassignment where 2 HACs were reported on the same admission. The four HAC categories that had the most discharges resulting in MS–DRG reassignment were: (1) Falls and Trauma; (2) Pulmonary Embolism and DVT Orthopedic (Orthopedic PE/DVT); (3) Pressure Ulcer Stages III & IV; and (4) Catheter-Associated Urinary Tract Infection (UTI).

Codes falling under the Falls and Trauma HAC category were the most frequently reported secondary diagnoses with 154,371 discharges. Of these 154,371 discharges, 5,454 (3.53 percent) were coded as not POA and identified as HAC discharges. This category also contained the greatest number of discharges that resulted in an MS–DRG reassignment. Of the 5,454 discharges within this HAC category that were not POA, 1,672 (30.66 percent) resulted in an MS–DRG reassignment.

Of the 317,644 total discharges reporting HAC-associated diagnoses as a secondary diagnosis, 3,494 discharges were coded with a secondary diagnosis of PE/DVT Orthopedic. Of these 3,494 discharges, 2,876 (82.31 percent) were coded as not POA and identified as HAC discharges. This category contained the second greatest number of discharges resulting in an MS–DRG reassignment. Of the 2,876 discharges in this HAC category that were not POA, 1,206 discharges (41.93 percent) resulted in an MS–DRG reassignment.

The Pressure Ulcer Stages III & IV category had the second most frequently coded secondary diagnoses, with 114,138 discharges. Of these discharges, 1,444 (1.27 percent) were coded as not POA and identified as HAC discharges. This category contained the third greatest number of discharges resulting in an MS–DRG reassignment. Of the 1,444 discharges in this HAC category that were not POA, 292 discharges (20.22 percent) resulted in an MS–DRG reassignment.

The Catheter-Associated UTI category had the third most frequently coded secondary diagnoses, with 18,247 discharges. Of these discharges, 3,885 (21.29 percent) were coded as not POA and identified as HAC discharges. This category contained the fourth greatest number of discharges resulting in an MS–DRG reassignment. Of the 3,885 discharges in this HAC category that were not POA, 223 discharges (5.74 percent) resulted in a MS–DRG reassignment.

The remaining 6 HAC categories only had 194 discharges that ultimately resulted in MS–DRG reassignment. We note that, even in cases where a large number of HAC-associated secondary diagnoses were coded as not POA, this finding did not necessarily translate into a large number of discharges that resulted in MS–DRG reassignment. For example, only 22 of the 4,366 Vascular Catheter-Associated Infection secondary diagnoses that were coded as not POA and identified as HAC discharges resulted in a MS–DRG reassignment.

There were a total of 364 discharges with a HAC-associated secondary diagnosis reporting a POA indicator of ''N'' or ''U'' that were excluded from acting as a HAC discharge (subject to MS–DRG reassignment) due to the CC Exclusion List logic within the GROUPER. The CC Exclusion List identifies secondary diagnosis codes designated as a CC or MCC that are disregarded by the GROUPER logic when reported with certain principal diagnoses. For example, a claim with the principal diagnosis code of 250.83 (Diabetes with other specified manifestations, type 1 [juvenile type], uncontrolled) and a secondary diagnosis code of 250.13 (Diabetes with ketoacidosis, type 1, [juvenile type], uncontrolled) with a POA indicator of ''N'' would result in the HAC-associated secondary diagnosis code 250.13 being ignored as a CC. According to the CC Exclusion List, code 250.13 is excluded from acting as a CC when code 250.83 is the principal diagnosis. As a result, the HAC logic would not be applicable to that case. For a detailed discussion on the CC Exclusion List, we refer readers to section II.G.9. of this preamble.

Discharges where the HAC logic was not applicable due to the CC Exclusion List occurred among the following 6 HAC categories: Pressure Ulcer Stages III and IV (29 cases); Falls and Trauma (263 cases); Catheter-Associated UTI (16 cases); Vascular Catheter-Associated Infection (5 cases); Manifestations of Poor Glycemic Control (50 cases); and Surgical Site Infection Following Certain Orthopedic Procedures (1 case). Further information regarding the specific number of cases that were excluded for each HAC-associated secondary diagnosis code within each of the above mentioned HAC categories is also available in the RTI detailed report, which can be found at: *http://www.rti.org/reports/cms/.*

In summary, Chart C below demonstrates that there were a total of 317,644 discharges with a reported HAC-associated secondary diagnosis. Of the total 317,644 discharges, 6.0 percent, or 19,143 discharges, were HACs reported with a POA indicator of ''N'' or ''U'' that were identified as a HAC discharge. Approximately 18.7 percent, or 3,587 discharges, of these 19,143 discharges resulted in MS–DRG reassignments.

CHART C—DISCHARGE FREQUENCIES OF CURRENT CMS HACS OCTOBER 2009 THROUGH SEPTEMBER 2010

Selected HAC category	Discharges with this condition as secondary diagnosis		Discharges identified as a HAC		Discharges that change MS–DRG due to HAC	
	Number (column a)	Percent [2] (column b)	Number (column c)	Percent [3] (column d)	Number (column e)	Percent [4] (column f)
1. Foreign Object Retained After Surgery	563	0.01	278	49.38	44	15.83
2. Air Embolism	42	0.00	29	69.05	15	51.72
3. Blood Incompatibility	35	0.00	12	34.29	0	0.00
4. Pressure Ulcer Stages III & IV	114,138	1.12	1,444	1.27	292	20.22
5. Falls and Trauma						
a. Fracture	137,888	1.35	4,700	3.41	1,439	30.62

CHART C—DISCHARGE FREQUENCIES OF CURRENT CMS HACS OCTOBER 2009 THROUGH SEPTEMBER 2010—Continued

Selected HAC category	Discharges with this condition as secondary diagnosis		Discharges identified as a HAC		Discharges that change MS–DRG due to HAC	
	Number (column a)	Percent [2] (column b)	Number (column c)	Percent [3] (column d)	Number (column e)	Percent [4] (column f)
b. Dislocation	1,105	0.01	35	3.17	4	11.43
c. Intracranial Injury	15,844	0.16	706	4.46	234	33.14
d. Crushing Injury	41	0.00	2	4.88	1	50.00
e. Burn	2,297	0.02	39	1.70	6	15.38
f. Electric Shock	818	0.01	9	1.10	0	0.00
Less: Discharges with multiple Falls & Trauma	−3,622	−0.04	−37	−1.02	−12	−32.43
5. Falls and Trauma: Unduplicated Total	154,371	1.52	5,454	3.53	1,672	30.66
6. Catheter-Associated UTI	18,247	0.18	3,885	21.29	223	5.74
7. Vascular Catheter-Associated Infection	10,066	0.10	4,366	43.37	22	0.50
8. Poor Glycemic Control	16,267	0.16	526	3.23	107	20.34
9a. SSI Mediastinitis CABG	40	0.04	36	90.00	4	11.11
9b. SSI Orthopedic	363	0.31	220	60.61	2	0.91
9c. SSI Bariatric	18	0.11	17	94.44	0	0.00
10. Pulmonary Embolism & DVT Orthopedic	3,494	0.79	2,876	82.31	1,206	41.93
Total [1]	317,644	.....	19,143	.....	3,587	.....

[1] Discharges can appear in more than one row. The total figure is not adjusted for the 94 discharges with more than one HAC that appear as secondary diagnoses (15 of these resulted in MS–DRG reassignment).
[2] Percent computed relative to total discharges "at risk" for this HAC. For HACs 1–8, this is 10,189,168. For HAC 9a, this is 97,341. For HAC 9b, this is 118,815. For HAC 9c, this is 15,698. For HAC 10, this is 440,571.
[3] Percent computed relative to discharges with condition as a secondary diagnosis.
[4] Percent computed relative to discharges with this HAC (Column C).
Source: RTI Analysis of MedPAR IPPS Claims, October 2009 through September 2010.

An extremely small number of discharges had multiple HACs reported during the same stay. In reviewing the approximately 10.2 million claims, RTI found approximately 94 cases in which 2 HACs were reported on the same discharge. Chart D below summarizes these cases. Thirty-two of the cases with 2 HACs involved Pressure Ulcer Stages III & IV, and 31 cases involved Falls or Trauma. Other multiple HAC cases included 27 Catheter-Associated UTI cases, 3 Vascular Catheter-Associated Infection cases and 1 Foreign Object Retained After Surgery case. There were eight cases in which a Falls and Trauma HAC was reported together with a Pressure Ulcer Stages III & IV HAC.

Some of these cases with multiple HACs reported had both HAC codes ignored in the MS–DRG assignment. Of these 66 claims, 49 did not receive higher payments based on the presence of these reported HACs, and we describe these claims in section II.F.3.f.(2) of this preamble. Depending on the MS–DRG to which the cases were originally assigned, ignoring the HAC codes would have led to a MS–DRG reassignment if there were no other MCCs or CCs reported, if the MS–DRG was subdivided into severity levels, and if the case were not already in the lowest severity level prior to ignoring the HAC codes.

CHART D—CLAIMS WITH MORE THAN ONE HAC SECONDARY DIAGNOSIS OCTOBER 2009 THROUGH SEPTEMBER 2010

HAC	1. Foreign object—CC	4. Pressure ulcer stages III & IV—MCC	5. Falls and trauma—MCC & CC	6. Catheter-associated UTI—CC	7. Vascular catheter-associated infection—CC
5. Falls and trauma—MCC & CC	.....	8	.....	.....	.....
6. Catheter-Associated UTI—CC	.....	8	12	.....	.....
7. Vascular Catheter-Associated Infection—CC	.....	12	6	21	.....
8. Poor Glycemic Control—MCC	.....	1	2	.....	1
9B. Surgical Site Infection Following Certain Orthopedic Procedures—CC	1	.....	.....	.....	2
10. Pulmonary Embolism & DVT Orthopedic—MCC	.....	3	11	6	.....
Total	1	32	31	27	3

f. RTI Analysis of Circumstances When Application of HAC Provisions Would Not Result in MS–DRG Reassignment for Current HACs

As discussed in section II.F.1. and illustrated in the diagram in section II.F.1.c. of this preamble, there are instances when the MS–DRG assignment does not change even when there is a HAC as a secondary diagnosis (meaning a HAC-associated secondary diagnosis has a POA indicator of either "N" or "U.") In analyzing our claims data, RTI identified four main reasons why a MS–DRG assignment would not change despite the presence of a HAC. Those four reasons are described below and are shown in Chart E below. Column A shows the frequency of discharges that included a HAC-associated secondary diagnosis. Column

B shows the frequency of discharges where the HAC-associated secondary diagnosis was coded as not POA and, therefore, identified as a HAC discharge. Column C shows the frequency of discharges in which the HAC-associated secondary diagnosis coded as not POA resulted in a change in MS–DRG. Columns D, E, F, and G show the frequency of discharges in which the HAC-associated secondary diagnosis coded as not POA did not result in a change in MS–DRG assignment. Columns D, E, F, and G are explained in more detail below.

(1) Other MCCs/CCs Prevent Reassignment

Column D (Other MCC/CCs that Prevent Reassignment) in Chart E below indicates the number of cases reporting a HAC (cases with HAC-associated diagnosis codes with a POA of ''N'' or ''U'') that did not have a MS–DRG reassignment because of the presence of other secondary diagnoses on the MCC or CC list. A claim that is coded with a HAC-associated secondary diagnoses and a POA status of either ''N'' or ''U'' may have other secondary diagnoses that are classified as an MCC or a CC. In such cases, the presence of these other MCC and CC diagnoses will still lead to the assignment of a higher severity level, despite the fact that the GROUPER software is disregarding the ICD–9–CM code that identifies the selected HAC in making the MS–DRG assignment for that claim. For example, there were 156 cases in which the ICD–9–CM codes for the Foreign Object Retained After Surgery HAC category were present, but the presence of other secondary diagnoses that were MCCs or CCs resulted in no change to the MS–DRG assignment. Chart E shows that a total of 11,818 cases with HACs did not have a change in the MS–DRG assignment because of the presence of other reported MCCs and CCs. This represents approximately 76 percent of the 15,556 cases with HACs that did not have a change in MS–DRG assignment.

(2) Two Severity Levels Where HAC Does Not Impact MS–DRG Assignment

Column E (Number of MS–DRGs with Two Severity Levels Where HAC Does Not Impact MS–DRG Assignment) shows the frequency with which discharges with a HAC (cases with HAC-associated diagnosis codes with a POA of ''N'' or ''U'') did not result in an MS–DRG change because the MS–DRG is subdivided solely by the presence or absence of an MCC. A claim with a HAC and a POA indicator of either ''N'' or ''U'' may be assigned to an MS–DRG that is subdivided solely by the presence or absence of an MCC. In such cases, removing a HAC ICD–9–CM CC code will not lead to further changes in the MS–DRG assignment. Examples of these MS–DRG subdivisions are shown in the footnotes to the chart and include the following examples:

- MS–DRGs 100 and 101 (Seizures with or without MCC, respectively)
- MS–DRGs 102 and 103 (Headaches with or without MCC, respectively)

The codes that fall under the HAC category of Foreign Object Retained After Surgery are CCs. If this case were assigned to a MS–DRG with an MCC subdivision such as MS–DRGs 100 and 101, the presence of the HAC code would not affect the MS–DRG severity level assignment. In other words, if the Foreign Object Retained After Surgery code were the only secondary diagnosis reported, then the case would be assigned to MS–DRG 101 (Seizure without MCC). If the POA indicator was ''N,'' the HAC Foreign Object Retained After Surgery code would be ignored in the MS–DRG assignment logic. Despite the fact that the code was ignored, the case would still be assigned to the same, lower severity level MS–DRG. Therefore, there would be no impact on the MS–DRG assignment.

Column E in Chart E below shows that there were 2,282 cases where the HAC code was reported with an ''N'' or ''U'' and the MS–DRG assignment did not change because the case was already assigned to the lowest severity level. This represents approximately 15 percent of the 15,556 cases with HACs that did not have a change in MS–DRG assignment.

(3) No Severity Levels

Column F (Number of MS–DRGs with No Severity Levels) shows the frequency with which discharges with an HAC (cases with HAC-associated diagnosis codes with a POA of ''N'' or ''U'') did not result in an MS–DRG change because the MS–DRG that the case was assigned to is not subdivided by severity levels. For instance, MS–DRG 311 (Angina Pectoris) has no severity level subdivisions; this MS–DRG is not split based on the presence of an MCC or a CC. If a patient assigned to this MS–DRG develops a secondary diagnosis such as a Stage III pressure ulcer after admission, the condition would be considered a HAC. The code for the Stage III pressure ulcer would be ignored in the MS–DRG assignment because the condition developed after the admission (the POA indicator was ''N''). Despite the fact that the ICD–9–CM code for the HAC Stage III pressure ulcer was ignored, the MS–DRG assignment would not change. The case would still be assigned to MS–DRG 311. Chart E below shows that 1,449 cases reporting a HAC (cases with HAC-associated diagnosis codes with a POA of ''N'' or ''U'') did not undergo a change in the MS–DRG assignment based on the fact that the case was assigned to a MS–DRG that had no severity subdivisions (that is, the MS–DRG is not subdivided based on the presence or absence of an MCC or a CC, rendering the presence of the HAC irrelevant for payment purposes). This represents approximately 9 percent of the 15,556 cases with HACs that did not have a change in MS–DRG assignment.

(4) MS–DRG Logic

Column G (MS–DRG Logic Issues) shows the frequency with which a HAC (cases with HAC-associated diagnosis codes with a POA of ''N'' or ''U'') did not result in an MS–DRG change because of MS–DRG assignment logic. There were seven discharges where the HAC criteria were met and the HAC logic was applied. However, due to the structure of the MS–DRG logic, these cases did not result in MS–DRG reassignment. These cases may appear similar to those discharges where the MS–DRG is subdivided into two severity levels by the presence or absence of an MCC and did not result in MS–DRG reassignment. However, these discharges differ slightly in that the MS–DRG logic also considers specific procedures that were reported on the claim. In other words, for certain MS–DRGs, a procedure may be considered the equivalent of an MCC or a CC. The presence of the procedure code dictates the MS–DRG assignment despite the presence of the HAC-associated secondary diagnosis code with a POA indicator of ''N'' or ''U.''

For example, a claim with the principal diagnosis code of 441.1 (Thoracic aneurysm, ruptured) with HAC-associated secondary diagnosis code of 996.64 (Infection and inflammatory reaction due to indwelling urinary catheter) and non-HAC secondary diagnosis code 599.0 (Urinary tract infection, site not specified), having POA indicators of ''Y,'' ''N,'' and ''N,'' respectively, and procedure code 39.73 (Endovascular implantation of graft in thoracic aorta) currently results in an assignment to MS–DRG 237 (Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm Repair). In this case, the thoracic aortic aneurysm repair is what dictated the MS–DRG assignment, and the presence of the HAC-associated secondary diagnosis code, 996.64, did not affect the MS–DRG assignment. Other examples of MS–

DRGs that are subdivided in this same manner are as follows:

- MS–DRG 029 (Spinal procedures with CC or Spinal Neurostimulators)
- MS–DRG 129 (Major Head & Neck Procedures with CC/MCC or Major Device)
- MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents)

Column G in the chart below shows that three of the seven cases that did not result in MS–DRG reassignment due to the MS–DRG logic were in the Falls and Trauma HAC category, two cases were in the Catheter Associated UTI HAC category and two cases were in the Vascular Catheter-Associated Infection HAC Category.

In conclusion, a total of 15,556 cases (11,818 + 2,282 +1,449 + 7) did not have a change in MS–DRG assignment, regardless of the presence of a HAC. The reasons described above explain why only 3,587 cases had a change in MS–DRG assignment despite the fact that there were 19,143 HACs (cases with HAC-associated diagnosis codes with a POA of ''N'' or ''U'').

CHART E—REASONS HAC DID NOT CHANGE MS–DRG ASSIGNMENT OCTOBER 2009 THROUGH SEPTEMBER 2010

Selected HAC category	Number of discharges with this condition as secondary diagnosis (Column A)	Number of discharges identified as a HAC (Column B)	Number of HAC discharges that change MS–DRG due to HAC (Column C)	HAC discharges that do not change MS–DRG			
				Number of other MCCs/CCs that prevent reassignment (Column D)	Number of MS–DRGs with two severity levels where HAC does not affect MS–DRG assignment * (Column E)	Number of MS–DRGs with no severity levels (Column F)	Other MS–DRG logic issues ** (Column G)
1. Foreign Object Retained After Surgery—CC	563	278	44	156	67	11	0
2. Air Embolism—MCC	42	29	15	14	0	0	0
3. Blood Incompatibility—CC	35	12	0	9	0	3	0
4. Pressure Ulcer Stages III & IV—MCC	114,138	1,444	292	895	0	257	0
5. Falls and Trauma—MCC & CC	154,371	5,454	1,672	2,858	570	351	3
6. Catheter-Associated UTI—CC	18,247	3,885	223	2,930	490	240	2
7. Vascular Catheter-Associated Infection—CC	10,066	4,366	22	3,656	189	497	2
8. Poor Glycemic Control—MCC & CC	16,267	526	107	364	3	52	0
9A. Surgical Site Infection, Mediastinitis, Following Coronary Artery Bypass Graft (CABG)—MCC	40	36	4	24	0	8	0
9B. Surgical Site Infection Following Certain Orthopedic Procedures—CC	363	220	2	136	79	3	0
9C. Surgical Site Infection Following Bariatric Surgery for Obesity—CC	18	17	0	17	0	0	0
10. Pulmonary Embolism & DVT Orthopedic—MCC & CC	3,494	2,876	1,206	759	884	27	0
Total [1]	317,644	19,143	3,587	11,818	2,282	1,449	7

[1] Discharges can appear in more than one row. The total figure is not adjusted for the approximately 94 discharges with more than one HAC that appear as secondary diagnoses (15 of these discharges resulted in MS–DRG reassignment).

* Examples where an HAC classified as a CC would not affect the DRG assignment if it were removed. The MS–DRG is subdivided by the presence or absence of an MCC. A CC would not impact this DRG assignment.

■ MS–DRGs 100 and 101 (Seizures with or without MCC, respectively).

■ MS–DRGs 102 and 103 (Headaches with or without MCC, respectively).

** Examples where HAC did not change MS–DRG assignment because of the MS–DRG logic.

■ MS–DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators).

■ MS–DRG 120 (Major Head & Neck Procedures with CC/MCC or Major Device).

Source: RTI Analysis of MedPAR IPPS Claims, October 2009 through September 2010.

g. RTI Analysis of Coding Changes for HAC-Associated Secondary Diagnoses for Current HACs

In addition to studying claims from October 2009 through September 2010, RTI evaluated claims data from 3 years prior to determine if there were significant changes in the number of discharges with a HAC-associated code being reported as a secondary diagnosis. To provide consistency with the FY 2010 data studied, RTI examined claims using discharge dates from October 2006 through September 2007 (for FY 2007), October 2007 through September 2008 (for FY 2008), October 2008 through September 2009 (FY 2009) and compared these data to the FY 2010 data.

We refer readers to the RTI detailed report for further information regarding all the conditions in each fiscal year (FY 2007 through FY 2010) as described above at the Web site: *http://www.rti.org/reports/cms/.*

h. RTI Analysis of Estimated Net Savings for Current HACs

RTI determined estimates of the net savings generated by the HAC payment policy based on MedPAR claims for FY 2010, from October 2009 through September 2010.

(1) Net Savings Estimation Methodology

The payment impact of a HAC is the difference between the IPPS payment amount under the initially assigned MS–DRG and the amount under the reassigned MS–DRG. The amount for the reassigned MS–DRG appears on the MedPAR files. To calculate this payment impact, RTI modeled the IPPS payments for each MS–DRG following the same approach that we use to model the impact of IPPS annual rule changes. Specifically, RTI replicated the payment computations carried out in the IPPS PRICER program using payment factors for IPPS providers as identified in various CMS downloaded files. The files used are as follows:

- Version 27 of the Medicare Severity GROUPER software (applicable to discharges between October 1, 2009 and September 30, 2010). IPPS MedPAR claims were run through this file to obtain needed HAC–POA output variables.
- The FY 2010 MS–DRG payment weight file. This file includes the weights, geometric mean length of stay (GLOS), and the postacute transfer payment indicators.
- CMS standardized operating and capital rates. Tables 1A through 1C, as downloaded from the Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS2010,* include the full update and reduced update amounts, as well as the information needed to compute the blended amount for providers located in Puerto Rico.
- The IPPS impact file for FY 2010, as downloaded from the Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS2010/.* This file includes the wage index and geographic adjustment factors plus the provider type variable to identify providers qualifying for alternative hospital-specific amounts and their respective hospital-specific payment rates.
- The IPPS impact file for FY 2011, as downloaded from the Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/11FR/.* This file includes indirect medical education (IME) and disproportionate share (DSH) percent adjustments as well as the operating and capital CCRs that were in effect as of March 2010.
- CMS historical provider-specific files (PSFs). These files include the indicator to identify providers subject to the full or reduced standardized rates and the applicable operating and capital CCRs. A SAS version was downloaded from the Web site at: *http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/04_psf_SAS.asp.* There were 50 providers with discharges in the final HAC analysis file that did not appear in the FY 2010 impact file, of which 11 also did not appear in the FY 2011 impact file. For these providers, we identified the geographic CBSA from the historical PSF and assigned the wage index using values from Tables 4A and 4C as downloaded from the Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS2010/.* For providers in the FY 2011 file but not the FY 2010 file, we used IME and DSH rates from FY 2011. The 11 providers in neither impact file were identified as non-IME and non-DSH providers in the historical PSF file.

The steps for estimating the HAC payment impact are as follows:

Step 1: Re-run the Medicare Severity GROUPER on all records in the analysis file. This is needed to obtain information on actual HAC-related MS–DRG reassignments in the file, and to identify the CCs and MCCs that contribute to each MS–DRG assignment.

Step 2: Model the base payment and outlier amounts associated with the initial MS–DRG if the HAC were excluded using the computations laid out in the CMS file ''Outlier Example FY 2007 new.xls,'' as downloaded from the Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/04_outlier.asp#TopOfPage,* and modified to accommodate FY 2010 factors. RTI's first round of computations treated all claims as though paid under standard IPPS rules without adjusting for short-stay transfers or hospital-specific payment amounts.

Step 3: Model the base payment and outlier amounts associated with the final MS–DRG where the HAC was excluded using the computations laid out in the CMS file ''Outlier Example FY 2007 new.xls,'' as downloaded from the Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/04_outlier.asp#TopOfPage* and modified to accommodate FY 2010 factors. RTI's first round of computations treated all claims as though paid under standard IPPS rules without adjusting for short-stay transfers or hospital-specific payment amounts.

Step 4: Compute MS–DRG base savings as the difference between the nonoutlier payments for the initial and final MS–DRGs. Compute outlier amounts as the difference in outlier amounts due under the initial and final reassigned MS–DRG. Compute net savings due to HAC reassignment as the sum of base savings plus outlier amounts.

Step 5: Adjust the model to incorporate short-stay transfer payment adjustments.

Step 6: Adjust the model to incorporate hospital-specific payments for qualifying rural providers receiving the hospital-specific payment rates.

It is important to mention that using the methods described above, the MS–DRG and outlier payments amounts that are modeled for the final assigned MS–DRG do not always match the MS–DRG price and outlier amounts that appear in the MedPAR record. There are several reasons for this. Some discrepancies are caused by using single wage index, IME, and DSH factors for the full period covered by the discharges, when, in practice, these payment factors can be adjusted for individual providers during the course of the fiscal year. In addition, RTI's approach disregards any Part A coinsurance amounts owed by individual beneficiaries with greater than 60 covered days in a spell of illness. Five percent of all HAC discharges showed at least some Part A coinsurance amount due from the beneficiary, although less than 2 percent of reassigned discharges (55 cases in the analysis file) showed Part A coinsurance amounts due. Any Part A coinsurance payments would reduce the actual savings incurred by the Medicare program.

There are also a number of less common special IPPS payment situations that are not factored into

RTI's modeling. These could include new technology add-on payments, payments for blood clotting factors, reductions for replacement medical devices, adjustments to the capital rate for new providers, and adjustments to the capital rate for certain classes of providers who are subject to a minimum payment level relative to capital cost.

(2) Net Savings Estimate

Chart F below summarizes the estimated net savings of current HACs based on MedPAR claims from October 2009 through 2010, based on the methodology described above. Column A shows the number of discharges where a MS–DRG reassignment for each HAC category occurred. For example, there were 15 discharges with an air embolism that resulted in an actual MS–DRG reassignment. Column B shows the total net savings caused by MS–DRG reassignments for each HAC category. Continuing with the example of air embolism, the chart shows that the 15 discharges with an MS–DRG reassignment resulted in a total net savings of $118,785. Column C shows the net savings per discharge for each HAC category. For the Air Embolism HAC category, the net savings per discharge is $7,919. Because a single discharge can have more than one HAC, discharges can appear in more than one row. The total net savings shown in the last line of Column B is adjusted to avoid duplicate counting and is therefore less than the sum of the net savings from the lines above.

CHART F—ESTIMATED NET SAVINGS OF CURRENT HACS OCTOBER 2009 THROUGH SEPTEMBER 2010

Selected HAC	Number of discharges that change MS–DRG due to HAC	Net savings (in dollars)	Net savings per discharge (in dollars)
	(Column A)	(Column B)	(Column C)
1. Foreign Object Retained After Surgery	44	$159,841	$3,633
2. Air Embolism	15	118,785	7,919
3. Blood Incompatibility	0	0	0
4. Pressure Ulcer Stages III & IV	292	1,795,456	6,149
5. Falls and Trauma:			
a. Fracture	1,439	8,119,308	5,642
b. Dislocation	4	13,244	3,311
c. Intracranial Injury	234	1,127,066	4,817
d. Crushing Injury	1	7,826	7,826
e. Burn	6	15,594	2,599
f. Shock	0	0	0
Less: Discharges with Multiple Falls & Trauma [1]	−12	−82,330	−6,861
5. Falls and Trauma: Unduplicated Total	1,672	9,200,708	5,503
6. Catheter-Associated UTI	223	696,662	3,124
7. Vascular Catheter-Associated Infection	22	77,690	3,531
8. Poor Glycemic Control	107	604,308	5,648
9a. SSI Mediastinitis CABG	4	32,392	8,098
9b. SSI Orthopedic	2	15,044	7,522
9c. SSI Bariatric	0	0	0
10. Pulmonary Embolism & DVT Orthopedic	1,206	8,826,912	7,319
Total	3,587	21,527,798	6,002
Less: Discharges with Multiple HACs [2]	−15	−77,703	−5,180
Unduplicated Total	3,572	21,450,095	6,005

[1] Discharges can have more than one Falls and Trauma HAC and therefore appear in more than one row.
[2] Discharges can have more than one HAC and therefore appear in more than one row.
Source: RTI Analysis of MedPAR IPPS Claims, October 2009 through September 2010.

As shown in Chart F above, the unduplicated total net savings calculated for the 12-month period from October 2009 through September 2010 was approximately $21.5 million. The three HACs with the largest number of discharges resulting in MS–DRG reassignment, Falls and Trauma, Orthopedic PE/DVT, and Pressure Ulcer Stages III & IV, generated approximately $19.83 million of net savings for the 12-month period. Estimated net savings for the 12-month period associated with the Falls and Trauma category were approximately $9.20 million. Estimated net savings associated with Orthopedic PE/DVT for the 12-month period were approximately $8.83 million. Estimated net savings for the 12-month period associated with Pressure Ulcer Stages III & IV were approximately $1.80 million.

The mean net savings per discharge calculated for the 12-month period from October 2009 through September 2010 was approximately $6,005. The HAC categories of Air Embolism; SSI, Mediastinitis, Following Coronary Artery Bypass Graft (CABG); and SSI Following Certain Orthopedic Procedures had the highest net savings per discharge, but represented a small proportion of total net savings because the number of discharges that resulted in MS–DRG reassignment for these HACs was low. With the exception of Blood Incompatibility and SSI Following Bariatric Surgery for Obesity, where no savings occurred because no discharges resulted in MS–DRG reassignment, Catheter-Associated UTI had the lowest net savings per discharge.

We refer readers to the RTI detailed report available at the Web site: *http://www.rti.org/reports/cms/*.

As mentioned previously, an extremely small number of cases in the 12-month period of FY 2010 analyzed by RTI had multiple HACs during the same stay. In reviewing approximately 10.2 million claims, RTI found

approximately 94 cases where 2 HACs were reported on the same admission as noted in section II.F.3.g.(2) of this preamble. Of these approximately 94 claims, 15 resulted in MS–DRG reassignment. Chart G below summarizes these cases. There were 15 cases that had 2 HACs not POA that resulted in an MS–DRG reassignment. Of these, four discharges involved Pressure Ulcer Stages III & IV, four discharges involved Falls and Trauma, and seven discharges involved Vascular Catheter-Associated Infection.

CHART G—CLAIMS WITH MORE THAN ONE HAC SECONDARY DIAGNOSIS WHERE MS–DRG REASSIGNMENT OCCURRED OCTOBER 2009 THROUGH SEPTEMBER 2010

Selected HAC	4. Pressure Ulcer Stages III & IV–MCC	5. Falls and Trauma—MCC & CC	7. Vascular Catheter-Associated Infection—CC
5. Falls and Trauma—MCC & CC	2	.....	.....
6. Catheter-Associated Urinary Tract Infection (UTI)—CC	1	2	6
7. Vascular Catheter-Associated Infection—CC	1	2	.....
9B. Surgical Site Infection Following Certain Orthopedic Procedures—CC	.....	.....	1
Total	4	4	7

As we discuss in section II.F.1.b. of this preamble, implementation of this policy is the part of an array of Medicare VBP tools that we are using to promote increased quality and efficiency of care. We point out that a decrease over time in the number of discharges where these conditions are not POA is a desired consequence. We recognize that estimated net savings would likely decline as the number of such discharges decline. However, we believe that the sentinel effect resulting from CMS identifying these conditions is critical. (We refer readers to section IV.A. of this preamble for a discussion of the inclusion of the incidence of these conditions in the Hospital IQR Program.) It is our intention to continue to monitor trends associated with the frequency of these HACs and the estimated net payment impact through RTI's program evaluation and possibly beyond.

i. Previously Considered Candidate HACs—RTI Analysis of Frequency of Discharges and POA Indicator Reporting

RTI evaluated the frequency of conditions previously considered, but not adopted as HACs in prior rulemaking, that were reported as secondary diagnoses (across all approximately 10.2 million discharges), as well as the POA indicator assignments for these conditions. Chart H below indicates that the four previously considered candidate conditions most frequently reported as a secondary diagnosis were: (1) Clostridium Difficile-Associated Disease (CDAD), which demonstrated the highest frequency, with a total of 90,243 secondary diagnoses codes being reported for that condition, of which 29,306 reported a POA indicator of ''N''; (2) Methicillin-Resistant Staphylococcus aureus, with a total of 72,313 secondary diagnoses codes being reported for that condition, with 2,165 of those reporting a POA indicator of ''N''; and (3) Staphylococcus aureus Septicemia, with a total of 24,327 secondary diagnoses codes being reported for that condition, with 5,490 of those reporting a POA indicator of ''N''; and (4) Iatrogenic Pneumothorax, with a total of 22,506 secondary diagnoses codes being reported for that condition, with 19,581 of those reporting a POA indicator of ''N.'' As these four conditions had the most significant impact for reporting a POA indicator of ''N,'' it is reasonable to believe that these same three conditions would have the greatest number of potential MS–DRG reassignments. The frequency of *discharges* for the previously considered HACs that could lead to potential changes in MS–DRG assignment is discussed in the next section. We take this opportunity to remind readers that because more than one previously considered HAC diagnosis code can be reported per discharge (on a single claim) that the frequency of these diagnosis codes may be more than the actual number of *discharges* with a previously considered candidate condition reported as a secondary diagnosis.

CHART H—POA STATUS OF PREVIOUSLY CONSIDERED ''CANDIDATE'' HAC CONDITIONS—OCTOBER 2009 THROUGH SEPTEMBER 2010

Previously considered HAC condition	Frequency as a secondary diagnosis	Not Present on Admission				Present on Admission			
		POA = N		POA = U		POA = Y		POA = W	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
1. Clostridium Difficile-Associated Disease (CDAD)	90,243	29,306	32.47	416	0.46	60,397	66.93	124	0.14
2. Delirium	757	190	25.10	.....	.....	567	74.90	0	0.00
3. Legionnaire's Disease	426	27	6.34	2	0.47	397	93.19	0	0.00
4. Staphylococcus aureus Septicemia	24,327	5,490	22.57	65	0.27	18,738	77.03	34	0.14
5. Methicillin-Resistant Staphylococcus aureus	72,313	2,165	2.99	124	0.17	70,008	96.81	16	0.02
6. Iatrogenic Pneumothorax	22,506	19,581	87.00	15	0.07	2,907	12.92	3	0.01
7. Ventilator-Associated Pneumonia	4,278	3,159	73.84	5	0.12	1,110	25.95	4	0.09

In Chart I below, Column A shows the number of discharges for each previously considered candidate HAC category when the condition was reported as a secondary diagnosis. For example, there were 90,243 discharges that reported CDAD as a secondary diagnosis. Previously considered candidate HACs reported with a POA indicator of ''N'' or ''U'' may cause MS–DRG reassignment (which would result in reduced payment to the facility).

Column C shows the discharges for each previously considered candidate HAC reported with a POA indicator of ''N'' or ''U.'' Continuing with the example of CDAD, Chart I shows that, of the 90,243 discharges, 29,722 discharges (32.94 percent) had a POA indicator of ''N'' or ''U.'' Therefore, there were a total of 29,722 discharges that could potentially have had an MS–DRG reassignment. Column E shows the number of discharges where an actual MS–DRG reassignment could have occurred; the number of discharges with CDAD that could have resulted in actual MS–DRG reassignments is 830 (2.79 percent). Thus, while there were 29,722 discharges with CDAD reported with a POA indicator of ''N'' or ''U'' that could potentially have had an MS–DRG reassignment, the result was 830 (2.79 percent) potential MS–DRG reassignments. As discussed above, there are a number of reasons why a condition reported with a POA indicator of ''N'' or ''U'' would not result in a MS–DRG reassignment.

In summary, Chart I below demonstrates there were a total of 214,785 discharges with a previously considered candidate HACs reported as a secondary diagnosis. Of those 60,538 discharges were reported with a POA indicator of ''N'' or ''U.'' The total number of discharges that could have resulted in MS–DRG reassignments is 3,768.

CHART I—PREVIOUSLY CONSIDERED ''CANDIDATE'' HAC DISCHARGE FREQUENCIES—OCTOBER 2009 THROUGH SEPTEMBER 2010

Previously considered HAC condition	Discharges with this condition as secondary diagnosis [2]		Discharges with this condition not present on Admission (POA = ''N'' or ''U'') [3]		Cases that could change MS–DRG due to previously considered candidate HAC [4]	
	Number (Column A)	Percent (Column B)	Number (Column C)	Percent (Column D)	Number (Column E)	Percent (Column F)
1. Clostridium Difficile-Associated Disease (CDAD)	90,243	0.89	29,722	32.94	830	2.79
2. Delirium	757	0.01	190	25.10	14	7.37
3. Legionnaire's Disease	426	0.00	29	6.81	3	10.34
4. Staphylococcus aureus Septicemia	24,288	0.24	5,549	22.85	97	0.02
5. Methicillin-Resistant Staphylococcus aureus	72,287	0.71	2,288	3.17	0	0.00
6. Iatrogenic Pneumothorax	22,506	0.22	19,596	87.07	2,821	14.40
7. Ventilator-Associated Pneumonia	4,278	0.04	3,164	73.96	3	0.09
Total [1]	214,785	.....	60,538	.....	3,768	.....

[1] Discharges can appear in more than one row.
[2] Percent computed relative to total cases ''at risk,'' which is 10,189,168 for all candidate conditions.
[3] Percent computed relative to discharges with condition as a secondary diagnosis.
[4] Percent computed relative to discharges with condition as a secondary diagnosis and identified as a previously considered HAC (that is, coded as not present on admission).
Source: RTI Analysis of MedPAR IPPS Claims, October 2009 through September 2010.

j. Current and Previously Considered Candidate HACs—RTI Report on Evidence-Based Guidelines

The RTI program evaluation includes an annual 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 10 selected conditions. In addition, evidence-based guidelines were also found for the previously considered candidate conditions.

RTI prepared the annual report to summarize its findings regarding evidence-based guidelines, which can be found on the Web site at: *http://www.rti.org/reports/cms.*

k. Final Policy Regarding Current HACs and Previously Considered Candidate HACs

We believe that the RTI analysis summarized above does not provide additional information that would require us to change our previous determinations regarding either current HACs (as described in section II.F.2. of this preamble) or previously considered candidate HACs in the FY 2008 IPPS final rule with comment period (72 FR 47200 through 47218), the FY 2009 IPPS final rule (73 FR 48471 through 48491), and the FY 2010 IPPS/RY 2010 LTCH final rule (74 FR 43782 through 43785). We note that we are finalizing revisions to the Falls and Trauma HAC category, Surgical Site Infection Following Certain Bariatric procedures and DVT/PE Following Certain Orthopedic Procedures HAC categories as discussed in section II.F.2. of this preamble. (We also note that, as discussed in section II.F.3.b. of this preamble, we are not contemplating changing our current policy regarding the treatment of the ''U'' POA indicator.) However, we continue to encourage public dialogue about refinements to the HAC list.

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 48474 through 48491) for detailed discussion supporting our determination regarding each of these conditions.

G. Changes to Specific MS–DRG Classifications

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25816), we invited 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 are also discussed below. In some cases, we proposed changes to the MS–DRG classifications based on our analysis of claims data. In other cases, we proposed to maintain the existing MS–DRG classification based on our analysis of

claims data. Below, we summarize the public comments that we received, if any, on our proposals, present our responses, and state our final policies.

1. Pre-Major Diagnostic Categories (Pre-MDCs)

a. Noninvasive Mechanical Ventilation

We received a request from the National Association for Medical Direction of Respiratory Care (NAMDRC) which suggested that we create a new MS–DRG for patients with certain respiratory conditions who receive noninvasive mechanical ventilation (NIV). The requestor stated that patients who receive NIV are almost always placed within an intensive care unit (ICU) or an emergency department and use the resources available in those areas. The requestor recommended that this new MS–DRG recognize current practice and allow for appropriate reimbursement for the technical complexity and monitoring required for NIV as a form of acute life support. According to the requestor, NIV has evolved to become first-line supportive therapy for several forms of acute respiratory failure. Lastly, the requestor recommended that the new MS–DRG identify NIV usage of approximately 6 to 12 hours to account for the ''legitimate but very short term use of this therapy.''

Historically, the concept of mechanical ventilation for critically ill patients included establishment of an artificial airway, invasively, through endotracheal intubation or a tracheostomy. According to the requestor, a significant portion of these patients can now be treated through *noninvasive* mechanical ventilation with the use of a face or nasal mask. In the ICD–9–CM classification system, NIV is described by procedure code 93.90 (Noninvasive mechanical ventilation), while invasive mechanical ventilation is described by procedure codes 96.70 (Continuous invasive mechanical ventilation of unspecified duration), 96.71 (Continuous invasive mechanical ventilation for less than 96 consecutive hours), and 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more). The requestor submitted external data to illustrate trends in NIV use over the past decade. These data were derived from a survey conducted during 2002–2003 of several hospitals located in Massachusetts and Rhode Island. The requestor believed that these data indicate patients with exacerbation of chronic obstructive pulmonary disease (COPD), acute pulmonary edema, or worsening congestive heart failure are successfully managed with NIV.

For the FY 2012 IPPS/LTCH PPS proposed rule, we analyzed FY 2010 MedPAR claims data that are representative of the respiratory conditions the requestor identified when reported with NIV. We found 14 MS–DRGs reporting procedure code 93.90 using the above specifications. The MS–DRGs are as follows:

Pre-MDC MS–DRGs:

- MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation 96+ Hrs or PDX Except Face, Mouth & Neck with Major O.R.)
- MS–DRG 004 (Tracheostomy with Mechanical Ventilation 96+ Hrs or PDX Except Face, Mouth & Neck without Major O.R.)
- MS–DRGs:
- MS–DRG 189 (Pulmonary Edema & Respiratory Failure)
- MS–DRG 190 (Chronic Obstructive Pulmonary Disease with MCC)
- MS–DRG 191 (Chronic Obstructive Pulmonary Disease with CC)
- MS–DRG 192 (Chronic Obstructive Pulmonary Disease without CC/MCC)
- MS–DRG 204 (Respiratory Signs & Symptoms)
- MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support 96+ Hours)
- MS–DRG 208 (Respiratory System Diagnosis with Ventilator Support <96 Hours)
- MS–DRG 222 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC)
- MS–DRG 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC)
- MS–DRG 291 (Heart Failure & Shock with MCC)
- MS–DRG 292 (Heart Failure & Shock with CC)
- MS–DRG 293 (Heart Failure & Shock without CC/MCC)

As shown in the list above and in the chart below, the MS–DRGs identified also include those that describe invasive mechanical ventilation. The ICD–9–CM coding convention instructs the reporting of both types of mechanical ventilation when patients are admitted on noninvasive mechanical ventilation that subsequently requires invasive mechanical ventilation therapy.

The data demonstrate that, in certain MS–DRGs, for example, MS–DRGs 003, 004, and 222 that the cases with NIV primarily have shorter lengths of stay and lower average costs compared to all the cases in those MS–DRGs. Alternatively, the data for MS–DRGs 189, 190, 191, and 192 demonstrate that the cases with NIV have an increased length of stay and higher average costs, but a relatively low volume compared to all the cases in those MS–DRGs. Combining the current surgical and medical MS–DRGs into a single, new MS–DRG would include noninvasive mechanical ventilation cases with a wide range of costs for several indications with varying levels of severity. The average costs for these cases range from a low of $5,794 in MS–DRG 293 to a high of $95,940 in MS–DRG 003. In the proposed rule, we indicated that we believe the cases are more appropriately assigned and reimbursed in the MS–DRGs to which they are currently assigned.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 003—All cases	18,223	34.7	$103,492
MS–DRG 003—Cases with code 93.90 without code 96.70, 96.71, or 96.72	58	33.3	95,940
MS–DRG 004—All cases	19,599	25.79	63,022
MS–DRG 004—Cases with code 93.90 without code 96.70, 96.71, or 96.72	170	25.43	58,500
MS–DRG 189—All cases	87,668	5.36	8,317
MS–DRG 189—Cases with code 93.90 without code 96.70, 96.71, or 96.72	22,023	6.07	10,383
MS–DRG 190—All cases	130,731	5.30	7,140
MS–DRG 190—Cases with code 93.90 without code 96.70, 96.71 or 96.72	8,450	6.78	11,207
MS–DRG 191—All cases	135,851	4.49	6,236
MS–DRG 191—Cases with code 93.90 without code 96.70, 96.71 or 96.72	4,563	5.41	8,819
MS–DRG 192—All cases	115,153	3.52	4,621
MS–DRG 192—Cases with code 93.90 without code 96.70, 96.71 or 96.72	2,334	4.25	6,803
MS–DRG 204—All cases	21,049	2.61	4,310
MS–DRG 204—Cases with code 93.90 without code 96.70, 96.71 or 96.72	265	4.17	7,591
MS–DRG 207—All cases	32,752	14.61	32,897

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 207—Cases with code 93.90 without code 96.70, 96.71 or 96.72	0	0	0
MS–DRG 208—All cases	67,724	6.98	14,742
MS–DRG 208—Cases with code 93.90 without code 96.70, 96.71 or 96.72	0	0	0
MS–DRG 222—All cases	2,279	11.98	57,478
MS–DRG 222—Cases with code 93.90 without code 96.70, 96.71 or 96.72	52	11.79	55,011
MS–DRG 223—All cases	3,230	6.17	41,754
MS–DRG 223—Cases with code 93.90 without code 96.70, 96.71 or 96.72	19	11.05	47,064
MS–DRG 291—All cases	170,399	6.05	9,585
MS–DRG 291—Cases with code 93.90 without code 96.70, 96.71 or 96.72	14,274	6.95	12,320
MS–DRG 292—All cases	220,031	4.72	6,584
MS–DRG 292—Cases with code 93.90 without code 96.70, 96.71 or 96.72	5,171	5.58	9,180
MS–DRG 293—All cases	98,134	3.20	4,410
MS–DRG 293—Cases with code 93.90 without code 96.70, 96.71 or 96.72	1,381	3.43	5,794

As mentioned in the requestor's comments, and our clinical advisors agree, NIV encompasses a broad range of interventions and utilizes periods of time that range from a few hours to a few days of continuous chronic use. Resource requirements are vastly different for the various intended indications. For example, as also noted by the requestor, respiratory failure can have many forms. Our clinical advisors provided three subsets of patients as an example: Those that are given oxygen support, those that are given pressure (rate) support, and those that are intubated. There is overlap between the three subsets in that a patient may require one, two, or all three types of therapy and there are multiple options for any given patient. Our clinical advisors stated that these various subsets of patients can require significantly different resources. Lastly, respiratory failure reflects the severity of the diagnosis (it is a complication) while NIV is a therapeutic option. Unlike a major surgical intervention where the intervention creates morbidity, NIV merely reflects the severity of the underlying respiratory failure.

The requestor further noted in its comments that a significant number of patients who receive NIV fail this therapy and must be intubated and subsequently placed on a ventilator. However, those patients who require both noninvasive and invasive mechanical ventilation are already accounted for in the invasive mechanical ventilation MS–DRGs. Similar to patients with respiratory failure, patients with heart failure and shock have a comparable severity of illness where each condition reflects the severity of the diagnosis (it is a complication). Therefore, the cost is already reflected in the high resource expenditure estimates for MS–DRGs 222, 223, 291, 292, and 293, as are all other severity-correlated resource costs.

In conclusion, we indicated in the proposed rule that we believe that the data do not support the creation of a single MS–DRG to identify NIV cases. As stated previously, the average costs for the NIV cases range from a low of $5,794 in MS–DRG 293 to a high of $95,940 in MS–DRG 003. If created, this single MS–DRG would include patients with a wide range in average costs. We believe the cases are more appropriately captured in their current MS–DRGs. In addition to the clinical points raised by our clinical advisors and outlined above, the volume and length of stay data for cases where NIV was reported with the specified respiratory conditions further support their present MS–DRG assignments. Therefore, we did not propose to create a new MS–DRG for patients receiving NIV. We invited public comment on our proposal not to create a new MS–DRG for patients receiving NIV for FY 2012.

Comment: Several commenters agreed with CMS' proposal to not create a new MS–DRG for patients receiving NIV for FY 2012. One commenter did not have a position on whether or not a new MS–DRG should be created for patients receiving noninvasive mechanical ventilation. However, the commenter was concerned that reported hospital data may be incomplete. The commenter indicated that procedure code 93.90 (Noninvasive mechanical ventilation) is most likely underreported or not reported consistently because it is not required for reporting purposes. Another commenter stated that the data analysis performed on patients receiving NIV appeared to be supported by the current MS–DRG assignment. Therefore, the commenter agreed with the proposal not to create a new MS–DRG. This commenter also urged CMS to consider the Uniform Hospital Discharge Data Set (UHDDS) definition of a ''reportable condition'' in future analyses. This commenter noted that the UHDDS requires all significant procedures to be reported and that Medicare requires the reporting of any procedure that affects payment, whether or not it meets the definition of significant procedure. This commenter further noted that procedure code 93.90 is not considered significant by the UHDDS definition nor does it affect payment.

Response: We appreciate the commenters' support of our proposal to not create a new MS–DRG for patients receiving NIV for FY 2012. We agree with the commenters that procedure code 93.90 is likely not reported consistently and, therefore, the data included in evaluating the request may be incomplete. We encourage complete and accurate reporting of ICD–9–CM codes on each admission. As discussed in section II.G.13.b. of this final rule, we have expanded our ability to accept and process up to 25 diagnosis codes and 25 procedure codes with the implementation of 5010. We agree with the commenters who state that the current data do not support a new MS–DRG for patients receiving NIV.

We also agree with the commenter that NIV (procedure code 93.90) is not considered to be a significant procedure under UHDDS definitions and does not affect payment under Medicare policy. UHDDS definitions are used by hospitals to report inpatient data elements in a standardized manner. For further information regarding UHDDS data elements and their definitions, we refer readers to the July 31, 1985 **Federal Register** (50 FR 31038 through 31040) and the Internet Web site at: *http://www.ncvhs.hhs.gov/ncvhsr1.htm.*

Comment: The organization that submitted the original request to create a new MS–DRG for NIV expressed appreciation to CMS for considering their request and for providing data that was unavailable to them at the time they submitted their original request. The commenter also acknowledged the potential for underreporting of NIV (procedure code 93.90). However, the commenter specifically asked to further

refine their original request based on the data that were displayed in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25818). The commenter suggested that CMS now limit consideration of a new MS–DRG for NIV to only the data that were displayed for 4 of the 14 MS–DRGS analyzed in response to their original request. The commenter asked CMS to now only focus on the data that was provided for the following MS–DRGs:

- MS–DRG 189 (Pulmonary Edema & Respiratory Failure)
- MS–DRG 190 (Chronic Obstructive Pulmonary Disease with MCC)
- MS–DRG 191 (Chronic Obstructive Pulmonary Disease with CC)
- MS–DRG 192 (Chronic Obstructive Pulmonary Disease without CC/MCC)

The commenter recommended that CMS utilize respiratory failure, pulmonary edema, and chronic obstructive pulmonary disease as diagnoses that, when present with NIV, define the structure of a new NIV MS–DRG.

Response: We acknowledge the commenter's request that we now consider a refined request that focuses on only 4 of the 14 MS–DRGs originally analyzed. However, due to time constraints, we were unable to conduct the necessary analysis for evaluation. We would need to perform a new and separate analysis with exact specifications that were not provided by the commenter in their modified request before we could make a final determination. For example, there are numerous ICD–9–CM codes that describe respiratory failure, pulmonary edema, and chronic obstructive pulmonary disease. The commenter did not specify the exact codes they believe would warrant this modified MS–DRG when reported with procedure code 93.90 (NIV) for us to conduct a thorough analysis in time to include our evaluation in this final rule.

Therefore, after consideration of public comments we received, we are finalizing our proposal to not create a new MS–DRG for NIV for FY 2012.

b. Debridement With Mechanical Ventilation Greater Than 96 Hours With Major Operating Room (O.R.) Procedure

We received a comment concerning the use of excisional debridement in cases with complications that lead to the need for extended mechanical ventilation. The commenter stated that patients undergoing procedures such as excisional debridement may also develop extensive complications such as respiratory failure and sepsis. The commenter indicated that these patients tend to use significant resources. The commenter stated that these cases are currently assigned to MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support 96+ Hours) or MS–DRG 870 (Septicemia with or Severe Sepsis with Mechanical Ventilation 96+ Hours). The commenter expressed a concern that the operating room (OR) procedure of the excisional debridement was not fully recognized through either of these two medical MS–DRGs. The commenter requested that a new MS–DRG be created that would include mechanical ventilation of greater than 96 hours with the presence of an additional major OR procedure.

We agree that patients with long-term mechanical ventilation greater than 96 hours and a major OR procedure utilize extensive resources. However, we point out that these patient cases are not currently assigned to MS–DRG 207 or MS–DRG 870 as the commenter stated. Many of these long-term mechanical ventilation patient cases are instead assigned to MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation 96+ Hours or PDX, Excluding Face, Mouth & Neck with Major Operating Room Procedure). Cases that require mechanical ventilation for greater than 96 hours, that have a tracheostomy performed, and that have a procedure on the major O.R. list (including excisional debridement) are assigned to MS–DRG 003. We specifically created MS–DRG 003 to capture these complicated patients on long-term mechanical ventilation who also have a major O.R. procedure. Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we did not propose to create a second MS–DRG to capture these patients. We welcomed public comments on our proposal not to create a new MS–DRG for these patients for FY 2012.

Comment: Several commenters supported our proposal not to create a second MS–DRG to capture patients with mechanical ventilation of greater than 96 hours with the presence of an additional major OR procedure. One commenter stated that the limited data and documentation from the requestor for the creation of a second MS–DRG prohibited them from evaluating the need for this new MS–DRG.

Response: We agree with the commenters that CMS should not create a second MS–DRG to capture patients with mechanical ventilation of greater than 96 hours with the presence of an additional major OR procedure. MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation 96+ Hours or PDX, Excluding Face, Mouth & Neck with major Operating Room Procedure) appropriately captures these patients.

After consideration of the public comments we received, we are not creating a new MS–DRG to capture patients on mechanical ventilation of greater than 96 hours who also have an additional major OR procedure for FY 2012.

c. Autologous Bone Marrow Transplant

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50101), effective October 1, 2011, we deleted MS–DRG 009 (Bone Marrow Transplant) and created two new MS–DRGs: MS–DRG 014 (Allogeneic Bone Marrow Transplant) and MS–DRG 015 (Autologous Bone Marrow Transplant). We created new MS–DRGs 014 and 015 because of differences in costs associated with these procedures. During the comment period for the FY 2011 IPPS/LTCH PPS proposed rule, two commenters who supported the proposed reclassification of the bone marrow transplant MS–DRGs requested further refinement to account for severity of illness. At that time, we did not subdivide MS–DRG 014 and MS–DRG 015 based on severity of illness because they did not meet our criteria for subdivision (75 FR 50102).

As we outlined in our FY 2008 IPPS/LTCH PPS final rule with comment period (72 FR 47169), in designating an MS–DRG as one that would be subdivided into subgroups based on the presence of a CC or an MCC, we developed a set of criteria to facilitate our decision-making process. The original criteria were based on average charges; we now use average costs (FY 2007 IPPS final rule, 71 FR 47882). In order to warrant creation of a CC or an MCC subgroup within a base MS–DRG, the subgroup must meet all of the following five criteria:

- A reduction in variance of cost of at least 3 percent.
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup.
- At least 500 cases are in the CC or MCC subgroup.
- There is at least a 20-percent difference in average cost between subgroups.
- There is a $2,000 difference in average cost between subgroups.

For the FY 2012 IPPS/LTCH PPS proposed rule, we examined FY 2010 MedPAR claims data for these newly created MS–DRGs, and based on these criteria, we identified MS–DRG 015 as a possible MS–DRG that would require further subdivision. MS–DRG 014 was not identified, as this MS–DRG did not meet the criteria stated above for possible subdivision. Autologous bone

marrow transplantation utilizes the patient's own bone marrow or stem cells in the treatment of certain cancers and bone marrow diseases. These procedures restore stem cells that have been destroyed either by chemotherapy and/or radiation treatment.

In our analysis, we found 1,338 total cases assigned to MS–DRG 015 with average costs of approximately $38,608 and an average length of stay of approximately 18.8 days. There were 1,092 cases that had a secondary diagnosis code reported on the claim that was designated as a CC or an MCC with average costs of approximately $40,974 and an average length of stay of approximately 19.7 days. There were 246 cases without a secondary diagnosis code reported on the claim that had a CC or an MCC designation with average cost of approximately $28,105 and an average length of stay of approximately 14.6 days. The following table illustrates our findings:

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 015—All cases	1,338	18.8	$38,608
MS–DRG 015—Cases with MCC/CC	1,092	19.7	40,974
MS–DRG 015—Cases without MCC/CC	246	14.6	28,105

We found that the cases reported with a secondary diagnosis code of a CC or an MCC were more costly and had a longer average length of stay than both the overall cases assigned to MS–DRG 015 and the cases without a CC or an MCC. The cases without a CC or an MCC were less costly and had a shorter average length of stay than both the cases with a CC or an MCC and the overall cases assigned to that MS–DRG. Based on our analysis, all five criteria for a subgroup division were met, thereby supporting a 2-level severity split for MS–DRG 015. Therefore, for FY 2012, we proposed to delete MS–DRG 015 and create two new MS–DRGs:

- Proposed MS–DRG 016 (Autologous Bone Marrow Transplant with MCC/CC); and
- Proposed MS–DRG 017 (Autologous Bone Marrow Transplant without MCC/CC).

We invited public comment on our proposal to delete MS–DRG 015 and create two new MS–DRGs 016 and 017 for autologous bone marrow transplant for FY 2012.

Comment: Several commenters supported our proposed changes for a 2-level severity split for autologous bone marrow transplant cases. One commenter stated that it appreciated CMS' further refinement to account for severity of illness as it reflects current experience with transplant eligible patients who present with a range of comorbidities and other complicating factors.

Response: We appreciate the support of the commenters.

Comment: One commenter disagrees with our proposed refinement of MS–DRG 014 to account for severity of illness. The commenter contended that the recipient patient population for both autologous and allogeneic transplants is similar and that recognition of the variation in the patient population for both is warranted. The commenter requested a re-review of the cost variances for MS–DRG 014 because allogeneic transplant patients are often treated for similar comorbidities as autologous transplant patients prior to transplant and during post transplant care.

Response: As we outlined in the proposed rule (76 FR 25819), to warrant creation of a CC or MCC subgroup within a base MS–DRG, the subgroup must meet all of the five criteria. MS–DRG 014 did not meet the criteria for possible subdivision because at least 500 cases were not in the CC or MCC subgroup.

After consideration of the public comments we received, we are finalizing our proposal to delete MS–DRG 015 and to create two new MS–DRGs: MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC); and MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC). We note that we have amended the final titles of new MS–DRGs 015 and 016 to place ''CC'' before ''MCC.''

2. MDC 1 (Diseases and Disorders of the Nervous System): Rechargeable Dual Array Deep Brain Stimulation System

We received a public comment in response to the FY 2011 IPPS/LTCH PPS proposed rule regarding the MS–DRG assignment for rechargeable dual array deep brain neurostimulators. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50128), we indicated that we considered this comment outside of the scope of the proposed rule as we did not propose any changes for these procedures for FY 2011. However, we addressed this issue in the FY 2012 IPPS/LTCH PPS proposed rule.

Deep brain stimulation is a surgical treatment that involves the implantation of a neurostimulator, used in the treatment of essential tremor, Parkinson's disease, dystonia, and chronic pain. The commenter recommended that CMS assign the combination of procedure codes representing rechargeable systems for deep brain stimulation therapy, procedure code 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)) and procedure code 86.98 (Insertion or replacement of dual array rechargeable neurostimulator pulse generator) to MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemo Implant) and MS–DRG 024 (Craniotomy with Major Device Implant/Acute Complex CNS PDX without MCC).

The commenter stated that this recommendation would allow all full system dual array deep brain stimulation cases to be appropriately grouped to the same MS–DRGs. Currently, procedure codes 02.93 and 86.98 are assigned to MS–DRG 025 (Craniotomy and Endovascular Intracranial Procedures with MCC), MS–DRG 026 (Craniotomy and Endovascular Intracranial Procedures with CC), and MS–DRG 027 (Craniotomy and Endovascular Intracranial Procedures without CC/MCC), while the procedure codes for the nonrechargeable dual array systems, procedure codes 02.93 and 86.95 (Insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable), are already assigned to MS–DRGs 023 and 024. The commenter stated that the procedures to implant the rechargeable and nonrechargeable dual array systems are similar clinically as well as comparable in resource utilization.

For the FY 2012 IPPS/LTCH PPS proposed rule, we analyzed FY 2010 MedPAR data and found a total of 16 full system rechargeable dual array deep brain stimulation systems reported with procedure codes 02.93 and 86.98 assigned to MS–DRGs 025 through 027. We found one case assigned to MS–DRG 025 and one case assigned to MS–DRG

026. The majority of the cases, 14, were assigned to MS–DRG 027, with average costs of approximately $23,870 and an average length of stay of approximately 2.2 days. We found that the deep brain stimulation cases assigned to MS–DRG 027 had higher average costs than the overall cases assigned to MS–DRG 027 of approximately $14,200. However, the average length of stay was shorter for these cases than the overall length of stay for MS–DRG 027 cases of approximately 3.7 days.

We also examined the data for the nonrechargeable dual array systems to assess the commenter's assumption that both the rechargeable and nonrechargeable dual array systems are similar in resource use. We found 155 total nonrechargeable dual array systems (procedure codes 02.93 and 86.95) assigned to MS–DRGs 023 and 024. There were 5 cases assigned to MS–DRG 023, with average costs of approximately $36,159 and an average length of stay of approximately 10 days. We found that the majority of the cases, 150, were assigned to MS–DRG 024, with average costs of approximately $25,855 and an average length of stay of approximately 2.2 days. We believe that these data support the commenter's statement that, for the majority of these cases, the resource use is similar for both systems.

For comparison purposes, if we proposed the changes that the commenter suggested, those deep brain stimulation cases currently assigned to MS–DRG 027 and the one case assigned to MS–DRG 026 (with average costs of approximately $27, 836) would be reassigned to MS–DRG 024. The average costs of approximately $23,870 of these deep brain stimulation cases assigned to MS–DRG 027 are similar to the overall average costs of approximately $23,249 for MS–DRG 024. The one case assigned to MS–DRG 025 (with average costs of approximately $29,361) would be reassigned to MS–DRG 023 (with average costs of approximately $34,168). The following table illustrates our findings:

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 023—All cases	4,238	11.8	$34,168
MS–DRG 023—Cases with codes 02.93 and 86.95	5	10.0	36,159
MS–DRG 024—All cases	1,592	7.6	23, 249
MS–DRG 024—Cases with codes 02.93 and 86.95	150	2.2	25,855
MS–DRG 025—All cases	11,505	11.0	29,524
MS–DRG 025—Cases with codes 02.93 and 86.98	1	2.0	29, 361
MS–DRG 026—All cases	9,782	7.0	19,125
MS–DRG 026—Cases with codes 02.93 and 86.98	1	3.0	27,836
MS–DRG 027—All cases	10,936	3.7	14,200
MS–DRG 027—Cases with codes 02.93 and 86.98	14	2.2	23,870

Based on our findings, in the proposed rule, we indicated that we believe that the data support reassigning the combination of procedure codes representing rechargeable systems for deep brain stimulation therapy, code 02.93 and code 86.98, to MS–DRGs 023 and 024. Our clinical advisors support this reassignment. Therefore, we proposed to assign rechargeable dual array systems for deep brain stimulation cases identified by reporting both procedure codes 02.93 and 86.98 to MS–DRGs 023 and 024 for FY 2012. We invited public comment on our proposal to assign these cases to MS–DRG 023 and 024 for FY 2012.

Comment: Several commenters supported our proposal to reassign rechargeable dual array deep brain stimulation cases.

Response: We appreciate the support of the commenters. As stated above, we believe that the assignment of these cases to MS–DRG 023 and 024 is appropriate.

After consideration of public comments we received, we are adopting as final our proposal to assign rechargeable dual array systems for deep brain stimulation cases identified by reporting both procedure codes 02.93 and 86.98 to MS–DRGs 023 and 024 for FY 2012.

3. MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth, and Throat): Skull Based Surgeries

We received a request from a commenter recommending that CMS reclassify skull-based surgical procedures that are currently assigned to MS–DRGs 135 and 136 (Sinus and Mastoid Procedures with CC/MCC and without CC/MCC, respectively) and reassign them to MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively). The commenter stated that the current MS–DRG assignment does not reflect the resource utilization and technical complexity of these difficult procedures when performed for anterior skull base tumors.

Skull (or cranial) based surgery is performed for a variety of serious medical conditions including esthesioneuroblastomas, which are rare, malignant tumors that arise from the epithelium overlying the olfactory bulb; sinonasal melanomas, which are malignant melanomas that may develop in the mucosa of the nose and sinuses; and sinonasal undifferentiated carcinomas, which are rapidly growing malignant tumors arising in the nasal cavity and/or sinuses. These types of conditions are generally identified by the following ICD–9–CM diagnosis codes:

- 160.0 (Malignant neoplasm of nasal cavities)
- 160.1 (Malignant neoplasm of auditory tube, middle ear, and mastoid air cells)
- 160.2 (Malignant neoplasm of maxillary sinus)
- 160.3 (Malignant neoplasm of ethmoidal sinus)
- 160.4 (Malignant neoplasm of frontal sinus)
- 160.5 (Malignant neoplasm of sphenoidal sinus)
- 160.8 (Malignant neoplasm of other accessory sinuses)
- 160.9 (Malignant neoplasm of accessory sinus, unspecified)
- 210.7 (Benign neoplasm of nasopharynx)
- 212.0 (Benign neoplasm of nasal cavities, middle ear, and accessory sinuses)

According to the commenter, procedure code 22.63 (Ethmoidectomy) describes the type of surgery being performed for these patients and is currently assigned to MS–DRGs 135 and 136.

For the FY 2012 IPPS/LTCH PPS proposed rule, using the FY 2010 MedPAR file, we examined data on

cases identified by procedure code 22.63 when reported with one of the above listed diagnosis codes in MS–DRGs 135 and 136. We found a total of 402 cases in MS–DRG 135 with an average length of stay of 6.30 days and average costs of $12,869. We found only 23 cases in MS–DRG 135 identified by procedure code 22.63 with one of the diagnosis codes listed above with an average length of stay of 3.96 days and average costs of $10,510. In MS–DRG 136, there were a total of 320 cases with an average length of stay of 2.36 days and average costs of $6,683. We found only 27 cases in MS–DRG 136 identified by procedure code 22.63 with one of the diagnosis codes listed above with an average length of stay of 2.04 days and average costs of $6,844. As shown in the table below, the cases reporting procedure code 22.63 in MS–DRGs 135 and 136 have a lower volume, a shorter length of stay, and primarily lower average costs compared to all cases in MS–DRGs 135 and 136. As we indicated in the proposed rule, the data demonstrated that these cases are appropriately assigned to their current MS–DRG classifications.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 135—All cases	402	6.30	$12,869
MS— DRG 135—Cases with procedure code 22.63 and diagnosis code 160.0 through 160.9 or 210.7 or 212.0	23	3.96	10,510
MS–DRG 136—All cases	320	2.36	6,683
MS–DRG 136—Cases with procedure code 22.63 and diagnosis code 160.0 through 160.9 or 210.7 or 212.0	27	2.04	6,844

We also analyzed claims data for MS–DRGs 25 through 27. We determined that if the cases identified by procedure code 22.63 were to be reassigned to MS–DRGs 25–27, they would be significantly overpaid. As shown in the table below, we found that the average costs for these MS–DRGs range from $14,200 to $29,524.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 025—All cases	11,505	10.95	$29,524
MS–DRG 026—All cases	9,782	7.00	19,125
MS–DRG 027—All cases	10,936	3.71	14,200

In summary, we indicated in the proposed rule that the data did not support moving cases with procedure code 22.63 when reported with one of the previously listed diagnosis codes from MS–DRGs 135 and 136 to MS–DRGs 25, 26 and 27. We invited public comment on our proposal not to make any MS–DRG modifications for these codes for FY 2012.

Comment: Several commenters supported our proposal to not make any revisions to reclassify skull-based surgical procedures that are currently assigned to MS–DRGs 135 and 136 and reassign them to MS–DRGs 025, 026, and 027.

Response: We appreciate the commenters' support.

After consideration of the public comment we received, we are finalizing our proposal to not make any modifications for skull-based surgeries for FY 2012.

4. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Percutaneous Mitral Valve Repair With Implant

Procedure code 35.97 (Percutaneous mitral valve repair with implant) was created for use beginning October 1, 2010 (FY 2011) after the concept of a percutaneous valve repair was presented and approved at the February 2010 ICD–9–CM Coordination and Maintenance Committee Meeting. Procedure code 35.97 was created at that time to describe the MitraClip™ device and any other percutaneous mitral valve repair devices currently on the market. This procedure code is assigned to the following MS–DRGs: 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively); 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with 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).

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 believe that the most likely MS–DRG assignments would be MS–DRGs 250 and 251, as described above. However, because procedure code 35.97 has only been in use since October 1, 2010, there are no claims data in the most recent MedPAR update file with which to evaluate any alternative MS–DRG assignments. Therefore, we did not propose to make any MS–DRG changes for procedure code 35.97 for FY 2012. We proposed to keep procedure code 35.97 in its current MS–DRG assignments. We invited public comment on this proposal.

Comment: Several commenters addressed our proposal. One commenter supported our proposal not to make any MS–DRG changes in the current assignment of procedure code 35.97, but also recommended that CMS review the MS–DRG assignment for FY 2013 when more claims data become available. In addition, one commenter indicated that it "* * * has no objections to CMS' proposed changes to the MS–DRG classifications and the Medicare Code Editor, which seem reasonable, given the data and information provided."

Response: We appreciate the commenters' support and suggestion.

After consideration of the public comments we received, we are adopting as final without modification our

proposal to keep procedure code 35.97 (Percutaneous mitral valve repair with implant) in its current MS–DRG assignments of 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively); 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with 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).

In addition, we plan to conduct a review of the MedPAR data for code 35.97 in our next annual IPPS update cycle (that is, for FY 2013) to determine if the MS–DRG assignments as listed above are the most appropriate MS–DRGs for this procedure.

b. Aneurysm Repair Procedure Codes

Thoracic aorta defects, such as aneurysm, dissection, or injury, are uncommon but serious conditions that may arise from a disease or an accident. Some patients can be medically managed but most are treated with surgery. Often these defects result in death if they are not diagnosed and treated promptly. Currently, there are two techniques used for repair of aortic defects; both are O.R. procedures performed in an inpatient hospital setting. These two procedures are described by ICD–9–CM procedure codes 38.45 (Resection of vessel with replacement, thoracic vessel) and 39.73 (Endovascular implantation of graft in thoracic aorta). Both procedure codes 38.45 and 39.73 are currently assigned to MS–DRGs 237 (Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm Repair) and 238 (Major Cardiovascular Procedures without MCC).

We received a request that we consider the reassignment of procedure codes 38.45 and 39.73 within the MS–DRG structure by removing the procedure codes from MS–DRGs 237 and 238 and adding them to a more clinically coherent set of MS–DRGs reflecting higher resource consumption. The requestors believed that, based on their analysis of MedPAR claims data of MS–DRGs 237 and 238, the resource utilization of both the endovascular and open repairs of the abdominal and thoracic aortas are higher than the overall average resource utilization for the MS–DRGs to which these procedures are currently assigned. The requestors also believed that an unusually high number of cases probably fall into cost outlier status.

For the FY 2012 IPPS/LTCH PPS proposed rule, we reviewed the MedPAR claims data for these two procedure codes. Our findings are shown in the following two tables.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 237—All cases	20,680	10.03	$34,268
MS–DRG 237—Cases with procedure code 39.73	1,851	7.73	41,033
MS–DRG 237—Cases without procedure code 39.73	18,829	10.26	33,603
MS–DRG 238—All cases	35,705	4.08	20,597
MS–DRG 238—Cases with procedure code 39.73	0	0	0
MS–DRG 238—Cases without procedure code 39.73	35,705	4.08	20,597

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 237—All cases	20,680	10.03	$34,268
MS–DRG 237—Cases with procedure code 38.45	448	13.29	51,953
MS–DRG 237—Cases without procedure code 38.45	20,234	9.96	33,878
MS–DRG 238—All cases	35,705	4.08	20,597
MS–DRG 238—Cases with procedure code 38.45	466	7.29	30,219
MS–DRG 238—Cases without procedure code 38.45	35,239	4.03	20,465

Our findings of the analysis of the cases with procedure code 39.73 showed that the average costs are substantially higher than those costs for the cases overall in both MS–DRGs 237 and 238. We found that the average length of stay for the 1,851 cases identified in MS–DRG 237 is somewhat lower at 7.73 days than the average length of stay of 10.26 days in cases not containing procedure code 39.73.

Our findings of the analysis of the cases with procedure code 38.45 showed that both the average costs and the average length of stay are considerably higher than the average costs and the average length of stay for those cases without procedure code 38.45.

In addition, we reviewed the cases in which both procedure codes 38.45 and 39.73 were documented during the same admission. As can be seen in the charts below, we found 22 cases in which both procedure codes 38.45 and 39.73 were reported. Therefore, the sum of the values in the next two charts below will differ from the charts above because the cases containing both procedure codes have been removed and the data have been reworked.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 237—All cases	20,680	10.03	$34,268
MS–DRG 237—Cases with procedure code 39.73 and without procedure code 38.45	1,829	7.68	40,862
MS–DRG 237—Cases with procedure code 38.45 and without procedure code 39.73	424	13.36	51,783
MS–DRG 238—All cases	35,705	4.08	20,597

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 238—Cases with procedure code 39.73 and without procedure code 38.45	0	0	0
MS–DRG 238—Cases with procedure code 38.45 and without procedure code 39.73	466	7.29	30,219

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 237—All cases	20,680	10.03	$34,268
MS–DRG 237—Cases with procedure code 38.45 and with procedure code 39.73	22	11.86	55,243
MS–DRG 237—Cases without procedure code 38.45 or procedure code 39.73	18,405	10.19	33,184
MS–DRG 238—All cases	35,705	4.08	20,597
MS–DRG 238—Cases with procedure code 38.45 and with procedure code 39.73	0	0	0
MS–DRG 238—Cases without procedure code 38.45 or procedure code 39.73	35,239	4.03	20,465

We found in our analysis of the claims data for cases with both procedure codes 38.45 and 39.73 that the average costs are substantially higher than those costs for the cases overall in MS–DRG 237. In addition, we found that the average length of stay for the 22 cases with both procedure codes 38.45 and 39.73 is higher at 11.86 days than the average length of stay of 10.03 days for all cases in MS–DRG 237.

Our analysis of the claims data for the procedure codes in MDC 5 showed that procedure code 38.45 is also assigned to MS–DRGs 228 (Other Cardiothoracic Procedures with MCC), 229 (Other Cardiothoracic Procedures with CC), and 230 (Other Cardiothoracic Procedures without CC/MCC) when it occurs in combination with procedure code 38.44 (Resection of vessel with replacement, aorta, abdominal). Procedure code 39.73 is not assigned to MS–DRGs 228 through 230, and review of the data showed that there were no cases that had been reported in these MS–DRGs.

The table below shows our findings of the average costs and the average length of stay for procedure code 38.45 reported in combination with procedure code 38.44 in MS–DRGs 228 through 230 and the average costs and the average length of stay in all cases in MS–DRGs 228 through 230 when both procedure codes 38.45 and 38.44 are not assigned.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 228—All cases	2,084	13.79	$49,488
MS–DRG 228—Cases with procedure code 38.45 and procedure code 38.44	276	15.18	56,246
MS–DRG 228—Cases without procedure code 38.45 and without procedure code 38.44	1,808	13.58	48,456
MS–DRG 229—All cases	2,354	8.31	31,148
MS–DRG 229—Cases with procedure code 38.45 and procedure code 38.44	157	10.68	37,723
MS–DRG 229—Cases without procedure code 38.45 and without procedure code 38.44	2,197	8.14	30,678
MS–DRG 230—All cases	628	5.45	24,236
MS–DRG–230—Cases with procedure code 38.45 and procedure code 38.44	34	7.18	27,054
MS–DRG 230—Cases without procedure code 38.45 and without procedure code 38.44	594	5.35	24,075

Our findings show that both the average length of stay and average costs are higher in those cases containing procedure code 38.45 than those cases without this procedure code in MS–DRGs 228 through 230.

We then analyzed the 1,851 cases containing procedure code 39.73 in MS–DRGs 237 and 238 and the 912 cases containing procedure code 38.45 in MS–DRGs 237 and 238 to determine if they would meet the established criteria for a 3-way severity of illness split. This criterion is described in section III.G.1.c. of this preamble. The chart below shows our findings, with MS–DRG 237 acting as a severity of illness proxy for all cases, as there were no cases in MS–DRG 238. In the chart, the extensions ''–1,'' ''–2,'' and ''–3'' correspond to severity levels, with ''–1'' representing cases with MCC, ''–2'' representing cases with CC, and ''–3'' representing cases without CC/MCC.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 237–1—All cases	20,680	10.03	$34,268
MS–DRG 237–1—Cases with procedure code 39.73	637	12.14	57,834
MS–DRG 237–1—Cases with procedure code 38.45	446	13.29	51,954
MS–DRG 237–2—All cases	17,356	5.73	22,083
MS–DRG 237–2—Cases with procedure code 39.73	659	6.89	38,673
MS–DRG 237–2—Cases with procedure code 38.45	353	8.14	31,480
MS–DRG 237–3—All cases	18,349	2.52	19,183
MS–DRG 237–3—Cases with procedure code 39.73	555	3.65	27,993
MS–DRG 237–3—Cases with procedure code 38.45	113	6.30	26,280

Our next step was to analyze the claims data for the cases in the clinically coherent MS–DRGs to which we proposed to move these cases. These six MS–DRGs are: 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC); 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC); 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC); 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC), 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC); and 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC). For the sake of the grouping algorithm, procedure codes 39.73 and 38.45 must also be added to MS–DRGs 216 through 219. However, if these codes are documented in cases in which a cardiac catheterization occurs, they will be ''trumped'' by those catheterizations. Therefore, when we reviewed the data in order to make length of stay and cost comparisons, we only used the three MS–DRGs to which procedure codes 39.73 and 38.45 would appear without cardiac catheterization; that is MS–DRGs 219, 220, and 221. Our findings describing these three MS–DRGs are displayed in the following chart:

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 219	12,805	12.76	$51,399
MS–DRG 220	15,988	7.65	34,270
MS–DRG 221	4,043	5.90	28,974

Our evaluation of the severity levels in the cases containing procedure codes 39.73 and 38.45 using the proxy MS–DRGs 237–1, 237–2, and 237–3 compared to the claims data in the table above with MS–DRGs 219 through 221 demonstrates that the cases are similar in resource consumption. In addition, the cases are clinically coherent.

We indicated in the proposed rule that, by moving procedure code 38.45 to MS–DRGs 216 through 221, we did not believe that there is a need for combination codes 38.45 plus 38.44 to be specifically assigned to MS–DRGs 228, 229, and 230. Because MS–DRGs 216 through 221 are higher in the surgical hierarchy for MDC 5 than MS–DRGs 228 through 230, the result of the proposal would be that either procedure code 38.45 by itself or in combination with procedure code 38.44 will always be assigned to MS–DRGs 216 through 221. We indicated that when reported alone, under this policy, procedure code 38.44 would continue to be assigned to MS–DRGs 237 and 238, as it has been in the past.

Therefore, for FY 2012, we proposed to remove procedure codes 38.45 and 39.73 from MS–DRGs 237 and 238 and to add these codes to MS–DRGs 216, 217, 218, 219, 220, and 221 based on our findings of similar resource consumption and clinical coherence. To conform to this proposed change, we also proposed to revise the title of MS–DRG 237 (Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm Repair) by removing the terms ''or Thoracic Aortic Aneurysm Repair.'' Therefore, the new proposed title of MS–DRG 237 was ''Major Cardiovascular Procedures with MCC.'' We invited public comment on these proposals.

Comment: Several commenters supported the proposed changes.

Response: We appreciate the commenters' support.

Therefore, as we proposed, we are adopting our proposed changes as final. In summary, we are removing procedure codes 38.45 and 39.73 from MS–DRGs 237 and 238 and adding these two codes to the following six MS–DRGs: 216; 217; 218; 219; 220; and 221. In addition, we are revising the title of MS–DRG 237 to read ''Major Cardiovascular Procedures with MCC.'' The title of MS–DRG 238 (Major Cardiovascular Procedures without MCC) will remain the same.

5. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Artificial Discs

In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received a public comment that was outside of the scope of any proposal in that proposed rule. The commenter urged CMS to reassign procedure code 84.62 (Insertion of total spinal disc prosthesis, cervical) from MS–DRG 490 (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator) into MS–DRGs 471 through 473 (Cervical Spinal Fusion with MCC, with CC, and without CC/MCC, respectively). In addition, the commenter requested that CMS reassign procedure code 84.65 (Insertion of total spinal disc prosthesis, lumbosacral) from MS–DRG 490 (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator) to MS–DRGs 459 and 460 (Spinal Fusion Except Cervical with MCC and without MCC, respectively). However, the commenter also provided an alternative option to reassigning the procedure codes to different MS–DRGs. The commenter suggested the creation of a new, separate MS–DRG for the two artificial disc procedures if reassignment to the fusion MS–DRGs was not feasible.

We refer the reader to the FY 2008 IPPS proposed rule and final rule with comment period (72 FR 24731 through 24735 and 47226 through 47232) for discussion on the comprehensive evaluation of all the spinal DRGs in the development of the MS–DRG classification system. The modifications made to the spinal DRGs for FY 2008 recognized the similar utilization of resources, differences in levels of severity, and the complexity of the services being performed on patients undergoing the various types of spinal procedures.

For the FY 2012 IPPS/LTCH PPS proposed rule, we analyzed FY 2010 MedPAR claims data for procedure codes 84.62 and 84.65 in MS–DRG 490 and compared those results to the claims data for MS–DRGs 459, 460, 471, 472, and 473. We found a total of 19,840 cases in MS–DRG 490 with an average length of stay of 4.24 days and average costs of $11,940. As displayed in the chart below, we found 97 cases reporting procedure code 84.62, with an average length of stay of 1.80 days and average costs of $13,194 in MS–DRG 490. We also found 35 cases reporting procedure code 84.65, with an average length of stay of 2.91 days and average costs of $20,753. While average costs for the artificial disc cases were slightly higher ($1,254 for procedure code 84.62 and $8,813 for procedure code 84.65) compared to the average cost for all cases in MS–DRG 490, the artificial disc cases were of extremely low volume and reflected shorter lengths of stay

compared to all the cases in MS–DRG 490.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 459—All cases	3,650	8.92	$40,218
MS–DRG 460—All cases	60,865	3.75	25,268
MS–DRG 471—All cases	2,686	8.92	29,837
MS–DRG 472—All cases	8,586	3.78	18,494
MS–DRG 473—All cases	24,323	1.80	13,775
MS–DRG 490—All cases	19,840	4.24	11,940
MS–DRG 490—Cases with code 84.62	97	1.80	13,194
MS–DRG 490—Cases with code 84.65	35	2.91	20,753

We recognized the disparity in average costs for cases reporting the insertion of a cervical or lumbar artificial disc in MS–DRG 490 compared to all the cases in that MS–DRG. However, we did not believe this supports reassignment of procedure codes 84.62 and 84.65 to the MS–DRGs for spinal fusion as the commenter requested. Even with the disparity in costs, clinically, the insertion of an artificial disc is not a spinal fusion. Therefore, reassignment of the artificial disc cases to the fusion MS–DRGs would be clinically inappropriate. In addition, for certain Medicare populations, the insertion of an artificial disc is considered a noncovered procedure.

As stated earlier, the commenter also provided an alternative option to reassigning procedure codes 84.62 and 84.65. The commenter suggested the creation of a new, separate MS–DRG for the two artificial disc procedures if reassignment to the fusion MS–DRGs was not feasible. In our evaluation of the claims data and as shown above in the data chart, the artificial disc cases are of extremely low volume; therefore, we do not believe the findings warrant the creation of a separate MS–DRG.

We invited public comment on our proposal not to reassign procedure code 84.62 from MS–DRG 490 to MS–DRGs 471 through 473 and procedure code 84.65 from MS–DRG 490 to MS–DRGs 459 and 460. We also invited public comment on our proposal not to create a new, separate MS–DRG for artificial disc procedures (codes 84.62 and 84.65) for FY 2012.

Comment: Several commenters supported our proposal not to create a new MS–DRG for artificial disc procedures, as well as not to reassign the procedure codes for insertion of a cervical or lumbar artificial disc (codes 84.62 and 84.65) to the fusion MS–DRGs (459 and 460 and 471 through 473). One commenter agreed with our statement that the insertion of an artificial disc is not the same as a fusion and should not be included in the fusion MS–DRGs. Another commenter agreed that reassignment of the artificial discs to the fusion MS–DRGs does not appear to be a clinically appropriate classification despite comparative costs. This commenter believed that limitations in the data, such as the low volume of cases, may be due to artificial discs being a noncovered procedure for certain Medicare populations and recommended revisiting our analysis for a new separate MS–DRG if the coverage policy is revised in the future.

Response: We appreciate the commenters' support for our proposals. We also acknowledge the commenters recommendation to conduct further analysis for total disc replacement procedures should the coverage policy pertaining to certain Medicare populations be modified in the future.

Comment: One commenter expressed appreciation to CMS for reviewing the current MS–DRG assignment for total disc replacement (TDR) procedures involving the cervical and lumbar areas. However, the commenter disagreed with the proposed rule analysis, stating it was limited to only the MedPAR database. The commenter believed that information from two publicly available databases, the Healthcare Cost and Utilization Project (HCUP) database and the California Patient Discharge database, support modifications to the TDR procedures. According to the commenter, ''CMS' current MS–DRG assignment and resulting reimbursement at thirty to fifty percent (30–50%) of fusion procedures is well below the average eighty-eight percent (88%) ratio of TDR to fusion charges observed in the two additional databases analyzed.''

The commenter acknowledged that procedure code 84.62 and procedure code 84.65 are currently assigned to MS–DRG 490, regardless of whether or not the patient has a CC or MCC. The commenter also acknowledged the evaluation of the spinal procedure MS–DRGs in the FY 2008 IPPS proposed and final rules (72 FR 24731 through 24735 and 47226 through 47232), respectively. However, according to the commenter, the MS–DRG assignment for TDR procedures requires a more recent and thorough evaluation.

The commenter provided a comparison of how TDR procedures differ from other procedures assigned to MS–DRG 490. The commenter also stated that TDR procedures are more complex than other procedures in the MS–DRG. For example, the commenter noted that MS–DRG 490 includes procedure codes 84.58 and 84.59, representing spinal disc devices such as the X–Stop, Coflex, Dynesys, and M–Brace which do not involve removal of a disc. The commenter also noted that procedure code 80.51 (Excision of intervertebral disc), which comprises only one aspect of the total surgery required for TDR, is assigned to the same MS–DRG. The commenter further noted that because the two procedures are in the same MS–DRG, the hospital payment is the same for both procedures.

In addition, the commenter included a comparison of TDR cases and fusion cases, noting that there appeared to be greater similarity in resource use between fusion and TDR procedures than between TDR and other procedures in MS–DRG 490. The commenter reported that TDR is an alternative treatment option to spinal fusion and that patients receiving TDR have the same diagnosis as those receiving spinal fusion. In terms of similarity, the commenter stated that during both a TDR and spinal fusion surgery, the affected disc is removed, allowing normal disc height to be restored by the use of an implant. In spinal fusion, stability of the spinal segment is accomplished by the use of an implant and instrumentation such as plates, rods or screws and use of bone graft promotes osseous fusion of the vertebrae. For TDR procedures, an implant that allows motion is inserted into the disc space. According to the

commenter, these factors demonstrate clinical homogeneity and resource utilization for both TDR and spinal fusion.

The commenter did not dispute our findings that TDR procedures have shorter lengths of stay and are higher in costs compared to other procedures within MS–DRG 490. The commenter also acknowledged that TDR procedures are low volume and represent a fraction of all the procedures assigned to the MS–DRG.

Response: We appreciate and acknowledge the commenter's provision of data related to the HCUP database and the California Patient Discharge database. However, we point out that the commenter failed to identify the data related to each specified type of artificial disc replacement procedure in its analysis. We do not consider the data to be reliable for purposes of determining MS–DRG reclassifications in the form provided, as the data do not identify the number of cases, average length of stay, or average costs associated with a cervical versus a lumbar disc replacement. Further, in its own submitted comments, the commenter notes that the data provided were based on charges, not costs. In addition, as stated in the FY 2012 IPPS proposed rule (76 FR 25800), in order for us to consider using particular non-MedPAR data, we must have sufficient time to evaluate and test the data. This allows us time to test the data and make a preliminary assessment as to the feasibility of using the data. We evaluate patient care costs using average charges and lengths of stay as proxies for costs and rely on the judgment of our medical advisors to decide whether patients are clinically distinct or similar to other patients in the MS–DRG. We also consider variations and whether observed average differences are consistent across patients or attributable to cases that were extreme in terms of charges, length of stay, or both. Lastly, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In response to the commenter's comparison of how TDR procedures differ from other procedures in MS–DRG 490, we point out that procedure code 84.58 (Implantation of interspinous process decompression device), which previously identified the X–Stop device, was deleted effective October 1, 2007 (FY 2008). In addition, the other spinal disc devices that were noted by the commenter (Coflex, Dynesys, and M–Brace) were reassigned from procedure code 84.59 (Insertion of other spinal devices) to unique codes that were created in response to industry requests to describe a newer category of devices identified as motion preserving technologies. This new procedure code category, 84.8 (Insertion, replacement and revision of posterior spinal motion preservation device(s)), also became effective as of October 1, 2007 (FY 2008). As discussed above, the commenter recommended that CMS conduct a more recent and thorough evaluation of the spinal procedures in MS–DRG 490. However, in its own submitted comments, the commenter referred to outdated, deleted codes for its comparison to TDR.

With regard to clinical homogeneity and resource utilization, spinal fusion, TDR and a subset of the motion preserving technologies utilizing implant devices that allow motion in the spinal column were discussed extensively as noted above in the FY 2008 IPPS proposed rule and final rule with comment period (72 FR 24731 through 24735 and 47226 through 47232), respectively.

We will continue to evaluate the MS–DRGs on an annual basis and to respond to requests for code reassignments and MS–DRG reclassifications. We performed an analysis of the cervical and lumbar artificial disc replacement procedures in comparison to the fusion MS–DRGs in response to the commenter's request, as described above. Our data did not support reassignment of the artificial disc replacement codes, nor did our clinical advisors agree that these procedures are clinically coherent to be grouped in the same MS–DRGs. In addition, the data did not support the creation of a new, separate MS–DRG for total disc replacement procedures.

As mentioned previously, we performed a comprehensive analysis of all the spinal DRGs in our FY 2008 rulemaking process and we recognized the costs of procedures involving insertion of a disc device. As a result, we modified MS–DRG 490 (the higher severity level) to include those procedures with disc devices. The data analysis conducted at that time supported that modification.

We will continue to monitor the resource utilization of procedure codes 84.62 and 84.65 to determine if future MS–DRG reassignments are warranted.

After consideration of the public comments we received, we are finalizing our proposal to not create a new, separate MS–DRG for cervical or lumbar total disc replacement procedures and to not reassign procedure code 84.62 from MS–DRG 490 to MS–DRGs 471 through 473 and procedure code 84.65 from MS–DRG 490 to MS–DRGs 459 and 460 for FY 2012.

b. Major Joint Replacement or Reattachment of Lower Extremities

We received a request to add an additional severity level for MS–DRG 469 (Major Joint Replacement or Reattachment of Lower Extremity with MCC) and MS–DRG 470 Major Joint Replacement or Reattachment of Lower Extremity without MCC). For the FY 2012 IPPS/LTCH PPS proposed rule, we examined FY 2010 MedPAR claims data to determine if we could subdivide the base MS–DRG into three severity levels: with MCC, with CC, and without CC/MCC. We applied the criteria used in the development of the MS–DRGs included in the FY 2008 IPPS final rule with comment period (72 FR 47169). We refer readers to this final rule with comment period for a complete description of these criteria. As discussed earlier, the original criteria were based on average charges. However, subsequent to the FY 2007 IPPS final rule (71 FR 47882), we now use average costs. The five criteria using costs are listed below. In order to warrant creation of a CC or an MCC subgroup within a base MS–DRG, the subgroup must meet all of the following five criteria:

- A reduction in variance of costs of at least 3 percent.
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup.
- At least 500 cases are in the CC or MCC subgroup.
- There is at least a 20-percent difference in average costs between subgroups.
- There is a $2,000 difference in average costs between subgroups

The following table shows our determination of the number of cases and average costs by MCC, CC, and non-CC levels.

MS–DRGs 469 and 470	Number of cases	Average length of stay	Average costs
Cases with MCC	25,717	7.72	$21,016

MS–DRGs 469 and 470	Number of cases	Average length of stay	Average costs
Cases with CC	179,116	3.99	14,233
Cases without CC/MCC	220,739	3.21	13,250
Total	425,572	3.8	14,133

We determined that these cases do not meet our five criteria for adding a new severity level. The cases failed to meet criterion four (requiring at least a 20-percent difference in average costs between subgroups) and criterion five (requiring a $2,000 difference in average costs between subgroups). Therefore, we did not propose the addition of a new severity level for the base MS–DRG. Instead, we proposed to maintain the two existing severity levels for MS–DRGs 469 and 470. We welcomed public comments on our proposal not to add an additional severity level to MS–DRGs 469 and 470.

Comment: Several commenters supported our proposal to maintain the two existing severity levels for MS–DRGs 469 and 470 and not to add a third severity level. The commenters stated that the proposal seemed reasonable, given the data and information provided.

One commenter opposed our proposal. The commenter acknowledged the five criteria used to evaluate the establishment of a new severity level and the fact that this set of MS–DRGs did not meet the criterion requiring at least a 20-percent difference in average costs between subgroups or the criterion requiring a $2,000 difference in average costs between subgroups. However, the commenter stated that the large number of ''with CC'' cases that are currently classified in the ''without CC/MCC'' group places an unfair burden on providers who treat these patients and presents a distorted picture of the actual severity level of cases assigned to those providers. The commenter believed that adding an additional severity level to MS–DRGs 469 and 470 would better identify those conditions that lead to higher severity of illness and resource use relative to the average Medicare patient.

Another commenter opposed our proposal of maintaining the current two severity levels. The commenter stated that while the data appear to show that there is not a significant average cost difference between cases without CC/MCC compared to cases with CC, the commenter believed the data are biased. The commenter believed that diagnoses that do not affect DRG assignment are less likely to be reported on claims. The commenter speculated that it was reasonable to assume that, for cases assigned to these MS–DRGs, complications and comorbidities are underreported, as hospitals know that coding complications and comorbidities do not result in higher reimbursement. The commenter stated that a more reasonable approach would be to establish a third severity level for major joint replacement, with the intent of analyzing the data over the next 2 years to determine whether this was an appropriate MS–DRG modification. The commenter stated that the fact that ''Revision of a Hip or Knee Replacement'' has three levels strongly suggests that three levels would be appropriate for major joint replacement also.

Response: We agree with the commenters' statements that the data analysis shows that two of the five established criteria for creating a new severity level were not met. The cases failed to meet criterion two requiring at least a 20-percent difference in average costs between subgroups and criterion five requiring a $2,000 difference in average costs between subgroups. The criteria were developed to evaluate the need for severity levels across all MS–DRGs. We applied the criteria used in the development of the MS–DRGs included in the FY 2008 IPPS final rule with comment period (72 FR 47169). We refer readers to that final rule with comment period for a complete description of these criteria. As discussed earlier, the original criteria were based on average charges. However, subsequent to the FY 2007 IPPS final rule (71 FR 47882), we now use average costs. We believe it is important to apply these criteria consistently as requests are evaluated to create new severity levels. The cases in MS–DRGs 469 and 470 failed to meet the five criteria for adding a new severity level. We agree with the commenters who supported our proposal to maintain the two existing severity levels for MS–DRGs 469 and 470 and not creating a third severity level.

We disagree with the commenters who stated that CMS should ignore the criteria and add the additional severity level. One commenter suggested that we could retroactively review this new severity level by examining claims data 2 years after the update is made. We believe it is inappropriate to make an exception to the severity level criteria based on an assumption that hospitals may be under reporting secondary diagnoses that are on the CC list for certain types of cases. We encourage hospitals to code and report accurately. We will continue to review data to determine if additional severity levels are needed for specific MS–DRGs based on our published criteria. We do not believe it is appropriate to make exceptions for certain MS–DRGs.

After consideration of the public comments we received, as we proposed, we are maintaining MS–DRGs 469 and 470 with the current two severity levels for FY 2012.

c. Combined Anterior/Posterior Spinal Fusion

A manufacturer requested that CMS reassign spinal fusion cases utilizing the AxiaLIF technology from MS–DRGs 459 and 460 (Spinal Fusion Except Cervical with MCC and without MCC, respectively) to MS–DRGs 453, 454, and 455 (Combined Anterior/Posterior Spinal Fusion with MCC, with CC, and without CC/MCC, respectively). The commenter stated that an anterior lumbar interbody spinal fusion performed with a lateral approach, the extreme lateral interbody fusion (XLIF®), with posterior spinal fixation, can report two codes resulting in assignment to the combined fusion MS–DRGs. The commenter also stated that the AxiaLIF technology, which is also utilized in an anterior lumbar interbody spinal fusion and uses a pre-sacral approach, can only report one code, resulting in assignment to the single fusion MS–DRGs. The commenter expressed concern that the payment incentives are not properly aligned for the recently available minimally invasive spinal fusion technologies. The commenter compared the XLIF® to the AxiaLIF and urged CMS to consider the AxiaLIF technology similar to the XLIF® for purposes of MS–DRG assignment.

Spinal fusion is a surgical procedure that joins two or more vertebrae by the use of bone graft (or bone graft substitute), with the goal of maintaining

alignment, providing stability, decreasing pain, and restoring the function of the spinal nerves. Routinely, a spinal fusion also utilizes internal fixation devices (instrumentation) to assist in stabilizing the spine. These fixation devices may include pedicle screws, cages, rods, or plates. Effective October 1, 2010, ICD–9–CM procedure code 81.06 (Lumbar and lumbosacral fusion of the anterior column, anterior technique) describes the XLIF® procedure, and code 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique) describes the AxiaLIF technology.

The spinal fusion codes and their corresponding MS–DRG assignment include the use of bone graft and internal fixation. The requestor's comment regarding the assignment of one procedure code for one technology versus assigning two procedure codes for another technology indicates that the commenter may not fully understand the MS–DRG GROUPER logic for spinal fusions. For example, if an anterior lumbar interbody fusion is performed and posterior spinal fixation (or instrumentation) is also utilized, this requires one code and results in a single fusion MS–DRG assignment. However, if a posterior spinal fusion (procedure code 81.07 (Lumbar and lumbosacral fusion of the posterior column, posterior technique) was performed in addition to an anterior fusion, for example, the XLIF® procedure (procedure code 81.06), that scenario would necessitate the assignment of both codes, resulting in assignment to the combined spinal fusion MS–DRGs (453, 454, or 455). MS–DRGs 453, 454, and 455 were created to capture patients who have both an anterior and posterior fusion. We believe the requestor may have confused the terms ''fixation'' and ''fusion'' for MS–DRG assignment in its request.

For the FY 2012 IPPS/LTCH PPS proposed rule, we analyzed the FY 2010 MedPAR data to evaluate claims reporting procedure codes 81.06, 81.07, and 81.08 in MS–DRGs 456 through 458 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or 9+ Fusions with MCC, with CC and without CC/MCC, respectively) and MS–DRGs 459 and 460. We found a total of 1,115 cases in MS–DRG 456, with an average length of stay of 13.14 days and average costs of $63,856. We found 278 cases reporting procedure code 81.08, with an average length of stay of 12.04 days and average costs of $56,585. Similar results can be seen for procedure code 81.08 in the remaining MS–DRGs as shown in the chart below in terms of volume, length of stay, and average cost. Clearly, the data demonstrate that the AxiaLIF technology (procedure code 81.08) is appropriately assigned to its current MS–DRG assignments, as is the XLIF® procedure (procedure code 81.06).

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 456—All cases	1,115	13.14	$63,856
MS–DRG 456—Cases with code 81.06	54	14.37	52,392
MS–DRG 456—Cases with code 81.07	22	12.32	46,828
MS–DRG 456—Cases with code 81.08	278	12.04	56,585
MS–DRG 457—All cases	3,079	6.74	41,500
MS–DRG 457—Cases with code 81.06	119	6.42	36,468
MS–DRG 457—Cases with code 81.07	98	6.49	36,532
MS–DRG 457—Cases with code 81.08	1,194	5.73	35,272
MS–DRG 458—All cases	1,389	3.91	32,946
MS–DRG 458—Cases with code 81.06	115	3.49	29,089
MS–DRG 458—Cases with code 81.07	76	3.16	30,551
MS–DRG 458—Cases with code 81.08	827	3.60	30,570
MS–DRG 459—All cases	3,650	8.92	40,218
MS–DRG 459—Cases with code 81.06	164	9.12	40,150
MS–DRG 459—Cases with code 81.07	165	8.65	37,970
MS–DRG 459—Cases with code 81.08	2,468	8.25	38,010
MS–DRG 460—All cases	60,865	3.75	25,268
MS–DRG 460—Cases with code 81.06	2,681	3.27	26,464
MS–DRG 460—Cases with code 81.07	3,709	3.67	23,334
MS–DRG 460—Cases with code 81.08	46,565	3.66	24,571

We also analyzed data for combinations of the spinal fusion codes that result in assignment to MS–DRGs 453, 454, and 455. We evaluated the following combinations:

- 81.06 (Lumbar and lumbosacral fusion of the anterior column, anterior technique) and 81.07 (Lumbar and lumbosacral fusion of the posterior column, posterior technique).
- 81.06 (Lumbar and lumbosacral fusion of the anterior column, anterior technique) and 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique).

We further analyzed data with the following combination of spinal fusion codes in MS–DRGs 456, 457, and 458 and MS–DRGs 459 and 460:

- 81.07 (Lumbar and lumbosacral fusion of the posterior column, posterior technique) and 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique).

The chart below shows the results of the data analysis for the combination of procedure codes listed above where an anterior and posterior spinal fusion was performed in the same episode of care. There were a total of 1,190 cases in MS–DRG 453, with an average length of stay of 13.08 days and average costs of $71,693. The cases reporting the combination of procedure codes 81.06 and 81.08 in this same MS–DRG totaled 431, with an average length of stay of 11.59 days and average costs of $69,859. Results for the procedure code combination (81.06 and 81.08) in MS–DRGs 454 and 455 with regard to volume of cases, length of stay, and average costs data also support that these spinal fusion procedure code combinations are appropriately placed in their current MS–DRG assignments. Likewise, for MS–DRGs 456, 457, and 458, the data support that the spinal fusion procedure code combinations of 81.07 and 81.08 are appropriately placed in their current MS–DRG assignments. There were a total of 1,115 cases in MS–DRG 456 with an average length of stay of 13.14 days and average

costs of $68,856. The cases reporting the combination of procedure codes 81.07 and 81.08 in this same MS–DRG totaled 54, with an average length of stay of 14.37 days and average costs of $52,392. Results for the procedure code combination (81.07 and 81.08) in MS–DRGs 457 and 458 with regard to volume of cases and average length of stay were lower compared to all the cases in those two MS–DRGs. While the data show higher average costs for the procedure code combination of 81.07 and 81.08 in MS–DRGs 457 and 458, as stated previously, the volume was extremely low.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 453—All cases	1,190	13.08	$71,693
MS–DRG 453—Cases with codes 81.06 and 81.07	8	14.00	109,089
MS–DRG 453—Cases with codes 81.06 and 81.08	431	11.59	69,859
MS–DRG 454—All cases	3,052	6.38	48,311
MS–DRG 454—Cases with codes 81.06 and 81.07	47	6.83	60,743
MS–DRG 454—Cases with codes 81.06 and 81.08	1,825	5.71	47,144
MS–DRG 455—All cases	2,747	3.63	37,378
MS–DRG 455—Cases with codes 81.06 and 81.07	40	4.28	47,794
MS–DRG 455—Cases with codes 81.06 and 81.08	2,053	3.43	37,793
MS–DRG 456—All cases	1,115	13.14	63,856
MS–DRG 456—Cases with codes 81.07 and 81.08	54	14.37	52,392
MS–DRG 457—All cases	3,079	6.74	41,500
MS–DRG 457—Cases with codes 81.07 and 81.08	29	5.97	60,820
MS–DRG 458—All cases	1,389	3.91	32,946
MS–DRG 458—Cases with code 81.07 and 81.08	23	3.22	51,942

As the focus of the analysis was to evaluate procedure code 81.08 in comparison to procedure code 81.06, we believe the AxiaLIF technology (procedure code 81.08) is grouped appropriately in its current MS–DRG assignments, as is the XLIF® procedure (procedure code 81.06). The volume, length of stay, and cost data analyzed demonstrate that the complexity of services and resources utilized for each of these technologies are properly accounted for in their respective MS–DRG assignments. Therefore, the data did not support making changes for procedure code 81.08. As a result, we did not propose to reassign cases reporting this procedure code to the combined fusion MS–DRGs. We invited public comment on our proposal to not reassign procedure code 81.08 from MS–DRGs 456 through 460 to MS–DRGs 453 through 455 for FY 2012.

Comment: Several commenters supported our proposal to not reassign procedure code 81.08 to MS–DRGs 453 through 455.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to not reassign procedure code 81.08 to MS–DRGs 453 through 455.

6. MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue, and Breast): Excisional Debridement of Wound, Infection, or Burn

We received a request that we remove procedure code 86.22 (Excisional debridement of wound, infection, or burn) from the list of codes considered to be O.R. procedures. The commenter stated that many inpatient excisional debridements are performed in a patient's room instead of in an operating room. The commenter believed that the original assignment of procedure code 86.22 to the O.R. list served to help reflect the resource intensity required by a patient with wounds and ulcers that required an excisional debridement. The commenter stated that, by doing so, the code served as a proxy for severity of illness in the original CMS DRGs prior to the implementation of MS–DRGs in FY 2008. The commenter stated that the creation of the most serious pressure ulcer codes for stage 3 and stage 4 pressure ulcers (codes 707.23 and 707.24) allows these conditions to be classified as MCCs. Therefore, the commenter stated that the need to use procedure code 86.22 to capture severity of illness was no longer needed. The commenter also stated that procedure code 86.22 is a non-O.R. code under the APR–DRGs and does not affect the DRG assignment. The commenter requested that procedure code 86.22 be changed from an O.R. procedure code to a non-O.R. procedure code.

As the commenter stated, excisional debridements are currently captured in procedure code 86.22. Procedure code 88.22 is classified as an O.R. procedure in the current MS–DRGs and, therefore, leads to a surgical MS–DRG assignment. We examined MedPAR claims data on all excisional debridement cases and found that these debridement cases use appreciably fewer resources than other cases in their current surgical DRGs. However, for the proposed rule, we determined that if we were to classify debridement cases as non-O.R. cases and assign them to medical DRGs, we would significantly underpay these cases. The following chart shows differences in average costs for all excisional debridement cases compared to other cases within their current MS–DRG and compared to medical DRGs to which the patients would be assigned if the procedure were reclassified as a non-O.R. procedure.

Procedure code	All cases with no other OR procedure	Average cost (A)	Average costs in surgical DRGs to which the patients are assigned (B)	Average costs in medical DRGs to which the patients would be assigned (C)
86.22	32,152	$12,427	$17,332	$8,070

The chart illustrates that when debridement is the only O.R. procedure, it is assigned to MS–DRGs that have an average cost that is approximately $5,000 more than the actual cost of the debridement ($12,427 versus $17,332). Conversely, if the debridement is made a non-O.R. code, it would, on average, be assigned to MS–DRGs that have an average cost that is approximately $4,000 less than the actual cost of the debridement ($8,070 versus $12,427). Therefore, we believe it would be inappropriate to propose to classify these procedures as a non-O.R. procedure.

For the proposed rule, we explored alternative approaches to classifying procedure code 86.22 as a non-O.R. procedure. We evaluated the possibility of removing excisional debridements from their current MS–DRG assignments within the following skin-related MS–DRGs, where they are combined with skin grafts, and creating a new set of debridement MS–DRGs. The current MS–DRGs that combine skin grafts and debridements into the same MS–DRGs are as follows:

- MS–DRGs 573 through 575 (Skin Graft &/or Debridement for Skin Ulcer or Cellulitis with MCC, with CC, and without CC/MCC, respectively).
- MS–DRGs 576 through 578 (Skin Graft &/or Debridement Except for Skin Ulcer or Cellulitis with MCC, with CC, and without CC/MCC, respectively).

We analyzed MedPAR claims data on the severity level of graft cases without any debridements in these six MS–DRGs. Our findings are shown in the chart below.

SKIN GRAFTS WITHOUT DEBRIDEMENTS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 573–575—Cases with severity level of MCC	751	14.56	$23,975
MS–DRGs 573–575—Cases with severity level of CC	1,720	10.16	14.869
MS–DRGs 573–575—Cases with severity level of without CC/MCC	540	5.36	8,469
MS–DRGs 576–578—Cases with severity level of MCC	335	10.28	22,996
MS–DRGs 576–578—Cases with severity level of CC	1,482	5.28	11,299
MS–DRGs 576–578—Cases with severity level of without CC/MCC	1,849	3.01	6,986

We compared these data to a proposed new set of skin-related MS–DRGs that would include only debridements. The results of the findings of the severity levels of debridements without skin grafts in these six MS–DRGs are shown in the chart below.

DEBRIDEMENTS WITHOUT SKIN GRAFTS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 573–575—Cases with severity level of MCC	3,177	11.73	$18,381
MS–DRG 573–575—Cases with severity level of CC	6,649	7.67	10,730
MS–DRG 573–575—Cases with severity level of without CC/MCC	2,555	4.94	6,372
MS–DRG 576–578—Cases with severity level of MCC	271	11.59	19,429
MS–DRG 576–578—Cases with severity level of CC	638	7.61	11,913
MS–DRG 576–578—Cases with severity level of without CC/MCC	285	4.45	6,928

Our findings indicate that the graft procedure cases have higher average costs than the excisional debridement cases. The average costs for the excisional debridement cases in MS–DRGs 573 through 575 compared to the debridement cases in MS–DRGs 576 through 578 are very similar. We believe that the data support creating a single set of skin-related excisional debridement MS–DRGs composed of cases previously captured in MS–DRGs 573 through 575 as well as MS–DRGs 576 through 578. The following chart illustrates those combined average costs.

EXCISIONAL DEBRIDEMENTS FROM MS–DRGS 573 THROUGH 578 SPLIT ON SEVERITY LEVEL

MS–DRGs 573—578	Number of cases	Average length of stay	Average costs
Combined Excisional Debridement Cases with Severity Level of MCC	3,448	11.71	$18,463
Combined Excisional Debridement Cases with Severity Level of CC	7,287	7.76	10,833
Combined Excisional Debridement Cases with Severity Level of without CC/MCC	2,840	4.89	6,428

As we stated in the proposed rule, we believe that the data support separating skin graft procedures from excisional debridements by creating a new set of MS–DRGs. This would result in more accurate payment for both skin grafts and debridement. Therefore, we proposed to remove excisional debridements (procedure code 86.22) from their current MS–DRG assignments within MS–DRGs 573 through 578 for skin grafts and assign them to new excisional debridement MS–DRGs. We proposed to maintain MS–DRGs 573 through 578 for skin grafts. The following list describes the proposed new and revised MS–DRG titles:

Proposed new MS–DRGs based on procedure code 86.22:

- Proposed MS–DRG 570 (Skin Debridement with MCC)
- Proposed MS–DRG 571 (Skin debridement with CC)
- Proposed MS–DRG 572 (Skin Debridement without CC/MCC)

Proposed Revised MS–DRGs based on codes currently assigned to MS–DRGs 573 through 578, excluding procedure code 86.22:

- Proposed revised MS–DRG 573 (Skin Graft for Skin Ulcer or Cellulitis with MCC)
- Proposed revised MS–DRG 574 (Skin Graft for Skin Ulcer or Cellulitis with CC)
- Proposed revised MS–DRG 575 (Skin Graft for Skin Ulcer or Cellulitis without CC/MCC)
- Proposed revised MS–DRG 576 (Skin Graft Except for Skin Ulcer or Cellulitis with MCC)
- Proposed revised MS–DRG 577 (Skin Graft except for Skin Ulcer or Cellulitis with CC)
- Proposed revised MS–DRG 578 (Skin Graft Except for Skin Ulcer or Cellulitis without CC/MCC)

In the proposed rule, we invited public comments on our proposal for FY 2012 to create three new debridement MS–DRGs 570, 571, and 572 for skin debridement and to revise MS–DRGs 573 through 578 to include skin grafts only, as indicated above.

Comment: Several commenters supported our proposal to create three new debridement MS–DRGs, MS–DRGs 570, 571, and 572 for skin debridement and to revise MS–DRGs 573 through 578 to include skin grafts only, as described above. One commenter stated that the proposal seemed reasonable, given the data and the information provided. Another commenter who supported this MS–DRG modification expressed appreciation for the change because the relative weights better reflect resource intensive cases with the proposed new and revised MS–DRGs 570 through 578.

One commenter supported our recommendation not to remove the code for excisional debridement from the O.R. list. However, the commenter opposed removing excisional debridements (procedure code 86.22) from their current MS–DRG assignments within MS–DRGs 573 through 578 for skin grafts and assigning them to new excisional debridement MS–DRGs and maintaining MS–DRGs 573 through 578 for skin grafts. The commenter stated that excisional debridement is not exclusively a bedside procedure. Rather, the commenter noted, it can be performed in or out of the operation room, based on the judgment of the surgeon. The commenter stated that, in many instances, this procedure cannot be performed at the bedside due to variables such as patient anxiety, the size of the wound, bleeding risk, among others. The commenter stated that removing excisional debridements from their current MS–DRG assignments could harm many hospitals that perform procedures such as split thickness skin grafts for extensive wound or burns. The commenter recommended that, instead of removing excisional debridements from the current MS–DRG assignments, CMS create a separate ICD–9–CM code for debridement that is performed in the operating room due to anesthesia, equipment, or monitoring requirements.

Another commenter opposed the creation of separate debridement and skin graft MS–DRGs out of concern that this would create significant confusion among hospital coders. The commenter stated that skin grafts and skin debridements are often performed on the same patient. The commenter stated that the current descriptions of MS–DRGs 573 through 575 (Skin Graft and/or Debridement for Skin Ulcer or Cellulitis with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 576 through 578 (Skin Graft and/or Debridement Except for Skin Ulcer or Cellulitis with MCC, with CC, and without CC/MCC, respectively) appropriately describe the interrelationship between skin grafts and debridement. The commenter expressed concern that de-linking this relationship would lead to confusion for coders.

Response: We agree with the commenters that data support the creation of three new debridement MS–DRGs 570, 571, and 572 for skin debridement and the revision of MS–DRGs 573 through 578 to include skin grafts only.

We disagree with the commenter who recommends that, instead of creating separate MS–DRGs for skin debridements and skin grafts, CMS pursue the creation of a new skin debridement code that would be limited to those procedures performed in an operating room setting. ICD–9–CM codes are not currently subdivided based on the location of the procedure such as in an operating room, endoscopy room, catheterization room, treatment room, or patient room. ICD–9–CM codes are assigned based on the procedure performed, not the location in which the procedure was performed. Furthermore, we have just begun a period of a partial freeze of both ICD–9–CM and ICD–10 codes. This partial freeze is discussed in section II.G.13.b. of this preamble. We do not believe it is appropriate to postpone refinements to the MS–DRGs until a code update could be made and data on cases reported with the new code could be evaluated. We believe the current data support this proposed modification. However, as stated earlier, ICD–9–CM codes do not indicate the setting in which a procedure is performed. Therefore, it is unlikely that such a code would be created even if we were not in a period of a code freeze.

We also disagree with the commenter who stated that creating separate MS–DRGs for skin debridements and skin grafts will create confusion for coders. We believe that coders clearly understand the difference between skin debridements and skin grafts. If both are performed, then coders code and report both procedures. The fact that the MS–DRGs would be modified would not affect the way in which coders assign codes for skin debridements and skin grafts. We also note that organizations representing coders, including the American Health Information Management Association, supported this proposed MS–DRG modification. These organizations did not express concerns about any possible confusion for coders.

After consideration of the public comments we received, we are finalizing our proposal to create the following new and revised MS–DRGs:

New MS–DRGs based on procedure code 86.22:

- MS–DRG 570 (Skin Debridement with MCC)
- MS–DRG 571 (Skin debridement with CC)
- MS–DRG 572 (Skin Debridement without CC/MCC)

Revised MS–DRGs based on codes currently assigned to MS–DRGs 573 through 578, excluding procedure code 86.22:

- Revised MS–DRG 573 (Skin Graft for Skin Ulcer or Cellulitis with MCC)
- Revised MS–DRG 574 (Skin Graft for Skin Ulcer or Cellulitis with CC)
- Revised MS–DRG 575 (Skin Graft for Skin Ulcer or Cellulitis without CC/MCC)
- Revised MS–DRG 576 (Skin Graft Except for Skin Ulcer or Cellulitis with MCC)
- Revised MS–DRG 577 (Skin Graft except for Skin Ulcer or Cellulitis with CC)
- Revised MS–DRG 578 (Skin Graft Except for Skin Ulcer or Cellulitis without CC/MCC)

7. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders)

a. Nutritional and Metabolic Diseases: Update of MS–DRG Titles

We received a request to revise the MS–DRG titles for MS–DRGs 640 through 642 to more clearly capture the cases that are currently assigned to these MS–DRGs. The current titles for these MS–DRGs are: MS–DRGs 640 (Nutritional & Miscellaneous Metabolic Disorders with MCC); MS–DRG 641 (Nutritional & Miscellaneous Metabolic Disorders without MCC); and MS–DRG 642 (Inborn Errors of Metabolism). The requestor suggested that we change the titles to: MS–DRG 640 (Miscellaneous Disorders of Nutrition, Metabolism, and Fluids and Electrolytes with MCC); MS–DRG 641 (Miscellaneous Disorders of Nutrition, Metabolism, and Fluids and Electrolytes without MCC); and MS–DRG 642 (Inborn and Other Disorders of Metabolism).

Our clinical advisors supported these suggested changes to the titles, as the suggested changes would provide a better description of the diagnoses assigned to MS–DRGs 640, 641, and 642. Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to revise the MS–DRG titles for MS–DRGs 640, 641, and 642 as the requestor suggested. We invited public comment on our proposal to change the MS–DRG titles for MS–DRGs 640, 641, and 642 for FY 2012.

Comment: Several commenters supported our proposed changes to the titles of MS–DRGs 640 through 642 to better reflect the cases that are assigned to these MS–DRGs.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the titles for MS–DRGs 640 through 642. The final tiles are as follows:

- MS–DRG 640 (Miscellaneous Disorders of Nutrition, Metabolism, and Fluids and Electrolytes with MCC)
- MS–DRG 641 (Miscellaneous Disorders of Nutrition, Metabolism, and Fluids and Electrolytes without MCC)
- MS–DRG 642 (Inborn and Other Disorders of Metabolism).

b. Sleeve Gastrectomy Procedure for Morbid Obesity

Sleeve gastrectomy is a 70 percent to 80 percent greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. It may be the first step in a two-stage procedure when performing Roux-en-Y Gastric Bypass (RYGBP). Sleeve gastrectomy, whether open or laparoscopic, is currently coded using ICD–9–CM procedure code 43.89 (Other total gastrectomy). Procedure code 43.89 is currently assigned to several MS–DRGs. However, the code is not assigned to MS–DRG 619, 620, or 621 (O.R. Procedures for Obesity with MCC, with CC, and without CC/MCC, respectively).

We received a request for CMS to review MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders) for consistency. Specifically, the requestor questioned why diagnosis code 278.01 (Morbid obesity), when paired on a claim with procedure code 43.89, would be assigned to MS–DRG 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, or without CC/MCC, respectively) instead of MS–DRG 619, 620, or 621.

Upon review for the FY 2012 IPPS/LTCH PPS proposed rule, we determined that diagnosis code 278.01 is assigned to MDC 10. However, procedure code 43.89 is not assigned to any MS–DRG set in this MDC. Therefore, the cases are assigned to MS–DRGs 981 through 983, reflecting procedures not related to the principal diagnosis. This was an inadvertent oversight on CMS' part when the MS–DRGs were created. Therefore, we proposed to add a procedure code or codes identifying sleeve gastrectomy to MS–DRGs 619 through 621 for FY 2012.

Currently, sleeve gastrectomy is identified in the ICD–9–CM procedure code Index as follows: Gastrectomy (partial) (subtotal) NEC 43.89. At procedure code 43.89 in the ICD–9–CM procedure code Tabular, an inclusion note identifies this code as including sleeve resection of the stomach.

In our proposal to add a procedure code or codes to MS–DRGs 619 through 621, we pointed out that there is an NCD that has precluded coverage of sleeve gastrectomy when performed either open or laparoscopically. This decision may be found in the Medicare National Coverage Determination Manual, Section 100.1, Nationally Noncovered Indications for Bariatric Surgery for Treatment of Morbid Obesity, effective on February 12, 2009. This manual is available on the CMS Web site through a link at: *http://www.cms.gov/manuals/downloads/mcd103c1_Part2.pdf.* This manual entry affirms that treatment for obesity via use of the open or laparoscopic sleeve gastrectomy is determined to be noncovered for Medicare beneficiaries.

Noncoverage of these cases is determined by our Medicare contractors, the fiscal intermediary or A–B/MAC, because of the nature of procedure code 43.89, which is a code that identifies several gastrectomy procedures. To identify a code in the MCE that describes many procedures would inappropriately restrict other procedures which are also described by that code, but which are covered. We received a request to create specific codes uniquely identifying both laparoscopic sleeve gastrectomy and the open procedure, vertical sleeve gastrectomy. We addressed this request at the ICD–9–CM Coordination and Maintenance Committee meeting held on March 9, 2011.

We had stated that should a code or codes be created as a result of this request, we would then be able to add this code or codes to the MCE as a conforming noncoverage edit when combined with diagnosis code 278.01. The background information discussing sleeve gastrectomy coding can be accessed on the CMS Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticcodes/03_meetings.asp#TopOfPage.* A summary of the meeting can be found on CMS' Web site for the ICD–9–CM Coordination and Maintenance Committee at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp#TopOfPage* by scrolling down to the .pdf zip files containing the meeting agenda and handouts.

Therefore, for FY 2012, we proposed to add a procedure code or codes identifying sleeve gastrectomy to MS–DRGs 619 through 621. However, we also indicated that we intended to add any code or codes created at the ICD–9–CM Coordination and Maintenance Committee on March 9, 2011, to the MCE because sleeve gastrectomy, whether open or laparoscopic, is not covered for Medicare beneficiaries. The code or codes would appear in the ''Noncovered Procedures'' edit of the MCE. As the timing of the development of the proposed rule and the date of the March 2011 meeting of the ICD–9–CM Coordination and Maintenance Committee overlapped, we could not determine if additional sleeve gastrectomy codes would be created, to what code number or numbers they would be assigned, or how the narrative describing them would read. However, we indicated that should a code or codes be created, we proposed that they would simultaneously be placed in both MS–DRGs 619 through 621 and the MCE. This decision may seem to be counterintuitive, but CMS realizes that

our MS–DRGs and the Medicare GROUPER program are used for other beneficiaries and by other insurance plans rather than strictly for Medicare beneficiaries. Any new code or codes created as a result of the ICD–9–CM Coordination and Maintenance Committee meeting are included in Table 6B (which is listed in section VI. of the Addendum to this final rule and available via the Internet at *http://www.cms.gov/ICD9ProviderDiagnosticCodes/04_addendum.asp#TopOfPage*); we indicated that we did not have a mechanism to make the codes from the March 9, 2011 meeting available in the proposed rule prior to the final rule's publication.

As a result of the March 9, 2011 ICD–9–CM Coordination and Maintenance Committee Meeting, one code was created: Procedure code 43.82 (Laparoscopic vertical (sleeve) gastrectomy). To address open gastrectomies, the title of existing code 43.89 was revised to read ''Open and other partial gastrectomy''. Both codes can be found in Table 6B (New Procedure Codes) and Table 6F (Revised Procedure Code Titles), which are listed in the Addendum to this final rule and available via the Internet on the CMS Web site.

Comment: Several commenters addressed both the creation of a code or codes for laparoscopic or open sleeve gastrectomy discussed above and the proposed changes to the MCE. Several commenters indicated that they had no objections to the proposed changes to the MS–DRG classifications and the MCE, stating that the proposed changes seemed reasonable, given the data and information provided. One commenter specifically requested that CMS finalize its proposal to add new procedure code 43.82 to the MCE as a noncovered procedure.

Response: We appreciate the commenters' support of our proposal.

Comment: One commenter stated that they understood that procedure code 43.89 was inadvertently omitted from MS–DRGs 619, 620, and 621 when the MS–DRGs were created and supported the addition of this code to these MS–DRGs. In addition, this commenter stated that because procedure code 43.89 is not specific to open sleeve gastrectomy, it cannot be incorporated as a ''noncovered procedure'' in the MCE.

Response: We appreciate the commenter's support for this proposal and agree that procedure code 43.89 includes several gastrectomy procedures. Therefore, to identify a code describing many procedures in an MCE edit would inappropriately restrict other procedures included in that code that are covered.

After consideration of the public comments we received, we are adopting as final our proposal to assign both the new procedure code 43.82 (Laparoscopic vertical (sleeve) gastrectomy) and the existing procedure code 43.89 (Other total gastrectomy) to MS–DRGs 619, 620, and 621 (O.R. Procedures for Obesity with MCC, with CC, and without CC/MCC, respectively). In addition, we are adding procedure code 43.82 to the ''Noncovered Procedures'' edit of the MCE because laparoscopic sleeve gastrectomy is not covered for Medicare beneficiaries. Because procedure code 43.89 includes several gastrectomy procedures, its inclusion in the MCE would be inappropriate. Therefore, it will not be placed on the MCE.

8. MDC 15 (Newborns and Other Neonates With Conditions Originating in the Perinatal Period): Discharge Status Code 66 (Discharged/Transferred to Critical Assess Hospital (CAH))

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50236), we finalized our transfer policy regarding transfer of patients from an acute care hospital to a CAH. In that final rule, we stated that hospitals are required to use patient discharge status code 66 on the IPPS claims to identify transfers to CAHs.

With this new requirement, a discharge from an IPPS hospital to a CAH equates to a transfer status. However, discharge status code 66 is currently not included in the MS–DRG GROUPER logic for MS–DRG 789 (Neonate, Died or Transferred to Another Acute Care Facility). Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to add discharge status code 66 to the MS–DRG GROUPER logic for MS–DRG 789. We invited public comment on our proposal to add discharge status code 66 to the MS–DRG GROUPER logic for MS–DRG 789 for FY 2012.

Comment: Several commenters supported our proposal to add discharge status code 66 to the MS–DRG GROUPER logic for MS–DRG 789.

Response: We appreciate the support of the commenters.

After consideration of the public comments we received, we are finalizing our proposal to add discharge status code 66 (Discharged/Transferred to Critical Assess Hospital (CAH)) to the MS–DRG GROUPER logic for MS–DRG 789.

9. Medicare Code Editor (MCE) Changes

As explained under section II.B.1. of the preamble of this final rule, 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. In this final rule, we discuss our intention to make the following change to the MCE edits.

In section II.G.7.b. of this preamble, we discuss that the current ICD–9–CM procedure code for sleeve gastrectomy (43.89 (Other partial gastrectomy, other)) is a noncovered code when performed for resection of the stomach in patients with morbid obesity. We also discuss that noncoverage for Medicare beneficiaries of cases containing procedure code 43.89 is determined by the fiscal intermediaries or A–B/MACs because of the nature of procedure code 43.89. This code is imprecise and identifies several other gastrectomy procedures in addition to sleeve resection. Therefore, to limit coverage by identifying a code that describes many procedures through the use of the MCE would inappropriately restrict other procedures that are covered by Medicare. In that section, we also state that we received a request to create specific procedure codes identifying both laparoscopic sleeve gastrectomy and open vertical sleeve gastrectomy. As we stated above, we addressed this request at the ICD–9–CM Coordination and Maintenance Committee meeting held on March 9, 2011. In the FY 2012 IPPS/LTCH PPS proposed rule (FR 76 25833 and 25834), we indicated that if a code or codes should be created as a result of this request, we would then be able to add these codes to the MCE as a conforming noncoverage edit when combined with diagnosis code 278.01 (Morbid obesity).

As the timing of development of the proposed rule and the scheduling of the ICD–9–CM Coordination and Maintenance Committee meeting on March 9, 2011 overlapped, it was not possible to determine what those codes might be, or even if they would be created for FY 2012. However, we indicated in the proposed rule that should a code or codes be created, we proposed that any code or codes for laparoscopic or open sleeve resection of the stomach would be added to the MCE as a noncovered procedure or

procedures, in combination with diagnosis code 278.01. The background information discussing sleeve gastrectomy coding can be accessed on the CMS Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticcodes/03_meetings.asp#TopOfPage.* New codes describing sleeve gastrectomy are included in Table 6B (which is listed in section VI. of the Addendum to this final rule and are also available via the Internet at *http://www.cms.gov/ICD9ProviderDiagnosticCodes/04_addendum.asp#TopOfPage*). In the proposed rule, we indicated that we did not have a mechanism to make the codes available prior to the final rule's publication, and invited public comments on this proposal.

As a result of the March 9, 2011 ICD–9–CM Coordination and Maintenance Committee Meeting, one code was created: procedure code 43.82 (Laparoscopic vertical (sleeve) gastrectomy). To address open gastrectomies, the title of existing procedure code 43.89 was revised to read ''Open and other partial gastrectomy''. Both codes can be found in Tables 6B and 6F, which are listed in the Addendum to this final rule and available via the Internet.

Comment: Several commenters indicated that they had no objections to the proposed changes to the MS–DRG classifications and the MCE, stating that the proposed changes seemed reasonable, given the data and information provided. One commenter specifically requested that CMS finalize its proposal to add new procedure code 43.82 to the MCE as a noncovered procedure.

Response: We appreciate the commenters' support of our proposals.

Comment: Several commenters stated that because procedure code 43.89 is not specific to open sleeve gastrectomy it cannot be incorporated as a ''noncovered procedure'' in the MCE.

Response: We agree that procedure code 43.89 includes several gastrectomy procedures, and to identify this code describing many procedures in an MCE edit would be inappropriately restricting other procedures that are covered.

Comment: One commenter recognized that procedure codes discussed at the ICD–9–CM Coordination and Maintenance Committee Meeting of March 9, 2011 could not logistically be included in the IPPS proposed rule. The commenter urged CMS to apply current logic to code revisions that were discussed at the March 2011 ICD–9–CM Coordination and Maintenance Committee meeting, but which could not be finalized in time to include them in the proposed rule.

Response: We appreciate that the public understands some of the timing constraints under which we must operate. We assure the public that the same logic considerations regarding code assignment to predecessor MS–DRGs as well as O.R. determinations are applied to newly created codes from the March 2011 ICD–9–CM Coordination and Maintenance Committee Meeting as were applied to the codes created as a result of the September 15, 2010 ICD–9–CM Coordination and Maintenance Committee Meeting.

After consideration of the public comments we received, we are adopting as final our proposal to add procedure code 43.82 to the ''Noncovered Procedures'' edit of the MCE, given that laparoscopic sleeve gastrectomy is not covered for Medicare beneficiaries. Because procedure code 43.89 includes several gastrectomy procedures, its inclusion in the MCE would be inappropriate. Therefore, we are not placing it on the MCE.

10. 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, 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 1 and 2 and surgical class B includes MS–DRGs 3, 4, and 5. Assume also that the average costs of MS–DRG 1 is higher than that of MS–DRG 3, but the average costs of MS–DRGs 4 and 5 are higher than the average costs of MS–DRG 2. 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 in 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 a lower average costs than the class ordered below it.

As we proposed, based on the changes that we are make for FY 2012, as discussed in sections II.G.1. and 6. of this preamble, we are revising the surgical hierarchy for Pre-MDCs and MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue, and Breast) as follows:

In Pre-MDCs, we are reordering new MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) and new MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC) above MS–DRG 010 (Pancreas Transplant).

In MDC 9, we are reordering—

- MS–DRG 578 (Skin Graft Except for Skin Ulcer or Cellulitis without CC/MCC) above new MS–DRG 570 (Skin Debridement with MCC);
- New MS–DRG 570 above new MS–DRG 571 (Skin Debridement with CC);
- New MS–DRG 571 above new MS–DRG 572 (Skin Debridement without CC/MCC; and
- New MS–DRG 572 above MS–DRG 579 (Other Skin, Subcutaneous Tissue, and Breast Procedures with MCC).

Comment: Commenters generally supported our proposals.

Response: Based on these public comments and our review of the proposed revisions using the March 2011 update of the FY 2010 MedPAR file and the revised GROUPER software, we found that the revisions are still supported by the data. Therefore, we have incorporated the proposed revisions to the surgical hierarchy as final for FY 2012.

11. Complications or Comorbidity (CC) Exclusions List

a. Background

As indicated earlier in the preamble of this final rule, 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. We refer readers to section 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 47121 through 47152).

b. CC Exclusions List for FY 2012

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.
- 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.[2]

(1) Limited Revisions Based on Changes to the ICD–9–CM Diagnosis Codes

For FY 2012, we proposed to make limited revisions to the CC Exclusions List to take into account the changes made in the ICD–9–CM diagnosis coding system effective October 1, 2011. (We refer readers to section II.G.13. of the preamble of this final rule for a discussion of ICD–9–CM changes.) We proposed to make these changes in accordance with the principles established when we created the CC Exclusions List in 1987. In addition, we indicated on the CC Exclusions List some changes as a result of updates to the ICD–9–CM codes to reflect the exclusion of codes from being MCCs under the MS–DRG system that we adopted in FY 2008.

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2012, comments and suggestions should have been submitted by early December 2010. The following comments were submitted in a timely manner and, therefore, are being discussed in this section.

(A) Pressure Ulcer Diagnosis Codes

We received a comment recommending that CMS remove diagnosis codes 707.23 (Pressure ulcer, stage III) and 707.24 (Pressure ulcer, stage IV) from the CC Exclusion List when reported as a secondary diagnosis code with a principal diagnosis code for the pressure ulcer site: Diagnosis code 707.00 (Pressure ulcer, unspecified); diagnosis code 707.01 (Pressure ulcer,

[2] See 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); and the FY 2011 final rule (75 FR 50114). 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.

elbow); diagnosis code 707.02 (Pressure ulcer, upper back); diagnosis code 707.03 (Pressure ulcer, lower back); diagnosis code 707.04 (Pressure ulcer, hip); diagnosis code 707.05 (Pressure ulcer, buttock); diagnosis code 707.06 (Pressure ulcer, ankle); diagnosis code 707.07 (Pressure ulcer, heel); or diagnosis code 707.09 (Pressure ulcer, other site). Currently, when a patient is admitted with a pressure ulcer, the CC Exclusion List prevents a pressure ulcer stage diagnosis code from being designated as an MCC when reported as a secondary diagnosis. The commenter disagreed with this approach and contended that a patient admitted for treatment of a stage III or stage IV pressure ulcer likely requires resources that would qualify the case as a diagnosis with an MCC or, at a minimum, as a CC.

Our clinical advisors agreed with the commenter. Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to remove diagnosis codes 707.23 and 707.24 from the CC Exclusion List when a principal diagnosis code of one of codes 707.00 through 707.09 is reported. Under this proposal, diagnosis code 707.23 or diagnosis code 707.24 would be an MCC when reported as a secondary diagnosis code with a principal diagnosis code of one of codes 707.00 through 707.09.

Comment: Several commenters supported the proposed removal of diagnosis codes 707.23 and 707.24 from the CC Exclusion list when a principal diagnosis code of one of the codes 707.00 through 707.09 is reported.

Response: We appreciate the support of the commenters. As stated above, we believe this proposed change has merit.

After consideration of the public comments we received, we are adopting as final our proposal to remove diagnosis codes 707.23 (Pressure ulcer stage III) and 707.24 (Pressure ulcer stage IV) from the CC Exclusion List when reported as a secondary diagnosis code with a principal diagnosis code for the pressure ulcer site: diagnosis code 707.00 (Pressure ulcer, unspecified); diagnosis code 707.01 (Pressure ulcer, elbow); diagnosis code 707.02 (Pressure ulcer, upper back); diagnosis code 707.03 (Pressure ulcer, lower back); diagnosis code 707.04 (Pressure ulcer, hip); diagnosis code 707.05 (Pressure ulcer, buttock); diagnosis code 707.06 (Pressure ulcer, ankle); diagnosis code 707.07 (Pressure ulcer, heel); or diagnosis code 707.09 (Pressure ulcer, other site).

(B) End-Stage Renal Disease Diagnosis Code

We received a suggestion from a commenter that diagnosis code 585.6 (End-stage renal disease) be added to the CC Exclusion List when reported with a principal diagnosis code of 403.90 (Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage I through stage IV, or unspecified) or diagnosis code 403.91 (Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage V or end-stage renal disease). Currently, diagnosis code 585.6 is designated as an MCC.

According to the commenter, diagnosis codes 585.6 and 403.91 are essentially the same diagnosis but coding guidelines require the reporting of two codes to identify the stage of chronic kidney disease when associated with hypertensive chronic kidney disease. The commenter suggested that there is no need for diagnosis code 585.6 to be designated as an MCC when reported with a principal diagnosis of hypertensive chronic kidney disease, stage V or end-stage renal disease. The commenter also pointed out that, while coding guidelines would preclude diagnosis codes 403.90 and 585.6 from being reported together, the MS–DRG GROUPER allows diagnosis code 585.6 to act as an MCC when reported as a secondary diagnosis with principal diagnosis code 403.90.

As discussed in the proposed rule, in response to the first issue, our clinical advisors disagree with the commenter. Diagnosis code 403.91 includes chronic kidney disease stage V or end-stage renal disease. These are two separate conditions (or stages) that are identified by two unique codes. Diagnosis code 585.5 identifies stage V chronic kidney disease and is classified as a CC. Diagnosis code 585.6 identifies end-stage renal disease, is classified as an MCC, and describes patients who require chronic dialysis. The patients diagnosed with stage V chronic kidney disease are a different population who require different resources than those patients who are diagnosed with end-stage renal disease. Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we did not propose to add diagnosis code 585.6 to the CC Exclusion List when reported with a principal diagnosis of code 403.91.

On the second issue raised by the commenter, our clinical advisors agreed. Diagnosis code 403.90 identifies patients with chronic kidney disease, stages I through IV or unspecified, and diagnosis code 585.6 identifies end-stage renal disease. Our clinical advisors indicate that the reporting of diagnosis code 585.6 should not be designated as an MCC in this case. We agreed with the commenter that diagnosis codes 403.90 and 585.6 should not be reported together as instructed by the Coding Guidelines. Only a code from the 585.1 through 585.4 range (stages I through IV, or unspecified) should be reported with diagnosis code 403.90. Diagnosis code 585.6 is the exclusive code that uniquely identifies end-stage renal disease and should only be reported with diagnosis code 403.91. Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to add diagnosis code 585.6 to the CC Exclusion List when reported with a principal diagnosis code of 403.90.

Comment: Several commenters supported our proposal to add diagnosis code 585.6 to the CC Exclusion List when reported with a principal diagnosis code of 403.90.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are adopting as final our proposal to add diagnosis code 585.6 (End stage renal disease) to the CC Exclusion List when reported with a principal diagnosis code of 403.90 (Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage I through stage IV, or unspecified).

(C) Hypertensive Chronic Kidney Disease With Chronic Kidney Disease Stage V or End-Stage Renal Disease Code

We received a comment recommending the addition of diagnosis code 403.91 (Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage V or end-stage renal disease) to the CC Exclusion List when reported as a secondary diagnosis code with principal diagnosis code 585.6 (End stage renal disease). The commenter stated that it would be unlikely that diagnosis code 403.91 would be reported as a secondary diagnosis code with diagnosis code 585.6 as the principal diagnosis code due to sequencing rules for end-stage renal disease with hypertension. Currently, diagnosis code 403.91 is designated as a CC.

Our clinical advisors agreed with the commenter. Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to add diagnosis code 403.91 to the CC Exclusion List when reported as a secondary diagnosis code with principal diagnosis code 585.6.

Comment: Several commenters supported our proposal to add diagnosis code 403.91 to the CC Exclusion List

when reported as a secondary diagnosis code with principal diagnosis code 585.6.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are adopting as final our proposal to add diagnosis code 403.91 (Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage V or end stage renal disease) to the CC Exclusion List when reported as a secondary diagnosis code with principal diagnosis code 585.6 (End stage renal disease).

(2) Suggested Changes to Severity Levels for Encephalopathy

We received a request that we consider changing the following diagnosis codes from an MCC to a CC:

- 348.30 (Encephalopathy NOS)
- 348.31 (Metabolic encephalopathy)
- 348.39 (Encephalopathy NEC)
- 349.82 (Toxic encephalopathy)
- 572.2 (Hepatic encephalopathy)

For the FY 2012 IPPS/LTCH PPS proposed rule, we analyzed the claims data for the diagnosis codes mentioned above related to encephalopathy. We used the same approach we used in initially creating the MS–DRGs and classifying secondary diagnosis codes as non-CCs, CCs, or MCCs. A detailed discussion of the process and criteria we used in this process is described in the FY 2008 IPPS final rule (72 FR 47158 through 47161). We refer the readers to this discussion for complete information on our approach to developing the non-CC, CC, and MCC lists. Each diagnosis for which Medicare data were available was evaluated to determine its impact on resource use and to determine the most appropriate CC subclass (non-CC, CC, or MCC) assignment. In order to make this determination, the average cost for each subset of cases was compared to the expected cost for cases in that subset. The following format was used to evaluate each diagnosis:

Code	Diagnosis	Cnt1	C1	Cnt2	C2	Cnt3	C3

Count (Cnt) is the number of patients in each subset. C1, C2, and C3 are a measure of the impact on resource use of patients in each of the subsets. The C1, C2, and C3 values are a measure of the ratio of average costs for patients with these conditions to the expected average cost across all cases. The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is a MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is a MCC. A value close to 1.0 in the C1 field would suggest that the diagnosis code 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 non-CC. For additional details on this analysis, we refer readers to the FY 2008 IPPS final rule (72 FR 47158 through 47161).

The following chart shows the analysis for each of the encephalopathy diagnosis codes that are currently classified as MCCs.

Code	Diagnosis description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
34830	Encephalopathy NOS	MCC	10,082	2.1206	39,042	2.7774	60,381	3.3702
34831	Metabolic encephalopathy	MCC	6,389	2.0580	29,651	2.6952	49,343	3.4011
34839	Encephalopathy NEC	MCC	4,004	2.1118	15,003	2.7355	19,732	3.3708
34982	Toxic encephalopathy	MCC	4,333	2.3158	18,126	3.0023	26,009	3.5714
5722	Hepatic encephalopathy	MCC	1,375	1.5448	9,885	2.5054	12,421	3.4435

We ran the following data as described in FY 2008 IPPS final rule (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 a MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is a MCC.

The chart above shows that the C1 findings ranged from a low of 1.5448 to a high of 2.3158. As stated earlier, a C1 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. The C1 findings suggest that these codes are more like a CC than a MCC. However, the C2 findings ranged from a low of 2.5054 to a high of 3.0023. Values close to 3.0 suggests the condition is more similar to an MCC than a CC or non-CC. The C2 findings support maintaining the encephalopathy codes as an MCC level. The data are clearly mixed between the C1 and C2 findings, and does not consistently support a change in the severity level. Our clinical advisers recommended that these encephalopathy codes remain at an MCC level because these patients with encephalopathy typically utilize significant resources and are at a higher severity level. Based on the clinical analysis and the lack of consistent claims data support for the severity level change, we indicated in the proposed rule that we believe that the encephalopathy codes should remain on the MCC list. Therefore, we proposed to retain the following encephalopathy codes on the MCC list:

- 348.30 (Encephalopathy NOS)
- 348.31 (Metabolic encephalopathy)
- 348.39 (Encephalopathy NEC)
- 349.82 (Toxic encephalopathy)
- 572.2 (Hepatic encephalopathy)

We invited public comment on our proposal not to change the severity level classification for these codes.

Comment: Several commenters supported our proposal not to change the MCC severity level classification for the encephalopathy codes listed above. The commenters agreed with our findings that the data were mixed between the C1 and C2 findings for these codes, which are currently on the MCC list, and that clinical evaluation of these conditions supports maintaining them on the MCC list.

Response: We appreciate the commenters' support. As stated above, our data showed mixed findings for C1 and C2 with C1 findings supporting a change to CC, but C2 findings supporting maintaining the codes on the MCC list. Our clinical advisors' evaluation of encephalopathy patients supports our proposal to maintain these encephalopathy codes on the MCC list.

After consideration of the public comments we received, as we proposed, we are keeping the following encephalopathy codes on the MCC list.

- 348.30 (Encephalopathy NOS) MCC
- 348.31 (Metabolic encephalopathy) MCC
- 348.39 (Encephalopathy NEC) MCC
- 349.82 (Toxic encephalopathy) MCC
- 572.2 (Hepatic encephalopathy) MCC

(3) Suggested Changes to Severity Levels for Mechanical Complication and Infection Due to Device-Related Codes

We received a request to change the severity classification from CCs to MCCs for the following diagnosis codes:

- 996.01 (Mechanical of cardiac device, implant and graft due to cardiac pacemaker (electrode)).
- 996.04 (Mechanical complication of cardiac device, implant, and graft due to automatic implantable cardiac defibrillator).
- 996.61 (Infection and inflammatory reaction due to internal prosthetic device, implant, and graft due to cardiac device, implant, and graft).

Currently, all three diagnosis codes are classified as a CC. For the FY 2012 IPPS/LTCH PPS proposed rule, we analyzed claims data using the methodology described previously in this section for these diagnosis codes. The following chart shows our findings:

Code	Diagnosis description	CC Level	Cnt 1	Cnt 1 Impact	Cnt 2	Cnt 2 Impact	Cnt 3	Cnt 3 Impact
99601	Malfunc cardiac pacemaker	CC	1,296	1.6723	1,920	2.4332	1,333	3.1134
99604	Mch cmp autm mplnt dfbrl	CC	419	1.7041	1,032	2.5190	660	3.1508
99661	React-cardiac dev/graft	CC	149	1.9922	633	2.8134	1,253	3.5036

We reviewed the findings from these data. The C1 findings ranged from a low of 1.6723 to a high of 1.9922. As stated earlier, a value close to 2.0 in the C1 field suggests that the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C1 findings clearly support the current classification of these three codes on the CC list and the C2 findings supports this classification. Our clinical advisors agree that the data findings and their own clinical evaluation of the severity level of these conditions support the classification of these three codes on the CC list. Therefore, we proposed that these codes remain on the CC list. We invited public comment on this proposal.

Comment: Several commenters supported our proposal to maintain the mechanical complication and infection due to device-related codes mentioned above on the CC list. The commenters agreed that the data as well as our clinical advisors' evaluation support the current classification.

Several commenters opposed our proposal to keep the mechanical complication and infection due to device-related codes on the CC list. In support of their position, the commenters cited our decision to keep the encephalopathy codes on the MCC list. They pointed out that the encephalopathy codes had C1 findings of a low of 1.5448 to a high of 2.3158 and C2 findings of a low of 2.5054 to a high of 3.0023, yet they were maintained on the MCC list. The commenters believed that the same logic should be applied to the mechanical complication and infection due to device-related codes which had C1 findings of a low of 1.6723 to a high of 1.9922 and C2 findings of a low of 2.4332 to a high of 2.8134. One commenter also offered data from the Healthcare Utilization Project (HCUP) database which showed 2008 national statistics of average costs for patients admitted with one of these codes as a principal diagnosis. This commenter stated that these data showed average costs as follows:

2008 NATIONAL STATISTICS—PRINCIPAL DIAGNOSIS ONLY RANKED BY COSTS, DESCENDING ORDER: MEDICARE ONLY

ICD–9–CM Principal diagnosis code	Total number of discharges	Length of stay (LOS) (mean)	Charges $ (mean)	Costs $ (mean)
996.61—React-Cardiac Dev/Graft	8,944	10.7	95,251	26,893
996.04—Mch Comp Aut, Mplnt Dfbri	8,095	3.2	59,924	16,891
996.01—Malfunc Cardiac Pacemake	8,664	2.8	37,056	11,044
427.5—Cardiac Arrest	4,781	3.6	35,499	10,908
349.82—Toxic Encephalopathy	6,835	6.5	37,913	10,765
428.23—Ac On Chr Syst Hrt Fail	75,511	5.8	33,732	10,689
428.1—Left Heart Failure	2,261	5.1	26,777	10,252
348.39—Encephalopathy Nec	4,880	6.3	32,124	9,609
428.31—Ac Diastolic Hrt Failure	37,216	5.5	30,167	9,298
348.30—Encephalopathy Nos	11,057	5.9	31,933	9,232
572.2—Hepatic encephalopathy	20,154	5.4	28,056	8,580

The commenter stated that these data support changing these codes to the MCC list since the costs associated with these admissions were higher than admissions for encephalopathy.

Response: We agree with the commenters who supported maintaining the current CC severity level for the mechanical complication and infection due to device related codes. As discussed above the C1 and C2 findings as well as the advice of our clinical advisors supports this recommendation.

We disagree with the commenters who made comparisons to our proposals for the encephalopathy codes. The encephalopathy codes had C1 findings of a low of 1.5448 to a high of 2.3158 and C2 findings of a low of 2.5054 to a high of 3.0023. The encephalopathy codes C1 findings supported a change to a CC level. The C2 findings of a high of 3.0023 support the current MCC assignment for those codes.

The mechanical complication and infection due to device-related codes had C1 findings of a low of 1.6723 and

a high of 1.9922, which are more like a CC than a non-CC but not as significant in resource usage as an MCC. The C2 findings of a low of 2.4332 and a high of 2.8134 are also supportive of a CC classification because, while one was a high of 2.8134, the other was only 2.4332. Only one of the codes had a finding that approached 3.0 and neither exceeded 3.0. Furthermore, our clinical advisors' evaluation of data on patients with encephalopathy as a secondary diagnosis indicates that these patients are at a higher severity level. Our clinical advisors did not believe that patients who have one of the mechanical complication and infection due to device-related codes as a secondary diagnoses would require resources justifying the MCC severity level.

We point out that the data that the commenter shared focused on patients admitted for either a mechanical complication or infection due to device-related code or for encephalopathy. In other words, these conditions were the principal diagnosis in this data. These cases did not report the codes as secondary diagnoses. Our clinical criteria are based on these conditions being reported as a secondary diagnosis and the effect that has on all types of admissions. A detailed discussion of the process and criteria we used in this process is described in the FY 2008 IPPS final rule with comment period (72 FR 47158 through 47161). It may well make a difference in the overall costs of the admission if a patient were admitted for these types of complications and required a pacemaker insertion during the stay. Clearly, the encephalopathy cases would not have had a device inserted. Therefore, it is not possible to determine the effect of the impact of these conditions as a secondary diagnosis based on these data because the additional costs of a device is included. Our approach isolates the effect of the individual code on all types of admissions when it is reported as a secondary diagnosis. It also looks at whether this code is the only CC or MCC reported (C1 cases), reported with another CC diagnosis (C2 cases), or reported with another MCC diagnosis (C3). We cannot determine what, if any, secondary diagnoses were present for the cases shown in the HCUP data shown above.

We believe our consistent approach to evaluating the effect of a secondary diagnosis is more appropriate than looking at average costs when the condition is reported as a principal diagnosis in establishing the severity level of these codes. Modifying the approach by also looking at the principal diagnosis would significantly modify our current approach that focuses solely on evaluating the impact of secondary diagnoses on increasing the severity of the overall admission. We also note that our clinical advisors' evaluation of these cases, who advised that the codes should remain on the CC lists, supports the findings of the data and maintaining the codes on the CC list.

After consideration of the public comments we received, as we proposed, we are maintain the mechanical complication and infection due to device-related codes listed below on the CC list for FY 2012.

- 996.01 (Mechanical of cardiac device, implant and graft due to cardiac pacemaker (electrode))—CC
- 996.04 (Mechanical complication of cardiac device, implant, and graft due to automatic implantable cardiac defibrillator)—CC
- 996.61 (Infection and inflammatory reaction due to internal prosthetic device, implant, and graft due to cardiac device, implant, and graft)—CC

Tables 6G and 6H, Additions to and Deletions from the CC Exclusion List, respectively, which are effective for discharges occurring on or after October 1, 2011, are not being published in the Addendum to this final 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/AcuteInpatientPPS.* Each of these principal diagnoses for which there is a CC exclusion is shown in Tables 6G and 6H, which are listed in section VI. of the Addendum to this final rule (and available via the Internet) 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 also available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS.* Beginning with discharges on or after October 1, 2011, the indented diagnoses will not be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

To assist readers in identifying the changes to the MCC and CC lists that occurred as a result of updates to the ICD–9–CM codes, as described in Tables 6A, 6C, and 6E, which are listed in section VI. of the Addendum to this final rule and available via the Internet, we are providing the following summaries of those MCC and CC changes for FY 2012.

SUMMARY OF ADDITIONS TO THE MS–DRG MCC LIST—TABLE 6I.1

Code	Description
284.11	Antineoplastic chemotherapy induced pancytopenia.
284.12	Other drug-induced pancytopenia.
348.82	Brain death.
415.13	Saddle embolus of pulmonary artery.
444.01	Saddle embolus of abdominal aorta.
488.81	Influenza due to identified novel influenza A virus with pneumonia.
516.4	Lymphangioleiomyomatosis.
516.61	Neuroendocrine cell hyperplasia of infancy.
516.62	Pulmonary interstitial glycogenosis.
516.63	Surfactant mutations of the lung.
516.64	Alveolar capillary dysplasia with vein misalignment.
516.69	Other interstitial lung diseases of childhood.
518.51	Acute respiratory failure following trauma and surgery.
518.52	Other pulmonary insufficiency, not elsewhere classified, following trauma and surgery.
518.53	Acute and chronic respiratory failure following trauma and surgery.
747.31	Pulmonary artery coarctation and atresia.
747.32	Pulmonary arteriovenous malformation.
747.39	Other anomalies of pulmonary artery and pulmonary circulation.
808.54	Multiple open pelvic fractures without disruption of pelvic circle.
998.01	Postoperative shock, cardiogenic.

SUMMARY OF ADDITIONS TO THE MS–DRG MCC LIST—TABLE 6I.1—Continued

Code	Description
998.02	Postoperative shock, septic.
998.09	Postoperative shock, other.

SUMMARY OF DELETIONS FROM THE MS–DRG MCC LIST—TABLE 6I.2

Code	Description
518.5	Pulmonary insufficiency following trauma and surgery.
747.3	Anomalies of pulmonary artery.

SUMMARY OF ADDITIONS TO THE MS–DRG CC LIST—TABLE 6J.1

Code	Description
284.19	Other pancytopenia.
286.52	Acquired hemophilia.
286.53	Antiphospholipid antibody with hemorrhagic disorder.
286.59	Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors.
294.21	Dementia, unspecified, with behavioral disturbance.
358.30	Lambert-Eaton syndrome, unspecified.
358.31	Lambert-Eaton syndrome in neoplastic disease.
358.39	Lambert-Eaton syndrome in other diseases classified elsewhere.
425.11	Hypertrophic obstructive cardiomyopathy.
425.18	Other hypertrophic cardiomyopathy.
444.09	Other arterial embolism and thrombosis of abdominal aorta.
512.2	Postoperative air leak.
512.81	Primary spontaneous pneumothorax.
512.82	Secondary spontaneous pneumothorax.
512.83	Chronic pneumothorax.
512.84	Other air leak.
512.89	Other pneumothorax.
516.33	Acute interstitial pneumonitis.
516.35	Idiopathic lymphoid interstitial pneumonia.
516.36	Cryptogenic organizing pneumonia.
516.37	Desquamative interstitial pneumonia.
516.5	Adult pulmonary Langerhans cell histiocytosis.
539.01	Infection due to gastric band procedure.
539.09	Other complications of gastric band procedure.
539.81	Infection due to other bariatric procedure.
539.89	Other complications of other bariatric procedure.
596.81	Infection of cystostomy.
596.82	Mechanical complication of cystostomy.
596.83	Other complication of cystostomy.
808.44	Multiple closed pelvic fractures without disruption of pelvic circle.
996.88	Complications of transplanted organ, stem cell.
997.32	Postprocedural aspiration pneumonia.
997.41	Retained cholelithiasis following cholecystectomy.
997.49	Other digestive system complications.
998.00	Postoperative shock, unspecified.
999.32	Bloodstream infection due to central venous catheter.
999.33	Local infection due to central venous catheter.
999.34	Acute infection following transfusion, infusion, or injection of blood and blood products.
999.41	Anaphylactic reaction due to administration of blood and blood products.
999.42	Anaphylactic reaction due to vaccination.
999.49	Anaphylactic reaction due to other serum.
999.51	Other serum reaction due to administration of blood and blood products.
999.52	Other serum reaction due to vaccination.
999.59	Other serum reaction.

SUMMARY OF DELETIONS FROM THE MS–DRG CC LIST—TABLE 6J.2

Code	Description
284.1	Pancytopenia.
286.5	Hemorrhagic disorder due to intrinsic circulating anticoagulants.
425.1	Hypertrophic obstructive cardiomyopathy.
444.0	Embolism and thrombosis of abdominal aorta.
512.8	Other spontaneous pneumothorax.
516.3	Idiopathic fibrosing alveolitis.

SUMMARY OF DELETIONS FROM THE MS–DRG CC LIST—TABLE 6J.2—Continued

Code	Description
997.4	Digestive system complications.
998.0	Postoperative shock.
999.4	Anaphylactic shock due to serum.
999.5	Other serum reaction.

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 28.0, is available on a CD for $225.00. Version 29.0 of this manual, which will include the final FY 2012 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.

12. Review of Procedure Codes in MS DRGs 981 Through 983; 984 Through 986; and 987 Through 989

Each year, we review cases assigned to former CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and CMS DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these CMS DRGs. Under the MS–DRGs that we adopted for FY 2008, CMS DRG 468 was split three ways and became MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 476 became MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 477 became MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

MS–DRGs 981 through 983, 984 through 986, and 987 through 989 (formerly CMS DRGs 468, 476, and 477, respectively) are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS–DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. MS–DRGs 984 through 986 (previously CMS DRG 476) are assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

- 60.0, Incision of prostate
- 60.12, Open biopsy of prostate
- 60.15, Biopsy of periprostatic tissue
- 60.18, Other diagnostic procedures on prostate and periprostatic tissue
- 60.21, Transurethral prostatectomy
- 60.29, Other transurethral prostatectomy
- 60.61, Local excision of lesion of prostate
- 60.69, Prostatectomy, not elsewhere classified
- 60.81, Incision of periprostatic tissue
- 60.82, Excision of periprostatic tissue
- 60.93, Repair of prostate
- 60.94, Control of (postoperative) hemorrhage of prostate
- 60.95, Transurethral balloon dilation of the prostatic urethra
- 60.96, Transurethral destruction of prostate tissue by microwave thermotherapy
- 60.97, Other transurethral destruction of prostate tissue by other thermotherapy
- 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.[3]

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 2012, we did not propose to change the procedures assigned among these MS–DRGs.

We did not receive any public comments on this proposal. Therefore, as we proposed, we are not making any changes to the procedures assigned to MS–DRGs 981 through 983, 984 through 986, and 987 through 989 for FY 2012.

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

[3] The original list of the ICD–9–CM procedure codes for the procedures we consider nonextensive procedures, if performed with an unrelated principal diagnosis, was published in Table 6C in section IV. of the Addendum to the FY 1989 final rule (53 FR 38591). As part of the FY 1991 final rule (55 FR 36135), the FY 1992 final rule (56 FR 43212), the FY 1993 final rule (57 FR 23625), the FY 1994 final rule (58 FR 46279), the FY 1995 final rule (59 FR 45336), the FY 1996 final rule (60 FR 45783), the FY 1997 final rule (61 FR 46173), and the FY 1998 final rule (62 FR 45981), we moved several other procedures from DRG 468 to DRG 477, and some procedures from DRG 477 to DRG 468. No procedures were moved in FY 1999, as noted in the final rule (63 FR 40962); in FY 2000 (64 FR 41496); in FY 2001 (65 FR 47064); or in 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 the 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, FY 2010, and FY 2011, no procedures were moved, as noted in the FY 2008 final rule with comment period (72 FR 46241), the FY 2009 final rule (73 FR 48513), the FY 2010 final rule (74 FR 43796); and the FY 2011 final rule (75 FR 50122).

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 2012, we did not propose to remove any procedures from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned.

We did not receive any public comments on our proposal. Therefore, as we proposed, we are not making any changes to the procedures assigned to MS–DRGs 981 through 983 or 987 through 989 for FY 2012.

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 charges 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 2012, we did not propose to move any procedure codes among these MS–DRGs.

We did not receive any public comments on our proposal. Therefore, as we proposed, we are not moving any procedures assigned to MS–DRGs 981 through 983, 984 through 986, and 987 through 989 for FY 2012.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on the review of cases in the MDCs as described above in sections III.G.12.a. and b., we did not propose to add any diagnosis or procedure codes to MDCs for FY 2012.

We did not receive any public comments on our proposal. Therefore, as we proposed, we are not adding any diagnosis or procedure codes to MDCs for FY 2012.

13. 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

As described in section II.B.1. of the preamble of this final rule, 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, co-chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention, and CMS, charged with maintaining and updating the ICD–9–CM system. The 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 Version of the ICD–9–CM contains the list of valid diagnosis and procedure codes. (The Official Version of the ICD–9–CM is available from the Government Printing Office on CD–ROM for $19.00 by calling (202) 512–1800.) Complete information on ordering the CD–ROM is also available at: *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/05_CDROM.asp#TopOfPage.* The Official Version of the ICD–9–CM is no longer available in printed manual form from the Federal Government; it is only available on CD–ROM. Users who need a paper version are referred to one of the many products available from publishing houses.

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 2012 at a public meeting held on September 15–16, 2010 and finalized the coding changes after consideration of comments received at the meetings and in writing by November 19, 2010. Those coding changes were announced in Tables 6A through 6F, which were listed in section VI. of the Addendum to the proposed rule and available via the Internet.

The Committee held its 2011 meeting on March 9–10, 2011. New codes for which there was a consensus of public support and for which complete tabular and indexing changes were made by May 2011 are included in the October 1, 2011 update to ICD–9–CM. Code revisions that were discussed at the March 9–10, 2011 Committee meeting but that could not be finalized in time to include them in the tables listed in section VI. of the Addendum to the proposed rule are included in Tables 6A through 6F, which are listed in section VI. of the Addendum to this final rule and available via the Internet, and are marked with an asterisk (*).

Copies of the minutes of the procedure codes discussions at the Committee's September 15–16, 2010 meeting and March 9–10, 2011 meeting can be obtained from the CMS Web site at: *http://cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp.* The minutes of the diagnosis codes discussions at the September 15–16, 2010 meeting and March 9–10, 2011 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 E-mail 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 E-mail to: *patricia.brooks2@cms.hhs.gov.*

The ICD–9–CM code changes that have been approved will become effective October 1, 2011. The new ICD–9–CM codes are listed, along with their MS–DRG classifications, in Tables 6A and 6B (New Diagnosis Codes and New Procedure Codes, respectively), which are listed in section VI. of the Addendum to this final rule and available via the Internet. As we stated above, the code numbers and their titles were presented for public comment at the ICD–9–CM Coordination and Maintenance Committee meetings. Both oral and written comments were considered before the codes were approved.

In the FY 2012 IPPS/LTCH PPS proposed rule, we solicited comments on the proposed classification of these new codes, which were shown in Tables 6A and 6B listed in section VI. of the Addendum to the proposed rule and available via the Internet.

Comment: Several commenters generally supported the proposed changes to the MS–DRG classifications. One commenter supported the non-CC designation for the following new diagnosis codes: 282.40 (Thalassemia, unspecified); 282.43 (Alpha thalassemia); code 282.44 (Beta thalassemia); 282.45 (Delta-beta thalassemia); 282.46 (Thalassemia minor); 282.47 (Hemoglobin E-beta Thalassemia); 516.31 (Idiopathic pulmonary fibrosis); 516.32 (Idiopathic non-specific interstitial pneumonitis); and 516.34 (Respiratory bronchiolitis interstitial lung disease). The commenter also supported the non-CC designation for and the assignment of code 573.5 (Hepatopulmonary syndrome) in MDC 4, MS–DRGs 205 and 206 (Other Respiratory System Diagnoses with and without MCC, respectively).

However, the commenter did not support the non-CC designation of code 294.21 (Dementia, unspecified, with behavioral disturbance). The commenter noted that a similar diagnosis with behavioral disturbance such as code 294.11 (Dementia in conditions classified elsewhere with behavioral disturbance) is designated as a CC and questioned why the same logic had not been considered for code 294.21.

Response: Our medical advisors agree with the commenter's assessment that diagnosis code 294.21 should qualify as a CC, similar to code 294.11. Both codes identify dementia with behavioral disturbance and use similar resource use. Therefore, in this final rule, we are changing the proposed non-CC designation for code 294.21 and classifying it as a CC in Table 6A. This change is reflected in Table 6A of this final rule which is available via the Internet on the CMS Web site.

Comment: One commenter did not support the non-CC designation for diagnosis code 414.4 (Coronary atherosclerosis due to calcified coronary lesion). The commenter stated that this code should be designated as a CC, the same designation assigned to diagnosis code 414.02 (Coronary atherosclerosis of autologous vein bypass graft) and diagnosis code 414.03 (Coronary atherosclerosis of nonautologous biological bypass graft).

Response: Our medical advisors do not agree with the commenter. According to our medical advisors, diagnosis code 414.4 is similar to code 414.01 (Coronary atherosclerosis of native coronary artery) which is not designated as a CC. Both codes indicate general atherosclerosis and are not similar to codes 414.02 and 414.03, which indicate atherosclerosis of an artery that has been replaced by graft. Therefore, we are not making any modifications to the proposed non-CC designation for code 414.4.

Comment: One commenter supported the CC designation for the following diagnosis codes: 425.11(Hypertrophic obstructive cardiomyopathy); 425.18 (Other hypertrophic cardiomyopathy); 512.2 (Postoperative air leak); 512.81 (Primary spontaneous pneumothorax); 512.82 (Secondary spontaneous pneumothorax); 512.83 (Chronic pneumothorax); 512.84 (Other air leak); 512.89 (Other pneumothorax); 516.35 (Idiopathic lymphoid interstitial pneumonia); 516.36 (Cryptogenic organizing pneumonia); and 516.37 (Desquamative interstitial pneumonia). Some commenters supported the CC designations for code 998.00 (Postoperative shock, unspecified).

One commenter representing a national medical specialty society for neurology supported our proposed CC designations for codes 358.30 (Lambert-Eaton syndrome, unspecified); 358.31 (Lambert-Eaton syndrome in neoplastic disease); and 358.39 (Lambert-Eaton syndrome in other diseases classified elsewhere). The commenter stated that Lambert-Eaton syndrome is increasingly diagnosed and not always a paraneoplastic syndrome.

One commenter supported the CC designation for code 348.82 (Brain death), while another commenter did not support this proposed designation. The commenter that did not support the proposal stated that this code should be designated as an MCC.

Response: Our medical advisors agree with the commenter that code 348.82 should be designated as a MCC because this diagnosis requires extensive intensive care resources. Therefore, in this final rule, we are amending the proposed CC designation of code 348.82 (Brain death) to MCC for FY 2012 in Table 6A. This change is reflected in Table 6A in this final rule which is available via the Internet on the CMS Web site.

Comment: One commenter did not support the CC designation for code 516.30 (Idiopathic interstitial pneumonia, not other specified). The commenter did not see the differences among codes 516.30, 516.31 (Idiopathis pulmonary fibrosis), and 516.32 (Idiopathic nonspecific interstitial pneumonitis), recognizing that the nonspecific code is designated as a CC while the more specific codes are not designated as CCs.

Response: We agree with the commenter that code 516.30 should not be designated as a CC because this code identifies an unspecified pneumonia which is more reflective of a non-CC. Therefore, in this final rule, we are amending the proposed CC designation for of code 516.30 (Idiopathic interstitial pneumonia, not other specified) to non-CC for FY 2012 in Table 6A. This change is reflected in Table 6A, which, for this final rule, is available via the Internet on the CMS Web site.

Comment: Several commenters supported the MCC designation for the following diagnosis codes: 284.11 (Antineoplastic chemotherapy induced pancytopenia); 284.12 (Other drug induced pancytopenia); 488.81(Influenza due to identified novel influenza A virus with pneumonia); 998.01 (Postoperative shock, cardiogenic); 998.02 (Postoperative shock, septic); and 998.09 (Postoperative shock, other). In addition, one commenter supported the MCC designation for the following diagnosis codes: 518.51 (Acute respiratory failure following trauma and surgery); 518.52 (Other pulmonary insufficiency, not elsewhere classified);

and 518.53 (Acute and chronic respiratory failure following trauma and surgery).

Response: We appreciate the commenters' support.

Comment: One commenter representing a national organization for orthopedic surgeons did not support the proposed MCC designation for diagnosis code 415.13 (Saddle embolus of pulmonary artery). The commenter stated that this designation is clinically inaccurate as a saddle embolus is a subcategory of deep vein thrombosis/pulmonary embolism.

Response: Our medical advisors do not agree with the commenter's assessment that this diagnosis code does not warrant an MCC designation. The diagnosis of saddle embolus is life-threatening, requiring intensive care resources. Therefore, we are not making any modifications to the proposed MCC designation for code 415.13. We point out that diagnosis codes 415.11 (Iatrogenic pulmonary embolism and infarction), 415.12 (Septic pulmonary embolism) and 415.19 (Other Pulmonary embolism and infarction) are designated as MCCs.

Comment: One commenter suggested that, as new codes are added to the MS–DRG classification, the new codes be assigned to the same MS–DRG classification as its predecessor code.

Response: CMS' longstanding practice has been, where possible, to assign new ICD–9–CM codes to the same MS–DRGs(s) as their predecessor code.

Comment: One commenter supported the proposed MS–DRG assignment to MS–DRG 264 (Other Circulatory System O.R. Procedures) for procedure code 38.26 (Insertion of implantable pressure sensor without lead for intracardiac or great vessel hemodynamic monitoring). Another commenter supported the surgical classification of procedure code 68.24 (Uterine artery embolization [UAE] with coils) and code 68.25 (Uterine artery embolization [UAE] without coils).

Response: We appreciate the support of the commenters.

For codes that have been replaced by new or expanded codes, the corresponding new or expanded diagnosis codes are included in Table 6A, which is listed in section VI. of the Addendum to this final rule and available via the Internet. New procedure codes are shown in Table 6B, which is listed in section VI. of the Addendum to this final rule and available via the Internet. Diagnosis codes that have been replaced by expanded codes or other codes or have been deleted are in Table 6C (Invalid Diagnosis Codes), which is listed in section VI. of the Addendum to this final rule and available via the Internet. These invalid diagnosis codes will not be recognized by the GROUPER beginning with discharges occurring on or after October 1, 2011. Table 6D, which is listed in section VI. of the Addendum to this final rule and available via the Internet, contains invalid procedure codes. These invalid procedure codes will not be recognized by the GROUPER beginning with discharges occurring on or after October 1, 2011. Revisions to diagnosis code titles are in Table 6E (Revised Diagnosis Code Titles), which is listed in section VI. of the Addendum to this final rule and available via the Internet, and also includes the MS–DRG assignments for these revised codes. Table 6F, which is listed in section VI. of the Addendum to this final rule and available via the Internet includes revised procedure code titles for FY 2012.

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. As stated previously, ICD–9–CM codes discussed at the March 9–10, 2011 Committee meeting that received consensus and that were finalized by May 2011 are included in Tables 6A through 6F, which are listed in section VI. of the Addendum to this final rule and available via the Internet.

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 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, 2011 implementation of an ICD–9–CM code at the September 15–16, 2010 Committee meeting. Therefore, there were no new ICD–9–CM codes implemented on April 1, 2011.

Current addendum and code title information is published on the CMS Web site at: *http://www.cms.hhs.gov/icd9ProviderDiagnosticCodes/01_overview.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. Thus, 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 will be implemented on October 1, 2013, as described in the Health Insurance Portability and Accountability Act (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). 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.

We 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, we 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. There was an announcement at the September 15–16, 2010 ICD–9–CM Coordination and Maintenance Committee meeting that a partial freeze of both ICD–9–CM and ICD–10 codes would be implemented as follows:

- The last regular annual update to both ICD–9–CM and ICD–10 code sets will be made on October 1, 2011.
- On October 1, 2012, there will be only limited code updates to both ICD–9–CM and ICD–10 code sets to capture new technology and new diseases.
- There will be no updates to ICD–9–CM on October 1, 2013, as the system will no longer be a HIPAA standard. There will be only limited code updates to ICD–10 code sets on October 1, 2013, to capture new technology and new diseases.
- On October 1, 2014, 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, 2014, 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.gov/ICD9ProviderDiagnosticCodes/03.* A summary of the September 15–16, 2010 Committee meeting, along with both written and audio transcripts of this meeting, are posted on the ''Download'' section of this Web page.

Comment: Several commenters supported the partial code freeze. The commenters stated that the partial freeze was needed to allow providers time to prepare for the implementation of ICD–

10 and the accompanying system and product updates.

Response: We appreciate the commenters' support. We agree with the commenters that the partial code freeze will be useful in providing a greater opportunity to focus on ICD–10 implementation issues.

c. Processing of 25 Diagnosis Codes and 25 Procedure Codes on Hospital Inpatient Claims

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127), we discussed that we had received repeated requests from the hospital community to process 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 diagnoses and 6 procedures. We indicated in that final rule that, as part of our efforts to update Medicare systems prior to the implementation of ICD–10 on October 1, 2013, we were undergoing extensive system updates as part of the move to 5010, which includes the ability to accept ICD–10 codes. This complicated transition involved converting many internal systems prior to October 1, 2013, when ICD–10 will be implemented. We stated that, as one important step in this planned conversion process, we were planning to complete the 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 have completed this expansion, and, as a result, we were able to process up to 25 diagnosis codes and 25 procedure codes when received on the 5010 format starting on January 1, 2011. (We note that we made a typographical error in the proposed rule (76 FR 25843) and indicated that ''we have *not* completed this expansion.'' This error was pointed out to us by several commenters. We corrected this typographical error in a correction notice issued in the **Federal Register** on June 14, 2011 (76 FR 24633).) We continue to 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 on October 1, 2013 (FY 2014) when we implement the reporting of ICD–10 codes (75 FR 50127 and 50128). While we did not propose an ICD–10 version of the MS–DRGs in the FY 2011 IPPS/LTCH PPS proposed rule, we noted that we have been actively involved in converting 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 V26.0 (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://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp*. 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 at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp.*

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–DRG Version 28.0 also includes 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.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp.* 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 to be implemented in FY 2014 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.

14. Other Issues

a. O.R./Non-O.R. Status of Procedures

(1) Brachytherapy Code

We received a request that we add ICD–9–CM procedure code 92.27 (Implantation or Insertion of Radioactive Elements) [Brachytherapy] into 41 MS–DRGs that are listed below:

- 129 (Major Head and Neck Procedures with CC/MCC or Major Device)
- 130 (Major Head and Neck Procedures without CC/MCC)
- 163 (Major Chest Procedures with MCC)
- 164 (Major Chest Procedures with CC)
- 165 (Major Chest Procedures without CC/MCC)
- 180 (Respiratory Neoplasms with MCC)
- 181 (Respiratory Neoplasms with CC)
- 182 (Respiratory Neoplasms without CC/MCC)
- 326 (Stomach, Esophageal and Duodenal Procedures with MCC)
- 327 (Stomach, Esophageal and Duodenal Procedures with CC)
- 328 (Stomach, Esophageal and Duodenal Procedures without CC/MCC)
- 329 (Major Small and Large Bowel Procedures with MCC)
- 330 (Major Small and Large Bowel Procedures with CC)
- 331 (Major Small and Large Bowel Procedures without CC/MCC)
- 332 (Rectal Resection with MCC)
- 333 (Rectal Resection with CC)
- 334 (Rectal Resection without CC/MCC)
- 344 (Minor Small and Large Bowel Procedures with MCC)
- 345 (Minor Small and Large Bowel Procedures with CC)
- 346 (Minor Small and Large Bowel Procedures without CC/MCC)
- 347 (Anal and Stomal Procedures with MCC)
- 348 (Anal and Stomal Procedures with CC)
- 349 (Anal and Stomal Procedures without CC/MCC)
- 405 (Pancreas, Liver and Shunt Procedures with MCC)
- 406 (Pancreas, Liver and Shunt Procedures with CC)
- 407 (Pancreas, Liver and Shunt Procedures without CC/MCC)
- 490 (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator)
- 491 (Back and Neck Procedures Except Spinal Fusion without CC/MCC)

- 500 (Soft Tissue procedures with MCC)
- 501 (Soft Tissue procedures with CC)
- 502 (Soft Tissue procedures without CC/MCC)
- 584 (Breast Biopsy, Local Excision and Other Breast Procedures with CC/MCC)
- 585 (Breast Biopsy, Local Excision and Other Breast Procedures without CC/MCC)
- 597 (Malignant Breast Disorders with MCC)
- 598 (Malignant Breast Disorders with CC)
- 599 (Malignant Breast Disorders without CC/MCC)
- 653 (Major Bladder Procedures with MCC)
- 654 (Major Bladder Procedures with CC)
- 655 (Major Bladder Procedures without CC/MCC)
- 656 (Kidney and Ureter Procedures for Neoplasm with MCC)
- 657 (Kidney and Ureter Procedures for Neoplasm with CC)
- 658 (Kidney and Ureter Procedures for Neoplasm without CC/MCC)
- 662 (Minor Bladder Procedures with MCC)
- 663 (Minor Bladder Procedures with CC)
- 664 (Minor Bladder Procedures without CC/MCC)
- 668 (Transurethral Procedures with MCC)
- 669 (Transurethral Procedures with CC)
- 670 (Transurethral Procedures without CC/MCC)
- 671 (Urethral Procedures with CC/MCC)
- 672 (Urethral Procedures without CC/MCC)
- 707 (Major Male Pelvic Procedures with CC/MCC)
- 708 (Major Male Pelvic Procedures without CC/MCC)
- 736 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC)
- 737 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with CC)
- 738 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy without CC/MCC)
- 739 (Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with MCC)
- 740 (Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with CC)
- 741 (Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy without CC/MCC)
- 746 (Vagina, Cervix and Vulva Procedures with CC/MCC)
- 747 (Vagina Cervix and Vulva Procedures without CC/MCC)
- 748 (Female Reproductive System Reconstructive Procedures)
- 749 (Other Female Reproductive System O.R. Procedures with CC/MCC)
- 750 (Other Female Reproductive System O.R. Procedures without CC/MCC)

For the FY 2012 IPPS/LTCH PPS proposed rule, we examined MedPAR claims data on this request and only found 150 cases throughout these MS–DRGs. Our findings are presented in the table below.

MS–DRG with Code 92.27				MS–DRG without Code 92.27		
DRG	Number of cases	Average length of stay	Average costs	Number of cases	Average length of stay	Average costs
129	6	6.67	$15,793	1,326	5.35	$14,400
130	2	1.00	7,587	904	2.78	7,860
163	17	8.18	24,166	11,871	13.90	31,860
164	52	5.94	17,505	16,487	7.13	16,865
165	41	2.95	10,638	9,260	4.27	11,754
180	0	0	0	19,304	7.37	11,396
181	0	0	0	22,205	5.30	8,014
182	0	0	0	2,365	3.59	5,580
326	0	0	0	10,321	15.48	35,437
327	1	4.00	9,302	9,671	8.67	17,889
328	0	0	0	8,461	3.49	9,161
329	1	24.00	37,654	41,107	15.10	33,003
330	2	9.00	20,043	53,584	8.91	16,736
331	0	0	0	22,105	5.13	10,654
332	1	48.00	61,169	1,439	13.40	29,727
333	1	10.00	11,446	4,494	7.86	16,008
334	1	16.00	27,312	2,855	4.76	10,518
344	0	0	0	756	11.30	21,590
345	0	0	0	2,906	6.67	11,190
346	0	0	0	2,331	4.52	7,757
347	0	0	0	1,430	8.80	16,644
348	0	0	0	3,975	5.40	9,326
349	0	0	0	3,512	2.75	5,311
405	1	8.00	8,444	3,940	15.45	35,970
406	2	10.50	23,231	4,749	7.83	17,333
407	0	0	0	1,799	8.04	12,148
490	0	0	0	19,840	4.24	11,940
491	0	0	0	38,574	2.05	6,794
500	0	0	0	1,935	10.86	20,600
501	5	7.00	12,896	4,961	5.77	10,256
502	5	7.40	13,876	5,009	2.78	6,844
584	0	0	0	790	5.32	11,126
585	0	0	0	1,318	2.12	7,283
597	0	0	0	532	7.41	10,990
598	0	0	0	1,369	5.32	7,624
599	0	0	0	165	3.26	4,368
653				1,589	16.34	35,856
654				3,502	9.13	19,367
655	0	0	0	1,121	5.53	413,162

MS–DRG with Code 92.27				MS–DRG without Code 92.27		
DRG	Number of cases	Average length of stay	Average costs	Number of cases	Average length of stay	Average costs
656	1	20.00	77,737	3,110	10.00	24,022
657	0	0	0	7,885	5.63	13,345
658	0	0	0	6,150	3.25	9,718
662	0	0	0	763	10.21	19,455
663	0	0	0	1,818	2.18	9,729
664	0	0	0	2,705	1.86	7,457
668	2	3.50	3,972	2,908	8.99	16,852
669	4	6.50	7,832	13,776	4.25	8,398
670	2	1.50	5,639	7,321	2.24	5,158
671	0	0	0	746	5.45	9,778
672	0	0	0	613	2.31	5,575
707	0	0	0	4,719	4.26	12,080
708	1	3.00	11,252	14,329	1.80	8,572
736	0	0	0	775	13.18	29,827
737	1	6.00	13,045	2,844	6.49	13,348
738	0	0	0	642	3.47	7,966
739	0	0	0	790	10.18	23,070
740	0	0	0	3,914	4.34	10,214
741	1	1.00	3,225	4,917	2.31	7,438
746	0	0	0	2,282	3.97	8,504
747	0	0	0	6,243	1.72	5,995
748	0	0	0	14,682	1.67	6,285
749	0	0	0	920	8.58	16,781
750	0	0	0	285	2.88	7,116

The numbers of cases in any of the MS–DRGs listed were minimal. Many of the MS–DRGs listed had no occurrences of procedure code 92.27. The highest number of cases found was 52, in MS–DRG 164 (Major Chest Procedures with CC). Based on these findings, we do not believe that making a MS–DRG change based on such a minimal number of cases can be justified. Therefore, for FY 2012, we did not propose to add procedure code 92.27 to any of the 41 MS–DRGs listed above. Further, we did not propose any MS–DRG changes for procedure code 92.27. We welcomed public comment on our proposal not to make changes to procedure code 92.27.

Comment: Several commenters supported our proposal to not add procedure code 92.27 to any of the 41 MS–DRGs listed above and to not propose any MS–DRG changes for procedure code 92.27.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, as we proposed, we are not adding procedure code 92.27 to any of the 41 MS–DRGs listed above and are not making any MS–DRG changes for procedure code 92.27 for FY 2012.

(2) Intraoperative Electron Radiation Therapy (IOERT)

We received a public comment that was outside of the scope of the FY 2011 IPPS/LTCH PPS proposed rule regarding the MS–DRG assignment for intraoperative electron radiation therapy (IOERT). This issue was discussed briefly in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50128). However, we addressed this issue in the FY 2012 IPPS/LTCH PPS rulemaking. IOERT is the direct application of radiation to a tumor and/or tumor bed while the patient is undergoing surgery for cancer. This technology may be used for cancers of the rectum, head/neck, pancreas, lung, genitourinary, soft tissue, and breast. IOERT is a secondary procedure performed during the primary tumor removal surgery.

The commenter requested that CMS update the MS–DRG assignments for procedure code 92.41 (Intraoperative electron radiation therapy) to ensure that the cost of this technology is captured in each MS–DRG involving tumor removal in the rectum, head/neck, pancreas, lung, genitourinary, soft tissue, and breast. Currently, this code is not assigned to a specific MS–DRG as the primary procedure performed, the tumor removal, would determine the appropriate MS–DRG assignment.

The commenter provided a recommended list of MS–DRGs to which IOERT should be assigned:

MS–DRG	Description
129	Major Head and Neck Procedures with CC/MCC or Major Device.
130	Major Head and Neck Procedures without CC/MCC.
133	Other Ear, Nose, Mouth and Throat O,R, Procedures with CC/MCC.
134	Other Ear, Nose, Mouth and Throat O.R. Procedures without CC/MCC.
163	Major Chest Procedures with MCC.
164	Major Chest Procedures with CC.
165	Major Chest Procedures without CC/MCC.
166	Other Respiratory System O.R. Procedures with MCC.
167	Other Respiratory System O.R. Procedures with CC.
168	Other Respiratory System O.R. Procedures without CC/MCC.
326	Stomach, Esophageal and Duodenal Procedures with MCC.
327	Stomach, Esophageal and Duodenal Procedures with CC.
328	Stomach, Esophageal and Duodenal Procedures without CC/MCC.
329	Major Small and Large Bowel Procedures with MCC.
330	Major Small and Large Bowel Procedures with CC.
331	Major Small and Large Bowel Procedures without CC/MCC.
332	Rectal Resection with MCC.
333	Rectal Resection with CC.
334	Rectal Resection without CC/MCC.
344	Minor Small and Large Bowel Procedures with MCC.
345	Minor Small and Large Bowel Procedures with CC.
346	Minor Small and Large Bowel Procedures without CC/MCC.
347	Anal and Stomal Procedures with MCC.
348	Anal and Stomal Procedures with CC.

MS–DRG	Description
349	Anal and Stomal Procedures without CC/MCC.
356	Other Digestive System O.R. Procedures with MCC.
357	Other Digestive System O.R. Procedures with CC.
358	Other Digestive System O.R. Procedures without CC/MCC.
405	Pancreas, Liver and Shunt Procedures with MCC.
406	Pancreas, Liver and Shunt Procedures with CC.
407	Pancreas, Liver and Shunt Procedures without CC/MCC.
490	Back and Neck Procedures Except Spinal Fusion with CC/MCC.
491	Back and Neck Procedures Except Spinal Fusion without CC/MCC.
500	Soft Tissue Procedures with MCC.
501	Soft Tissue Procedures with CC.
502	Soft Tissue Procedures without CC/MCC.
579	Other Skin, Subcutaneous Tissue and Breast Procedures with MCC.
580	Other Skin, Subcutaneous Tissue and Breast Procedures with CC.
581	Other Skin, Subcutaneous Tissue and Breast Procedures without CC/MCC.
584	Breast Biopsy, Local Excision and Other Breast Procedures with CC/MCC.
585	Breast Biopsy, Local Excision and Other Breast Procedures without CC/MCC.
653	Major Bladder Procedures with MCC.
654	Major Bladder Procedures with CC.
655	Major Bladder Procedures without CC/MCC.
656	Kidney and Ureter Procedures For Neoplasm with MCC.
657	Kidney and Ureter Procedures For Neoplasm with CC.
658	Kidney and Ureter Procedures for Neoplasm without MCC/CC.
662	Minor Bladder Procedures with MCC.
663	Minor Bladder Procedures with CC.
664	Minor Bladder Procedures without CC/MCC.
668	Transurethral Procedures with MCC.
669	Transurethral Procedures with CC.
670	Transurethral Procedures without CC/MCC.
671	Urethral Procedures with CC/MCC.
672	Urethral Procedures without CC/MCC.
707	Major Male Pelvic Procedures with CC/MCC.
708	Major Male Pelvic Procedures without CC/MCC.
715	Other Male Reproductive System O.R. Procedures For Malignancy with CC/MCC.
716	Other Male Reproductive System O.R. Procedures For Malignancy without CC/MCC.
736	Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC.
737	Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with CC.
738	Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy without CC/MCC.
739	Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with MCC.
740	Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with CC.
741	Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy without CC/MCC.
746	Vagina, Cervix and Vulva Procedures with CC/MCC.
747	Vagina Cervix and Vulva Procedures without CC/MCC.
748	Female Reproductive System Reconstructive Procedures.
749	Other Female Reproductive System O.R. Procedures with CC/MCC.
750	Other Female Reproductive System O.R. Procedures without CC/MCC.

For the FY 2012 IPPS/LTCH PPS proposed rule, based on our review of the FY 2010 MedPAR claims data, we found a total of 12 cases with procedure code 92.41 reported. There were three cases assigned to MS–DRG 502; two cases each assigned to two different MS–DRGs: MS–DRG 333 and MS–DRG 501; and one case assigned each to five MS–DRGs: MS–DRGs 130, 168, 327, 329, and 330.

The IOERT cases were assigned to an MS–DRG that included the tumor removal of that particular site, which was listed on the table above. Therefore, the cost of this technology is appropriately identified in the MS–DRG assignment for the removal of the tumor by specific site, and no change is warranted at this time. Therefore, we did not propose any changes to the assignment for IOERT cases for FY 2012. We invited public comment on our proposal to not change the assignment for IOERT cases for FY 2012.

Comment: Several commenters supported our proposal to not make any MS–DRG modifications for FY 2012 for IOERT cases reported with procedure code 92.41.

Response: We appreciate the commenters' support. Based on our findings, these cases are appropriately assigned to the MS–DRG for the removal of the tumor by specific site and warrant no further modification.

After consideration of the public comments we received, we are finalizing our proposal to not make any MS–DRG modifications for FY 2012 for intraoperative electron radiation therapy cases.

b. IPPS Recalled Device Policy Clarification

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that has been recalled determined the base MS–DRG assignment. At that time, we specified that we would reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit equal to 50 percent or more of the cost of the device when a manufacturer provided a credit for a recalled device.

A similar policy was adopted under the Hospital Outpatient Prospective Payment System (OPPS) in CY 2008 (the ''partial credit'' policy). This policy can be viewed in its entirety at 72 FR 66743 though 66748. In general terms, under the partial credit policy, CMS reduces the amount of payment for an implanted device made under the OPPS for which CMS determines that a significant portion of the payment is attributable to the cost of an implanted device when the provider receives partial credit for the cost of a replaced device, but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the new replacement device being implanted.

It came to our attention that there is a discrepancy between the IPPS policy and the OPPS partial credit policy for replacement devices. In particular, the OPPS partial credit policy specifies that the credit must be 50 percent or greater of the cost of the replacement device. However, the IPPS policy does not specify whether the credit should be 50 percent or greater of the replacement device or the original device. We believe that the OPPS partial credit policy and the IPPS policy should be consistent with each other on the issue of whether the 50 percent or more credit is with respect to the replacement device or the original device. Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to clarify the IPPS policy to state that the policy applies where ''the hospital received a credit equal to 50 percent or more of the cost of the replacement device.'' We invited public comment on this proposal.

Comment: Several commenters approved of parallel policies for recalled

device credit for both the inpatient setting and the outpatient hospital setting.

Response: We appreciate the commenters' support.

Comment: One commenter suggested additional clarifications. The commenter recommended that CMS reconcile condition codes 49 and 50 with the ''FB'' and ''FC'' modifiers from OPPS to include devices obtained at reduced or no cost for reasons other than those currently specified in condition codes 49 and 50. Condition code 49 addresses ''product replacement within product lifecycle'' while condition code 50 covers ''product replacement for known recall of a product.'' The commenter stated that, as currently defined, these two condition codes do not represent all of the reasons that devices are obtained at reduced or no cost and, therefore, create confusion as to when the device credit policy applies. The commenter added that, by comparison, in OPPS, modifier ''FB'' covers ''devices that are obtained at no cost to the provider'' and modifier ''FC'' covers ''partial credit received for replaced device.'' Further, the commenter stated, the definitions of the ''FB'' and ''FC'' modifiers denote whether the replacement device was obtained at no cost or reduced cost, and generally reflect all situations when the device credit policy would apply. As part of the clarification, the commenter suggested that CMS further explain whether value code ''FD'' as well as modifiers ''FB'' and ''FC'' are for ''replacement'' devices only.

Response: We are not clear about the clarifications suggested by the commenter. The OPPS modifier ''-FB'' (Item Provided without Cost to Provider, Supplier or Practitioner) can be used to describe an item provided under warranty, replaced due to defect, or provided as a free sample. OPPS modifier ''-FC'' (Partial Credit Received for Replaced Device) describes cases in which the hospital receives a partial credit of 50 percent or more of the cost of a new replacement device under warranty, recall, or field action.

Value code ''FD'' is used for Medicare Part A reporting of replacement devices. Hospitals must use the combination of condition code 49 or 50, described above, along with value code ''FD'' to correctly bill for a replacement device that was provided with a credit or no cost. Condition code 49 or 50 identifies a replacement device while value code ''FD'' communicates to Medicare the amount of the credit, or cost reduction, received by the hospital for the replaced device. We do not believe that hospitals find these reporting requirements confusing. Regardless of the actual reason that a device is provided at no cost to a hospital or an ambulatory surgical center (ASC), the end result is that neither the hospital nor the ASC is incurring the full cost of the device, although the Medicare payment is calculated based on the full cost of the device.

Comment: One commenter pointed out that the FY 2009 IPPS/LTCH PPS final rule (73 FR 48496) finalized an MS–DRG change by removing several procedure codes for AICD leads from MS–DRG 245 as well as revising the title of that MS–DRG to read ''AICD Generator Procedures''. New MS–DRG 265 (AICD Lead Procedures) was also created and included the AICD lead procedure codes that were transferred from MS–DRG 245. The commenter pointed out that CMS has not issued a new table through its transmittal process indicating that MS–DRG 265 should also be included in the list of MS–DRGs that are subject to the device recall policy.

Response: We are aware of this oversight and have begun the process to create an updated Change Request to address this issue. We expect to issue the Change Request shortly.

Comment: One commenter suggested that no-charge devices should be removed from the calculation of MS–DRG relative weights.

Response: We appreciate this comment, but we point out that no-charge devices are not reported on claims. Therefore, charges for the device have not been included in the computation of the MS–DRG relative weights.

After consideration of the public comments we received, we are finalizing our proposed clarification of the IPPS recalled device policy to state that the policy applies where ''the hospital received a credit equal to 50 percent or more of the cost of the replacement device,'' and we will issue instructions to hospitals accordingly.

15. Public Comments on Issues Not Addressed in the Proposed Rule

We received a number of public comments regarding MS–DRG issues that were outside the scope of the proposals included in the FY 2012 IPPS/LTCH PPS proposed rule. We have summarized these public comments below. However, because these public comments were outside of the scope of the proposed rule, we are not addressing them in this final rule. As stated in section II.B.2. of this preamble, we encourage individuals with comments about MS–DRG classifications to submit these comments no later than December of each year so they can be considered for possible inclusion in the annual proposed rule and, if included, may be subjected to public review and comment. We will consider these comments for possible proposals in future rulemaking as part of our annual review process.

Commenters requested that CMS create new MS–DRGs for (1) disorders of porphyrin metabolism and (2) related and unrelated allogeneic bone marrow transplants. The commenters also requested that CMS create a new MS–DRG that would distinguish between ventricular assist device (VAD) implantation and heart transplants.

Commenters requested that CMS evaluate the non-CC, CC, or MCC designation of the following codes:

- 263.0 (Malnutrition of moderate degree)
- 263.1 (Malnutrition of mild degree)
- 263.9 (Unspecified protein-calorie malnutrition)
- 285.3 (Antineoplastic chemotherapy induced anemia)
- 425.4–425.9 (Cardiomyopathy)
- 428.0 (Heart failure, unspecified)
- 707.25 (Pressure ulcer, unstageable)

One commenter recommended that CMS consider the reassignment of cases of patients diagnosed with influenza with pneumonia and who also have secondary diagnoses that would otherwise qualify the assignment of the cases to MS–DRGs 177 (Respiratory Infections and Inflammations with MCC), 178 (Respiratory Infections and Inflammations with CC), and 179 (Respiratory Infections and Inflammations without MCC/CC). The commenter recommended these cases be reassigned from MS–DRGs 193 (Simple Pneumonia and Pleurisy with MCC), 194 (Simple Pneumonia and Pleurisy with CC), and 195 (Simple Pneumonia and Pleurisy without MCC/CC) to MS–DRGs 177, 178, and 179.

H. Recalibration of MS–DRG Weights

In developing the FY 2012 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 2010 MedPAR data used in this final rule include discharges occurring on October 1, 2009, through September 30, 2010, based on bills received by CMS through March 31, 2011, 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 2010

MedPAR file used in calculating the relative weights includes data for approximately 10,836,723 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the March 31, 2011 update of the FY 2010 MedPAR was updated to comply with version 5010 of the X12 HIPAA Transaction and Code Set Standards. The expansion of the MedPAR to the 5010 format includes a new variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types of ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, beginning with the calculation of the relative weights for FY 2012, we are also excluding 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 FY 2009 Medicare cost report data files from HCRIS (that is, cost reports beginning on or after October 1, 2008, and before October 1, 2009), which represents the most recent full set of cost report data available. We used the March 31, 2011 update of the HCRIS cost report files for FY 2009 in setting the relative cost-based weights.

The methodology we used to calculate the DRG cost-based relative weights from the FY 2010 MedPAR claims data and FY 2009 Medicare cost report data is as follows:

- To the extent possible, all the claims were regrouped using the FY 2012 MS–DRG classifications discussed in sections II.B. and G. of the preamble of this final rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2010 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 96.2 percent of the providers in the MedPAR file had charges for 10 of the 15 cost centers. Claims for providers that did not have charges greater than zero for at least 10 of the 15 cost centers were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the 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. Thus, 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 a ''N'' or an ''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 15 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals 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 15 cost groups so that each MS–DRG had 15 standardized charge totals. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2009 cost report data.

The 15 cost centers that we used in the relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the 15 national cost center CCRs.

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Cost Center Group Name (15 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-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Routine Days	Private Room Charges	011X and 014X		Adults & Pediatrics (General Routine Care)	C_1_C5_25	C_1_C6_25	D4_HOS_C2_25	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30
	Semi-Private Room Charges	012X, 013X and 016X-019X				C_1_C7_25	D4_HOS_C2_26		C_1_C7_30	D3_HOS_C2_31
	Ward Charges	015X								
Intensive Days	Intensive Care Charges	020X		Intensive Care Unit	C_1_C5_26	C_1_C6_26	D4_HOS_C2_26	C_1_C5_31	C_1_C6_31	D3_HOS_C2_31
						C_1_C7_26			C_1_C7_31	
	Coronary Care Charges	021X		Coronary Care Unit	C_1_C5_27	C_1_C6_27	D4_HOS_C2_27	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32
						C_1_C7_27			C_1_C7_32	
				Burn Intensive Care Unit	C_1_C5_28	C_1_C6_28	D4_HOS_C2_28	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
						C_1_C7_28			C_1_C7_33	

Cost Center Group Name (15 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-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Surgical Intensive Care Unit	C_1_C5_29	C_1_C6_29	D4_HOS_C2_29	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
						C_1_C7_29			C_1_C7_34	
				Other Special Care Unit	C_1_C5_30	C_1_C6_30	D4_HOS_C2_30	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
						C_1_C7_30			C_1_C7_35	
Drugs	Pharmacy Charges	025X, 026X and 063X		Intravenous Therapy	C_1_C5_48	C_1_C6_48	D4_HOS_C2_48	C_1_C5_64	C_1_C6_64	D3_HOS_C2_64
						C_1_C7_48			C_1_C7_64	
				Drugs Charged To Patient	C_1_C5_56	C_1_C6_56	D4_HOS_C2_56	C_1_C5_73	C_1_C6_73	D3_HOS_C2_73
						C_1_C7_56			C_1_C7_73	

Cost Center Group Name (15 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-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
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_55	C_1_C6_55	D4_HOS_C2_55	C_1_C5_71	C_1_C6_71	D3_HOS_C2_71
						C_1_C7_55			C_1_C7_71	
		0275, 0276, 0278, 0624		Implantable Devices Charged to Patients	C_1_C5_55.30	C_1_C6_55.30	D4_HOS_C2_55.30	C_1_C5_72	C_1_C6_72	D3_HOS_C2_72
						C_1_C7_55.30			C_1_C7_72	
	Durable Medical Equipment Charges	0290, 0291, 0292 and 0294-0299		DME-Rented	C_1_C5_66	C_1_C6_66	D4_HOS_C2_66	C_1_C5_96	C_1_C6_96	D3_HOS_C2_96
						C_1_C7_66			C_1_C7_96	
	Used Durable Medical Charges	0293		DME-Sold	C_1_C5_67	C_1_C6_67	D4_HOS_C2_67	C_1_C5_77	C_1_C6_97	D3_HOS_C2_97
						C_1_C7_67			C_1_C7_97	

Cost Center Group Name (15 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-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Therapy Services	Physical Therapy Charges	042X		Physical Therapy	C_1_C5_50	C_1_C6_50	D4_HOS_C2_50	C_1_C5_66	C_1_C6_66	D3_HOS_C2_66
						C_1_C7_50			C_1_C7_66	
	Occupational Therapy Charges	043X		Occupational Therapy	C_1_C5_51	C_1_C6_51	D4_HOS_C2_51	C_1_C5_67	C_1_C6_67	D3_HOS_C2_67
						C_1_C7_51			C_1_C7_67	
	Speech Pathology Charges	044X and 047X		Speech Pathology	C_1_C5_52	C_1_C6_52	D4_HOS_C2_52	C_1_C5_68	C_1_C6_68	D3_HOS_C2_68
						C_1_C7_52			C_1_C7_68	
Inhalation Therapy	Inhalation Therapy Charges	041X and 046X		Respiratory Therapy	C_1_C5_49	C_1_C6_49	D4_HOS_C2_49	C_1_C5_65	C_1_C6_65	D3_HOS_C2_65
						C_1_C7_49			C_1_C7_65	

Cost Center Group Name (15 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-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Operating Room	Operating Room Charges	036X		Operating Room	C_1_C5_37	C_1_C6_37	D4_HOS_C2_37	C_1_C5_50	C_1_C6_50	D3_HOS_C2_50
For all DRGs but Labor & Delivery						C_1_C7_37			C_1_C7_50	
		071X		Recovery Room	C_1_C5_38	C_1_C6_38	D4_HOS_C2_38	C_1_C5_51	C_1_C6_51	D3_HOS_C2_51
						C_1_C7_38			C_1_C7_51	
Labor & Delivery	Operating Room Charges	072X		Delivery Room and Labor Room	C_1_C5_39	C_1_C6_39	D4_HOS_C2_39	C_1_C5_52	C_1_C6_52	D3_HOS_C2_52
ONLY FOR THE 6 Labor & Delivery DRGs						C_1_C7_39			C_1_C7_52	
370, 371, 372, 373, 374, 375				Obstetrics Clinic	C_1_C5_63	C_1_C6_63	D4_HOS_C2_63	C_1_C5_93	C_1_C6_93	D3_HOS_C2_93
						C_1_C7_63			C_1_C7_93	

Cost Center Group Name (15 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-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Anesthesia	Anesthesia Charges	037X		Anesthesi-ology	C_1_C5_40	C_1_C6_40	D4_HOS_C2_40	C_1_C5_53	C_1_C6_53	D3_HOS_C2_53
						C_1_C7_40			C_1_C7_53	
Cardiology	Cardiology Charges	048X and 073X		Electro-cardiology	C_1_C5_53	C_1_C6_53	D4_HOS_C2_53	C_1_C5_69	C_1_C6_69	D3_HOS_C2_69
						C_1_C7_53			C_1_C7_69	
		0481		Cardiac Catheterization				C_1_C5_59	C_1_C6_59	D3_HOS_C2_59
									C_1_C7_59	
Laboratory	Laboratory Charges	030X, 031X, and 075X		Laboratory	C_1_C5_44	C_1_C6_44	D4_HOS_C2_44	C_1_C5_60	C_1_C6_60	D3_HOS_C2_60
						C_1_C7_44			C_1_C7_60	

Cost Center Group Name (15 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-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				PBP Clinic Laboratory Services	C_1_C5_45	C_1_C6_45	D4_HOS_C2_45	C_1_C5_61	C_1_C6_61	D3_HOS_C2_61
						C_1_C7_45			C_1_C7_61	
		074X, 086X		Electro-encephalography	C_1_C5_54	C_1_C6_54	D4_HOS_C2_54	C_1_C5_70	C_1_C6_70	D3_HOS_C2_70
						C_1_C7_54			C_1_C7_70	
Radiology	Radiology Charges	040X		Radiology - Diagnostic	C_1_C5_41	C_1_C6_41	D4_HOS_C2_41	C_1_C5_54	C_1_C6_54	D3_HOS_C2_54
						C_1_C7_41			C_1_C7_54	
		0333, 0339, 0342		Radiology - Therapeutic	C_1_C5_42	C_1_C6_42	D4_HOS_C2_42	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344		Radioisotope	C_1_C5_43	C_1_C6_43	D4_HOS_C2_43	C_1_C5_56	C_1_C6_56	D3_HOS_C2_56
						C_1_C7_43			C_1_C7_56	

Cost Center Group Name (15 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-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
		035X		Computed Tomography (CT) Scan				C_1_C5_57	C_1_C6_57	D3_HOS_C2_57
									C_1_C7_57	
	MRI Charges	061X		Magnetic Resonance Imaging (MRI)				C_1_C5_58	C_1_C6_58	D3_HOS_C2_58
									C_1_C7_58	
Emergency Room	Emergency Room Charges	045x		Emergency	C_1_C5_61	C_1_C6_61	D4_HOS_C2_61	C_1_C5_91	C_1_C6_91	D3_HOS_C2_91
						C_1_C7_61			C_1_C7_91	
Blood and Blood Products	Blood Charges	038x		Whole Blood & Packed Red Blood Cells	C_1_C5_46	C_1_C6_46	D4_HOS_C2_46	C_1_C5_62	C_1_C6_62	D3_HOS_C2_62
						C_1_C7_46			C_1_C7_62	

Cost Center Group Name (15 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-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Blood Storage / Processing	039x		Blood Storing, Processing, & Transfusing	C_1_C5_47	C_1_C6_47	D4_HOS_C2_47	C_1_C5_63	C_1_C6_63	D3_HOS_C2_63
						C_1_C7_47			C_1_C7_63	
Other Services	Other Service Charge	0002-0099, 022X, 023X, 024X,052X,053X								
		055X-060X, 064X-070X, 076X-078X, 090X-095X and 099X								
				ASC (Non Distinct Part)	C_1_C5_58	C_1_C6_58	D4_HOS_C2_58	C_1_C5_75	C_1_C6_75	D3_HOS_C2_75
						C_1_C7_58			C_1_C7_75	
	Outpatient Service Charges	049X and 050X		Other Ancillary	C_1_C5_59	C_1_C6_59	D4_HOS_C2_59	C_1_C5_76	C_1_C6_76	D3_HOS_C2_76
	Lithotripsy Charge	079X				C_1_C7_59			C_1_C7_76	
	Clinic Visit Charges	051X		Clinic	C_1_C5_60	C_1_C6_60	D4_HOS_C2_60	C_1_C5_90	C_1_C6_90	D3_HOS_C2_90

Cost Center Group Name (15 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-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_60			C_1_C7_90	
	Ambulance Charges	054X		Ambulance	C_1_C5_65	C_1_C6_65	D4_HOS_C2_65	C_1_C5_95	C_1_C6_95	D3_HOS_C2_95
						C_1_C7_65			C_1_C7_95	
				Observation beds	C_1_C5_62	C_1_C6_62	D4_HOS_C2_62	C_1_C5_92	C_1_C6_92	D3_HOS_C2_92
						C_1_C7_62			C_1_C7_92	
					C_1_C5_6201	C_1_C6_6201	D4_HOS_C2_6201	C_1_C5_92.01	C_1_C6_92.01	D3_HOS_C2_92.01
						C_1_C7_6201			C_1_C7_92.01	
	ESRD Revenue Setting Charges	080X and 082X-088X (but not 086X)								
	(excluding Labor & Delivery DRGs)									
				Rural Health Clinic	C_1_C5_6350	C_1_C6_6350	D4_HOS_C2_6350	C_1_C5_88	C_1_C6_88	D3_HOS_C2_88

Cost Center Group Name (15 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-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Professional Fees Charges	096X, 097X, and 098X				C_1_C7_6350			C_1_C7_88	
				FQHC	C_1_C5_6360	C_1_C6_6360	D4_HOS_C2_6360	C_1_C5_89	C_1_C6_89	D3_HOS_C2_89
						C_1_C7_6360			C_1_C7_89	
				Home Program Dialysis	C_1_C5_64	C_1_C6_64	D4_HOS_C2_64	C_1_C5_94	C_1_C6_94	D3_HOS_C2_94
						C_1_C7_64			C_1_C7_94	
				Other Reimbursable	C_1_C5_68	C_1_C6_68	D4_HOS_C2_68	C_1_C5_98	C_1_C6_98	D3_HOS_C2_98
						C_1_C7_68			C_1_C7_68	

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We developed the national average CCRs as follows:

Taking the FY 2009 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–4 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–4. 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 15 cost centers by the corresponding national average CCR, we summed the 15 ''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 new cost-based relative weights were then normalized by an adjustment factor of 1.5808272736 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 15 national average CCRs for FY 2012 are as follows:

Group	CCR
Routine Days	0.525
Intensive Days	0.453
Drugs	0.199
Supplies & Equipment	0.329
Therapy Services	0.380
Laboratory	0.146
Operating Room	0.251
Cardiology	0.155
Radiology	0.140
Emergency Room	0.236
Blood and Blood Products	0.402
Other Services	0.402
Labor & Delivery	0.454
Inhalation Therapy	0.191
Anesthesia	0.116

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. In the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to use that same case threshold in recalibrating the MS–DRG weights for FY 2012. Using the FY 2010 MedPAR data set, there were 8 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 heard 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 2012, because we do not have sufficient MedPAR data to set accurate and stable cost weights for these low-volume MS–DRGs, we proposed to compute weights for the low-volume MS–DRGs by adjusting their FY 2011 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
768	Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C.	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
789	Neonates, Died or Transferred to Another Acute Care Facility	FY 2011 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 2011 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
793	Full-Term Neonate with Major Problems	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
795	Normal Newborn	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

We did not receive any public comments on this section. Therefore, we are adopting the national average CCRs as proposed, with the MS–DRG weights recalibrated based on these CCRs.

I. 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 implementing these provisions 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. These three criteria are explained below in the ensuing paragraphs in further detail.

Under the first criterion, as reflected in 42 CFR 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. Typically, there is a lag of 2 to 3 years from the point a new medical service or technology is first introduced on the market (generally on the date that the technology receives FDA approval/clearance) and when data reflecting the use of the medical service or technology are used to calculate the MS–DRG weights. For example, data from discharges occurring during FY 2010 were used to calculate the FY 2012 MS–DRG weights in this final rule. Section 412.87(b)(2) of the regulations therefore provides 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 medical service or technology (depending on when a new code is assigned and data on the new medical service or technology become available for DRG recalibration). After CMS has recalibrated the MS–DRGs, based on available data to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion for this section.''

The 2-year to 3-year period during which a medical service or technology can be considered new would ordinarily begin on the date on which the medical service or technology received FDA approval or clearance. (We note that, for purposes of this section of this final rule, we generally refer to both FDA approval and FDA clearance as FDA ''approval.'') However, in some cases, there may be few to no Medicare data available for the new service or technology following FDA approval. For example, the newness period could extend beyond the 2-year to 3-year period after FDA approval is received in cases where the product initially was generally unavailable to Medicare patients following FDA approval, such as in cases of a national noncoverage determination or a documented delay in bringing the product onto the market after that approval (for instance, component production or drug production has been postponed following FDA approval due to shelf life concerns or manufacturing issues). After the MS–DRGs have been recalibrated to reflect the costs of an otherwise new medical service or technology, the medical service or technology is no longer eligible for special add-on payment for new medical services or technologies (as specified under § 412.87(b)(2)). For example, an approved new technology that received FDA approval in October 2009 and entered the market at that time may be eligible to receive add-on payments as a new technology for discharges occurring before October 1, 2012 (the start of FY 2013). Because the FY 2013 MS–DRG weights would be calculated using FY 2011 MedPAR data, the costs of such a new technology would be fully reflected in the FY 2013 MS–DRG weights. Therefore, the new technology would no longer be eligible to receive add-on payments as a new technology for discharges occurring in FY 2013 and thereafter.

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), we explained our policy regarding substantial similarity in detail and its relevance for assessing if the hospital charge data used in the development of the relative weights for the relevant DRGs reflect the costs of the technology. In that final rule, we stated that, for determining substantial similarity, we consider (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, and (2) whether a product is assigned to the same or a different DRG. We indicated that both of the above criteria should be met in order for a technology to be considered ''substantially similar'' to an existing technology. However, in that same final rule, we also noted that, due to the complexity of issues regarding the substantial similarity component of the newness criterion, it may be necessary to exercise flexibility when considering whether technologies are substantially similar to one another. Specifically, we stated that we may consider additional factors, depending on the circumstances specific to each application.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 and 43814), we noted that the discussion of substantial similarity in the FY 2006 IPPS final rule related to comparing two separate technologies made by different manufacturers. Nevertheless, we stated that the criteria discussed in the FY 2006 IPPS final rule also are relevant when comparing the similarity between a new use and existing uses of the same technology (or a very similar technology manufactured by the same manufacturer). In other words, we stated that it is necessary to establish that the new indication for which the technology has received FDA approval is not substantially similar to that of the prior indication. We explained that such a distinction is necessary to determine the appropriate start date of the newness period in evaluating whether the technology would qualify for add-on payments (that is, the date of the ''new'' FDA approval or that of the prior

approval), or whether the technology could qualify for separate new technology add-on payments under each indication.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43814), we added a third factor of consideration to our analysis of whether a new technology is substantially similar to one or more existing technologies. Specifically, in making a determination of whether a technology is substantially similar to an existing technology, we adopted a policy to consider 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 (74 FR 24130), in addition to considering the already established factors described in the FY 2006 IPPS final rule (that is, (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; and (2) whether a product is assigned to the same or a different DRG). As we noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule, if all three components are present and the new use is deemed substantially similar to one or more of the existing uses of the technology (that is, beyond the newness period), we would conclude that the technology is not new and, therefore, is ineligible for the new technology add-on payment.

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. In the FY 2004 IPPS final rule (68 FR 45385), we established the threshold at the geometric mean standardized charge for all cases in the MS–DRG plus 75 percent of 1 standard deviation above the geometric mean standardized charge (based on the logarithmic values of the charges and converted back to charges) for all cases in the MS–DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs, if the new medical service or technology occurs in more than one MS–DRG).

However, section 503(b)(1) of Public Law 108–173 amended section 1886(d)(5)(K)(ii)(I) of the Act to provide that, beginning in FY 2005, CMS will apply ''a threshold * * * that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved.'' (We refer readers to section IV.D. of the preamble to the FY 2005 IPPS final rule (69 FR 49084) for a discussion of the revision of the regulations to incorporate the change made by section 503(b)(1) of Public Law 108–173.) Table 10 that was included in the IPPS/LTCH PPS final rule published in the Federal Register on August 16, 2010, contained the final thresholds that were used to evaluate applications for new technology add-on payments for this final rule for FY 2012 (75 FR 50605 through 50613).

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. Specifically, we explained that health plans, including Medicare, and providers that conduct certain transactions electronically, including hospitals that would receive new technology add-on payments, are required to comply with the HIPAA Privacy Rule. We further explained how such entities could meet the applicable HIPAA requirements by discussing how the HIPAA Privacy Rule permitted providers to share with health plans information needed to ensure correct payment, if they had obtained consent from the patient to use that patient's data for treatment, payment, or health care operations. We also explained that, because the information to be provided within applications for new technology add-on payment would be needed to ensure correct payment, no additional consent would be required. The HHS Office for Civil Rights has since amended the HIPAA Privacy Rule, but the results remain. The HIPAA Privacy Rule does not require a covered entity to obtain consent from patients to use or disclose protected health information for the covered entity's treatment, payment, or health care operations purposes, and expressly permits such entities to use or to disclose protected health information for these purposes and for the treatment purposes of another health care provider and the payment purposes of another covered entity or health care provider. (We refer readers to 45 CFR 164.502(a)(1)(ii) and 164.506(c)(1) and (c)(3) and the Standards for Privacy of Individually Identifiable Health Information published in the Federal Register (67 FR 53208 through 53214) on August 14, 2002, for a full discussion of consent in the context of the HIPAA Privacy Rule.)

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 complete 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, Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology.

Section 1886(d)(4)(C)(iii) of the Act requires that the adjustments to annual MS–DRG classifications and relative weights be made in a manner that ensures that aggregate payments to hospitals are not more or less than they were in the prior fiscal year (that is, they are ''budget neutral''). Therefore, in the past, we accounted for projected payments under the new medical service and technology provision during the upcoming fiscal year, while at the

same time estimating the payment effect of changes to the MS–DRG classifications and recalibration. The impact of additional payments under this provision was then included in the budget neutrality factor, which was applied to the standardized amounts and the hospital-specific amounts. However, 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 Office of Clinical Standards and Quality (OCSQ) 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, OCSQ, 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.

CMS plans to continue its Open Door forums with stakeholders who are interested in CTI's initiatives. In addition, 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 2013 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.hhs.gov/AcuteInpatientPPS/08_newtech.asp*. To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2013, the Web site also will post the tracking forms completed by each applicant.

Comment: A number of commenters submitted public comments that addressed topics relating to the substantial similarity criteria, marginal cost factor for the new technology add-on payment, the use of external data in determining the cost threshold, paying new technology add-on payments for 2 to 3 years, mapping new technologies to the appropriate MS–DRG, and the use of the date that a ICD–9–CM code is assigned to a technology or the FDA approval date (whichever is later) as the start of the newness period.

Response: We did not invite public comments nor propose to make any changes to any of the issues summarized above. Because these public comments are outside of the scope of the provisions included in the proposed rule, we are not providing a complete summary of the comments or responding to them in this final rule.

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 2012 prior to publication of the FY 2012 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 29, 2010 (75 FR 73091 through 73094), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 2, 2011. 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 2012 new medical service and technology add-on payment applications before the publication of the FY 2012 proposed rule.

Approximately 50 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. Each of the three FY 2012 applicants presented information on its technology, 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, in our evaluation of the new technology add-on applications for FY 2012 in the FY 2012 proposed rule and in this final rule.

In response to the published notice and the new technology town hall meeting, we received three written comments regarding applications for FY 2012 new technology add-on payments. We summarized these comments or, if applicable, indicated that there were no comments received, at the end of each discussion of the individual applications in the proposed rule. We refer readers to the FY 2012 IPPS/LTCH PPS proposed rule for a complete iteration of the comments received in response to the published notice and the new technology town hall meeting and CMS' responses (76 FR 25861 through 25863).

3. FY 2012 Status of Technologies Approved for FY 2011 Add-On Payments

a. Spiration® IBV® Valve System

Spiration, Inc. submitted an application for new technology add-on payments for the Spiration® IBV® Valve System (Spiration® IBV®). The Spiration® IBV® is a device that 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, 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 the applicant, 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.

With regard to the newness criterion, the Spiration® IBV® received a HDE approval from the FDA on October 24, 2008. We were unaware of any previously FDA-approved predicate devices, or otherwise similar devices, that could be considered substantially similar to the Spiration® IBV®. However, the applicant asserted that the FDA had precluded the device from being used in the treatment of any patients until the Institutional Review Board (IRB) granted approvals regarding its study sites. Therefore, the Spiration® IBV® met the newness criterion once it obtained at least one IRB approval because the device would then be available on the market to treat Medicare beneficiaries. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43819), the applicant stated that the first IRB approval for the Spiration® IBV® was March 12, 2009. In that final rule, based on the information above from the applicant, we determined that the Spiration® IBV® meets the newness criterion and the newness period for the Spiration® IBV® begins on March 12, 2009.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the Spiration® IBV® and consideration of the public comments we received in response to the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, including the additional analysis of clinical data and supporting information submitted by the applicant, we approved the Spiration® IBV® for new technology add-on payments for FY 2010 with a maximum add-on payment of $3,437.50.

In the FY 2011 IPPS/LTCH PPS proposed rule, we did not propose any changes to the new technology add-on payments for the Spiration® IBV®. We did not receive any public comments on whether to continue or discontinue the new technology add-on payment for the Spiration® IBV® for FY 2011. Therefore, for FY 2011, we continued new technology add-on payments for cases involving the Spiration® IBV® in FY 2011, with a maximum add-on payment of $3,437.50.

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 medical service or technology'' (42 CFR 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 Spiration® IBV®, as stated above, we consider the beginning of the newness period for the device to have commenced on the date of the first IRB approval for the Spiration® IBV®, which was March 12, 2009. For FY 2012, as of March 12, 2012, the Spiration® IBV® will have been on the market for 3 years, and is therefore no longer considered ''new'' as of March 12, 2012. Because the 3-year anniversary date of the Spiration® IBV®'s entry onto the market will occur in the first half of the fiscal year, we proposed to discontinue its new technology add-on payment for FY 2012.

Comment: One commenter requested that the new technology add-on payments for the Spiration® IBV® be extended for a third year. The commenter reasoned that, although two hospital IRBs approved the use of the Spiration® IBV®, those two hospitals did not implant the valve until June 2010 and September 2010, respectively. The commenter explained that there was a delay in the hospitals' implantation of the device from the time of IRB approval due to the following

reasons: (1) Infrequent number of cases; and (2) the clinical, administrative, and operation processes that needed to be completed in order to make the technology available under HDE approval at each institution. Therefore, the commenter stated that even though a hospital would have received IRB approval, it would not expect the first case to be performed immediately. The commenter believed that for these reasons, the newness period should begin with the first implantation of the Spiration® IBV®, which occurred in June 2009. Using this date, the commenter determined that the newness period for the Spiration® IBV® would end June 2012, during the latter half of FY 2012, thus making the Spiration® IBV® eligible for a third year of new technology add-on payments.

Response: CMS' policy is that the newness period begins with the product's or device's FDA approval date, except in limited circumstances that could limit the availability of the product (69 FR 49002). In this case, the product was approved as an HDE, which included IRB approval as a requirement. Therefore, we determined that the date of IRB approval was the appropriate start date of the newness period (74 FR 43819). We do not agree that the start date for the newness period should be further adjusted if a hospital then decided not to immediately utilize the technology. In this case, the hospital's IRB approved the product for use on March 12, 2009, and the product was available, but no patients had the product implanted until June 2010. We believe this is similar to a situation in which a technology is FDA approved (without any additional qualifications for use, such as IRB approval), but no hospital uses the technology for a period of time after FDA approval. In such a case, the newness period would still begin with FDA approval, and we would not delay the beginning of the newness period until a hospital uses the drug or device for the first time. Therefore, we disagree with the commenter, and we continue to believe it is appropriate to start the newness period for the Spiration® IBV® with the first IRB approval, which was March 12, 2009. As mentioned above, for FY 2012, as of March 12, 2012, the Spiration® IBV® will have been available for hospitals' utilization for 3 years, and it is therefore no longer considered ''new'' as of March 12, 2012. Because this date occurs in the first half of the fiscal year, we are finalizing our proposal to discontinue its new technology add-on payment for FY 2012.

b. CardioWest™ Temporary Total Artificial Heart System (CardioWest™ TAH-t)

SynCardia Systems, Inc. submitted an application for approval of the CardioWest™ Temporary Total Artificial Heart System (TAH-t) in FY 2009. The TAH-t is a technology that is used as a bridge to heart transplant device for heart transplant-eligible patients with end-stage biventricular failure. The TAH-t pumps up to 9.5 liters of blood per minute. This high level of perfusion helps improve hemodynamic function in patients, thus making them better heart transplant candidates.

The TAH-t was approved by the FDA on October 15, 2004, for use as a bridge to transplant device in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. The TAH-t is intended to be used in hospital inpatients. One of the FDA's post-approval requirements is that the manufacturer agrees to provide a post-approval study demonstrating that success of the device at one center can be reproduced at other centers. The study was to include at least 50 patients who would be followed up to 1 year, including (but not limited to) the following endpoints: Survival to transplant; adverse events; and device malfunction.

In the past, Medicare did not cover artificial heart devices, including the TAH-t. However, on May 1, 2008, CMS issued a final national coverage determination (NCD) expanding Medicare coverage of artificial hearts when they are implanted as part of a study that is approved by the FDA and is determined by CMS to meet CMS' Coverage with Evidence Development (CED) clinical research criteria. (The final NCD is available on the CMS Web site at: *http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=211*.)

We indicated in the FY 2009 IPPS final rule (73 FR 48555) that, because Medicare's previous coverage policy with respect to this device had precluded payment from Medicare, we did not expect the costs associated with this technology to be currently reflected in the data used to determine the relative weights of MS–DRGs. As we have indicated in the past, and as we discussed in the FY 2009 IPPS final rule, although we generally believe that the newness period would begin on the date that FDA approval was granted, in cases where the applicant can demonstrate a documented delay in market availability subsequent to FDA approval, we would consider delaying the start of the newness period. This technology's situation represented such a case. We also noted that section 1886(d)(5)(K)(ii)(II) of the Act requires that we provide for the collection of cost data for a new medical service or technology for a period of at least 2 years and no more than 3 years ''beginning on the date on which an inpatient hospital code is issued with respect to the service or technology.'' Furthermore, the statute specifies that the term ''inpatient hospital code'' means any code that is used with respect to inpatient hospital services for which payment may be made under the IPPS and includes ICD–9–CM codes and any subsequent revisions. Although the TAH-t has been described by the ICD–9–CM code(s) since the time of its FDA approval, because the TAH-t had not been covered under the Medicare program (and, therefore, no Medicare payment had been made for this technology), this code could not be ''used with respect to inpatient hospital services for which payment'' is made under the IPPS, and thus we assumed that none of the costs associated with this technology would be reflected in the Medicare claims data used to recalibrate the MS–DRG relative weights for FY 2009. For this reason, as discussed in the FY 2009 IPPS final rule, despite the FDA approval date of the technology, we determined that TAH-t would still be eligible to be considered ''new'' for purposes of the new technology add-on payment because the TAH-t met the newness criterion on the date that Medicare coverage began, consistent with issuance of the final NCD, effective on May 1, 2008.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the TAH-t and consideration of the public comments we received in response to the FY 2009 IPPS proposed rule, we approved the TAH-t for new technology add-on payments for FY 2009 (73 FR 48557). We also continued to make new technology add-on payments for the TAH-t in FY 2010 and FY 2011.

We describe the new technology add-on payment requirements with regard to newness above. With regard to the newness criterion for the TAH-t, as stated above, we consider the beginning of the newness period for the device to have commenced from the Medicare NCD date of May 1, 2008; it is no longer considered new as of May 11, 2011. Because the 3-year anniversary date of the TAH-t will occur prior to the start of FY 2012, we proposed to discontinue the new technology add-on payment for the TAH-t in FY 2012.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to discontinue new technology add-on payments for the TAH-t in FY 2012.

c. 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 510K 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 (GBM) 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. The applicant explained that it was necessary to reduce the thermal damage lines from three to one and complete International Electrotechnical Commission/ Underwriter Laboratory testing, which led to the introduction of the technology to the market in December 2009, although the technology was approved by FDA in May 2009. The applicant also stated through supplementary information to its application that the first sale of the product took place on March 19, 2010. However, because the product was already available for use in December 2009, it appears that the newness date would begin in December 2009. In the FY 2011 IPPS/LTCH PPS proposed rule, we welcomed public comments on this issue.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the AutoLITT™ and consideration of the public comments we received in response to the FY 2011 IPPS/RY 2011 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. 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 MCC), 026 (Craniotomy and Endovascular Intracranial Procedures with 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 primary diagnosis codes 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.

We describe the new technology add-on payment requirements with regard to newness above. 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 from the market release date of December 2009. Therefore, the device will be considered ''new'' until December 2012. Because the 3-year anniversary date for the AutoLITT™ will occur after FY 2012, we proposed to continue to make new technology add-on payments for the AutoLITT™ in FY 2012.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to continue to make new technology add-on payments for the AutoLITT™ in FY 2012. The maximum add-on payment for a case involving the AutoLITT™ will continue to be $5,300 for FY 2012.

4. FY 2012 Applications for New Technology Add-On Payments

We received three applications for new technology add-on payments for FY 2012. However, one applicant, the Champion™ HF Monitoring System by CardioMems, Inc., withdrew its application after publication of the proposed rule because the applicant believed it would not receive FDA approval for its technology prior to the July 1 deadline, as required under § 412.87(c) of our regulations. Because the applicant withdrew its application, and we did not receive any public comments on this application, we are not discussing this application in this final rule. A discussion of the remaining two applications is presented below.

a. AxiaLIF® 2L+™ System

TranS1 submitted an application for new technology add-on payments for the AxiaLIF® 2L+™ System for FY 2012. The AxiaLIF® 2L+™ System is an implantable spinal fixation system, delivered through a pre-sacral approach, facilitating spinal fusion through axial stabilization of the anterior lumbar spine at Lumbar vertebrae 4 through Sacral vertebrae 1 (L4–S1).

The AxiaLIF® 2L+™ System received 510K FDA clearance (K092124) on January 21, 2010, and the applicant asserts that the device was available on the market immediately afterward through a limited market release program. The AxiaLIF® 2L+™ System is indicated for use to provide anterior stabilization of the L4–S1 spinal segments as an adjunct to spinal fusion. It is also indicated for minimally invasive access to the anterior portion of the lower spine for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy, or for assistance in the performance of L4–S1 interbody fusion. The AxiaLIF® 2L+™ System may be used in patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AxiaLIF® 2L+™ System is coded using ICD–9–CM procedure code 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique).

In the FY 2012 IPPS/LTCH PPS proposed rule, we expressed numerous

concerns regarding the application for new technology add-on payments for the AxiaLIF® 2L+™ System. With regard to the newness criterion, we were concerned that the AxiaLIF® 2L+™ System may be substantially similar to the other devices manufactured by the applicant, AxiaLIF® System and AxiaLIF® II™ System, the latter of which is listed as the predicate device on the AxiaLIF® 2L+™ System's application for FDA approval. Specifically, in making a determination of substantial similarity, we consider the following: (1) Whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or different DRG; and (3) whether the new use of a technology involves the treatment of the same or similar type of disease and the same or similar patient population.

We were particularly concerned that the AxiaLIF® 2L+™System uses the same or similar mechanism of action as the AxiaLIF® II™ System to achieve a therapeutic outcome. According to the applicant's 510K summary submitted to the FDA (K073514), the AxiaLIF® System is a multicomponent system including titanium alloy implantable devices and instrumentation for creating a pre-sacral axial track to the L5–S1 disk space. Similarly, the AxiaLIF® II™ System is described in the applicant's 510K summary submitted to the FDA (K073643) as a system of medical grade titanium alloy for the anterior stabilization of the L4–S1 spinal segments as an adjunct to spinal fusion. As we stated in the proposed rule, the applicant states that the AxiaLIF® 2L+™ System was created from the AxiaLIF® II™ System platform. The applicant submitted the following to distinguish the AxiaLIF® 2L+™ System from the AxiaLIF® II™ System:

- There have been internal thread changes for the 2L+ implant to accompany the Spanning Distraction Rod, which is designed to create and hold distraction in the L5–S1 disc space and allow for a higher degree of control over the Rod advancement and distraction;
- The design enhancements in the 2L+ System remove the dependence of distraction on size and placement of the S1 Rod, thus allowing precise implant placement in the vertebral bodies;
- In the 2L+ Implant, the L4 section of the L4–L5 Rod incorporates a conical design to increase fixation. The outer diameter (O.D.) of the L5 section is increased to be identical to the O.D. of the S1 implant to provide more surface area bone contact;
- The 2L+ Instrumentation incorporates Dilator Trials as an opportunity to enhance and simplify the intraoperative measuring technique by providing a direct visual means of measurement; and
- The 2L+ Fixation Rod fills the cannulation to prevent graft from moving into the rod from the disc space. The Fixation Rod also fixates the S1 Anchor and L4–L5 Rod together such that these components cannot passively separate.

Based on indications for use listed by the FDA for the AxiaLIF® System (K073514), the AxiaLIF® II™ System (K073643), and the AxiaLIF® 2L+™ System (as described above), we also were concerned that all of these devices involve the treatment of the same or similar type of disease and the same or similar patient population. With respect to whether a product is assigned to the same or different DRG, we noted in the proposed rule that currently the AxiaLIF® System and the AxiaLIF® 2L+™ System both generally map to MS–DRGs 459 (Spinal Fusion Except Cervical with MCC) and 460 (Spinal Fusion Except Cervical without MCC). Though the AxiaLIF® II™ System is no longer on the market, it would also map to the same DRGs.

If the AxiaLIF® 2L+™ System is found to be substantially similar to the AxiaLIF® System or the AxiaLIF® II™ System, the AxiaLIF® 2L+™ System would no longer qualify for the new technology add-on payment. Specifically, the appropriate start date for the AxiaLIF® 2L+™ System would be the start date of the device that is found to be substantially similar to the AxiaLIF® 2L+™ System. As noted above, the AxiaLIF® II™ System received FDA approval on April 28, 2008. The 3-year newness period for the AxiaLIF® II™ System ends prior to the start of FY 2012 (July 28, 2011). Given the length of time since the AxiaLIF® II™ System's entry into the market, cost-related data for the AxiaLIF® II™ System is already reflected in the most recent MS–DRG relative weights. Additionally, the AxiaLIF® System received multiple FDA approvals, the most recent of which was on January 11, 2008. The 3-year newness period for the AxiaLIF® System also ends prior to the start of FY 2012 (January 11, 2011). Given the length of time since the AxiaLIF® System's entry into the market, cost-related data for the AxiaLIF® System is already reflected in the most recent MS–DRG relative weights. However, if the AxiaLIF® 2L+™ System is not substantially similar to any of the predicate devices mentioned above, then the newness period for the AxiaLIF® 2L+™ System would begin on January 21, 2010 (the AxiaLIF® 2L+™ System's FDA approval date) and would be within the year newness period for FY 2012.

We invited public comment regarding whether or not the AxiaLIF® 2L+™ System meets the newness criteria, and, in particular, whether it is substantially similar to the AxiaLIF® System or the AxiaLIF® II™ System. We did not receive any public comments regarding the newness criteria or the substantial similarity of the AxiaLIF® 2L+™ System to the AxiaLIF® System or the AxiaLIF® II™ System.

In the proposed rule, we also expressed concerns with the applicant's methodology for demonstrating that it met the cost criterion. Specifically, in determining the projected standardized charge for the AxiaLIF® 2L+™ System, the applicant relied on a charge markup for defibrillators because it is also a high-cost implantable device for which a hospital purchase price is known. We were concerned about whether more direct data or different proxies are available, including a charge markup for the AxiaLIF® System or AxiaLIF® II™ System. In reviewing the applicant's charge markup, we also were concerned about the source data for determining the 2.77 charge markup ratio for defibrillators. We invited public comment on whether the AxiaLIF® 2L+™ System meets the cost criterion for a new technology add-on payment for FY 2012.

We did not receive any public comments that addressed our concerns regarding the cost criterion for new technology add-on payment.

With respect to the substantial clinical improvement criterion, the applicant asserted that it meets this criterion in its application. The applicant stated that substantial clinical improvement is demonstrated by the AxiaLIF® 2L+™ System's facilitation of spinal fusion surgery without a laparotomy. By avoiding a laparotomy, the AxiaLIF® 2L+™ System reduces blood loss, postoperative pain, narcotic use, denervation, morbidity, the probability of complications, and the risk of trauma to the tissue area surrounding the lumbar. The applicant further stated that the AxiaLIF® 2L+™ System reduces morbidity and has reduced risk of injuring vital organs and important intrinsic stabilizing structures, with a lower complication profile than traditional open fusion techniques. The applicant noted that long-term results can include better support of lordosis and prevention of adjacent level disease. In the proposed rule, we also expressed concern that this

does not demonstrate a substantial clinical improvement from the AxiaLIF® II™ System, which also facilitated spinal fusion surgery without a laparotomy.

The applicant has not conducted clinical trials, but the 300 cases of AxiaLIF® 2L+™ System's use (through the Limited Market Release) yielded a complication rate of 0.7 percent. The applicant also asserts that the pre-sacral approach results in a lower average length of stay than a non-sacral approach.

The applicant referred us to several sources of literature presenting data related to the pre-sacral approach for the applicant's AxiaLIF® device. Again, we expressed concern that the applicant generally repeated the statements made regarding the clinical improvement of its AxiaLIF® device and had not provided information that indicates that the AxiaLIF® 2L+™ System offers a substantial clinical benefit over the earlier AxiaLIF® or AxiaLIF® II™ devices. Moreover, the applicant failed to provide any clinical outcomes data for the AxiaLIF® 2L+™ System to substantiate its assertions regarding substantial clinical improvement for the AxiaLIF® 2L+™ System. While the applicant maintains that data from the AxiaLIF® device are relevant and can be used to substantiate its assertions for the AxiaLIF® 2L+™ System, we were concerned that data directly associated with the use of the AxiaLIF® 2L+™ System are not available. For example, we stated in the proposed rule that it was not clear the degree to which the population that required treatment with the AxiaLIF® 2L+™ System differed from the population that required treatment with the AxiaLIF® device or the AxiaLIF® II™ System, and that it was also not clear the degree to which the differences amongst the devices discussed above may affect clinical outcomes. We invited public comments on whether the AxiaLIF® 2L+™ System meets the substantial clinical improvement criterion for the new technology add-on payment for FY 2012. We did not receive any public comments regarding the substantial clinical improvement criterion.

We did not receive any public comments with regard to this application. In the absence of comments with information addressing our various concerns with this application, we are not approving the AxiaLIF® 2L+™ System for new technology add-on payments for FY 2012.

b. PerfectCLEAN With Micrillon®

UMF Corporation (the manufacturer) submitted an application for a technology called the PerfectCLEAN with Micrillon® (PerfectCLEAN). PerfectCLEAN is a cleaning textile product (or cleaning mat/wipe) with chlorine embedded or bound to the extruded fiber. The manufacturer asserts that PerfectCLEAN is intended to be used to trap and eliminate pathogens such as Methicillin-resistant Staphylococcus aureus (MRSA), Clostridium difficile (C diff.) and the H1N1 flu virus from surfaces within the hospital (as well as other health care facilities and locations). The applicant asserts that it can trap and remove more than 99.99 percent of bacteria on hard surfaces.

The manufacturer stated that the PerfectCLEAN is an Environmental Protection Agency (EPA) approved antimicrobial/disinfectant that will be available on the market in the first quarter of 2011. The applicant maintains that PerfectCLEAN is subject to review and approval by the EPA per the EPA's Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) Treated Article Exemption and, therefore, is not subject to review by the FDA. The applicant states that it was determined in a pre-registry meeting with the EPA that the underlying chemistries used to create the chlorine binding effects of Micrillon® chemistry are EPA and FDA approved even though no FDA claims are being sought.

With respect to whether the PerfectCLEAN is eligible for new technology add-on payments, in the proposed rule we noted that our regulations at § 412.87(c) state, ''CMS will only consider, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA approval or clearance by July 1 prior to the particular fiscal year.'' FDA ''approval,'' refers to the premarket approval application (PMA) process for most Class III devices, and FDA ''clearance'' refers to the 510(k) premarket notification submission process for most Class II devices and some Class I and Class III devices (section 515 of the Food, Drug and Cosmetic Act (FDCA) for PMA) and sections 510(k) and 513(i) of the FDCA (for premarket notification submission process)). Therefore, we believe our regulations, by requiring applicants to receive an FDA approval or clearance in order to be eligible for new technology add-on payments, limit the universe of items and services eligible to receive these payments to those that require FDA approval or clearance. The applicant has informed CMS that it is in the process of registering and listing its product with the FDA under section 510(b) through (d) and (j) and anticipates this process to be completed prior to the July 1 regulatory deadline. The registration process that the applicant is currently pursing will result in neither FDA approval nor clearance. In the proposed rule, we stated that we were therefore concerned that the PerfectCLEAN is not eligible for new technology add-on payments under our existing regulations, which require ''FDA approval or clearance by July 1 prior to the particular fiscal year'' (42 CFR § 412.87(c)). We welcomed public comments on whether the PerfectCLEAN is eligible for new technology add-on payments under the current regulations.

We did not receive any public comments in response to our concern that the PerfectCLEAN does not meet the newness criteria. Therefore, we conclude that the PerfectCLEAN does not meet the requirement specified under § 412.87(c) of our regulations that we requires applicants to receive an FDA approval or clearance by July 1 prior to the particular fiscal year, rather than registering and listing its product with the FDA, in order to be eligible for new technology add-on payments. As a result, we are not approving new technology add-on payments for the PerfectCLEAN for FY 2012. However, we will consider whether it would be appropriate for a product that is registered and listed with the FDA to be eligible for new technology add-on payments. If we conclude that such products should be eligible for new technology add-on payments in the future, we will propose changes to our regulations in a future rulemaking.

With regard to the cost criterion, the applicant used data from the FY 2011 After Outliers Removed (AOR) file (posted on the CMS Web site) for its cost analysis, which is based on the FY 2009 MedPAR file. The applicant considered MS–DRGs that relate to surgeries, skin abrasions, open sores, wounds, and similar inflamed tissue conditions where infection sites are thought to be more likely to occur for inpatient care situations. This resulted in the applicant determining that the technology would be most frequently used in 622 different MS–DRGs. The applicant noted that the charges from the FY 2011 AOR file were not inflated from FY 2009 to FY 2011; therefore the applicant applied a 2-year inflation factor of 12 percent (to update the charges from FY 2009 to FY 2011). The applicant based the 2-year inflation factor of 12 percent on a 3-year average of the 2 year rate-of-change in charges (the 2-year rate-of-change for FY 2009 of 11.841 percent (73 FR 48764); the 2-year rate-of-change for FY 2010 of 14.184

percent (74 FR 44010); and the 2-year rate-of-change for FY 2011 of 9.8843 percent (75 FR 50429)) that CMS uses in its outlier threshold calculation as published in section II. of the Addendum to the annual IPPS final rule. The applicant computed a case-weighted standardized charge per case of $40,442 for all 622 MS–DRGs, which did not include any charges related to the PerfectCLEAN. Therefore, it added the charges related to the technology to the case-weighted average standardized charge per case in evaluating the cost threshold criterion. The manufacturer estimates a charge per patient of $100 per day for the PerfectCLEAN. The applicant includes in this amount charges for payroll, treated textiles, packaging and protective gloves, laundering, storage, and distribution. The applicant multiplied the average length of stay for each MS–DRG (as found in Table 5 of the Addendum to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50547 through 50566)) by the charge per patient per day to determine the total charges per stay by MS–DRG related to the PerfectCLEAN. The applicant added additional charges per stay for the PerfectCLEAN to the case-weighted standardized charge per case and determined a total case-weighted average standardized charge per case of $41,105. Based on the 622 MS–DRGs to which the technology mapped, the applicant computed a case-weighted threshold of $40,834. Because the total case-weighted average standardized charge per case of $41,105 exceeds the case weighted threshold of $40,834, the applicant maintains that it meets the cost criteria.

In the proposed rule, we discussed several concerns regarding the applicant's cost analysis. First, although the technology can potentially be used in every single Medicare case, the application targets specific MS–DRGs. The applicant did not provide a detailed clinical justification regarding their selection of MS–DRGs, or a detailed justification for why the technology could not be used in other MS–DRGs. We believe it would be more appropriate to target all cases in every MS–DRG when conducting the cost analysis for this type of non-procedure or condition specific item. Using the FY 2011 AOR file, we conducted our own analysis with the same methodology above (and inflated the charges and included the total charges per stay related to the PerfectCLEAN) across all MS–DRGs. Based on our analysis, we determined a total case-weighted average standardized charge per case of $29,535. Using the applicant's methodology, we also determined a case-weighted threshold of $37,384 across all MS–DRGs. Because the total case-weighted average standardized charge per case of $29,535 is less than the case-weighted threshold of $37,384, we believe the PerfectCLEAN may not meet the cost criteria.

Second, the applicant included in the average charge per day more general charges unrelated to the specific new technology, such as payroll, packaging and protective gloves, laundering, storage and distribution. We do not believe it is appropriate to include charges for expenses already accounted for in MS–DRG based payments, such as laundering, storage, and distribution, and supplies already used by hospital staff such as packaging and protective gloves. We also note that the applicant states in its substantial clinical improvement discussion that the PerfectCLEAN represents the first comprehensive process for the removal and elimination of harmful micro-organisms responsible for HAIs from patient environments, the elimination of cross-contamination, and significant savings across many cost centers. If the PerfectCLEAN is a substitute for other cleaning mechanisms such as wiping down a hospital room with a spray and can produce significant savings across many cost centers, then it would be appropriate to deduct some charges from the average charge per day in order to accurately reflect the cost to hospitals of this technology. For these reasons, we remain concerned about the accuracy of the computation of a charge per patient of $100 per day and whether the PerfectCLEAN meets the cost criterion.

Thirdly, the applicant based the 12-percent, 2-year rate-of-change in charges on a 3-year average (FY 2009 through FY 2011) of the 2-year rate-of-change in charges as published in section II. of the Addendum to the annual IPPS final rule. We do not believe it is appropriate to use a 3-year average of the 2-year rate-of-change in charges as the 2-year rate-of-change in charges already uses the most recent data available to measure this change and, therefore, does not need to be averaged with prior years. Specifically, as described in section II. of the Addendum to this final rule, to calculate the proposed FY 2012 2-year rate-of-change in charges, we compared the 1-year average annualized rate-of-change in charges per case from the last quarter of FY 2009 in combination with the first quarter of FY 2010 (July 1, 2009 through December 31, 2009) to the last quarter of FY 2010 in combination with the first quarter of FY 2011 (July 1, 2010 through December 31, 2010). This rate-of-change was 4.43 percent (1.044394) or 9.07 percent (1.090759) over 2 years. If we substitute the FY 2012 proposed 2-year rate-of-change in charges of 9.07 percent for the 12-percent 3-year average of the 2-year rate-of-change in charges that the applicant used in its cost analysis, the total case-weighted average standardized charge per case would be $40,047 across the 622 MS–DRGs to which the applicant believes the technology would map. As mentioned above, the applicant computed a case-weighted threshold of $40,834. Because the total case-weighted average standardized charge per case of $40,047 is less than the case-weighted threshold of $40,834, it appears the applicant would not meet the cost criteria. We invited public comment on whether the PerfectCLEAN meets the cost criterion.

Comment: Several commenters expressed concerns that the cost estimates assume that this product would replace other items currently used in the hospital.

Response: As mentioned above, because PerfectCLEAN does not meet the requirements specified under § 412.87(c) of our regualtions it was not approved for FY 2012 new technology add-on payments. Once an applicant does not meet one of our criteria (newness, cost and substantial clinical improvement; in that order), we typically do not respond to public comments on the rest of the new technology add-on payment criteria. However, we are responding to the public comment above to ensure our cost criteria policy is clear.

The applicant substituted and added charges related to their product as part of its efforts to demonstrate that the product's costs exceed the cost threshold. While we have concerns regarding certain aspects of the applicant's methodology, it is common practice for new technology add-on payment applicants to substitute and/or add charges related to their technology in order to develop an average standardized charge per case to demonstrate that a technology exceeds the cost threshold.

The applicant maintained that it met the substantial clinical improvement criteria for the following reasons: The applicant believes the PerfectCLEAN significantly improves clinical outcomes for a patient population as compared to currently available treatments, decreases rate of subsequent diagnostic or therapeutic interventions, and decreases the number of future hospitalizations or physician visits. The applicant cited independent laboratory studies that set forth the level of removal and elimination of pathogens achieved by

the PerfectCLEAN. The applicant stated that the PerfectCLEAN includes ''more precise and focused patient room procedures that when properly applied utilize the textile and micro-denier efficacies'' listed in the product's independent test reports. The applicant stated that this results ''in a safer patient environment where the likelihood of cross contamination is reasonable.'' The applicant included test report data for the product, which demonstrated a 99.99 percent effectiveness of removing pathogens such as MRSA and C diff. The applicant cited industry and clinical support to demonstrate that improved patient environment can save lives. The applicant also stated that PerfectCLEAN represents the first comprehensive process for the removal and elimination of harmful micro-organisms responsible for hospital acquired infections from patient environments, the elimination of cross-contamination, and significant savings across many cost centers. The applicant stated that this new innovative system delivers reliable and repeatable results not currently achieved using currently available protocols and products. The applicant provided the following example: a traditional method of disinfection is to apply liquid disinfectants, which the applicant stated typically requires a 10-minute dwell time (which in most cases is not completed by the hospital) and then wiping or mopping up the nonevaporated liquids. Compared to this method, the applicant asserts that the PerfectCLEAN first removes the micro-organisms from those surfaces using specially designed microscopic fibers. The applicant asserted that these pathogens are trapped in a formulation of a chlorine binding technology which eliminates the pathogens.

The applicant further asserted that the PerfectCLEAN maintains its disinfecting capability longer than other methods because the chlorine-binding technology is introduced at the pellet stage of fiber extrusion so that it is present throughout the fiber, as opposed to a finish or coating process that wears off as textiles are used and laundered. Additionally, the applicant asserted that the technology's non-leaching chlorination system recharges in the wash process by attracting and binding free molecules of chlorine. The applicant further asserted that in this way the PerfectCLEAN recharges back to its original strength and efficacy which allows it to work more rapidly than other techniques. The applicant asserted that this reduces cross-contamination by those persons handling soiled textiles after the people contact surfaces which have been cleaned of harmful micro-organisms. The applicant added that the training in use of color coated textiles (different color mats) affords superior monitoring and compliance supervision of the hygiene specialists charged with responsibility to reduce cross contamination. We invited public comment on whether the PerfectCLEAN meets the substantial clinical improvement criterion.

Comment: Several commenters opposed consideration of this product for new technology add-on payments. The commenters stated that neither CMS nor the applicant provided sufficient supporting data to approve this technology for add-on payments. The commenters also stated that a cursory review of information sources on this product, including the company's own Web site, did not identify any scientific, peer-reviewed studies demonstrating efficacy against cross transmission, or prevention or mitigation of Healthcare-Acquired Infections (HAIs). The commenters urged CMS not to approve the application for new technology add-on payments for this or any product that lacks scientific evidence of its efficacy and urged CMS to use objective rigor to evaluate the methodological quality and strength of evidence submitted in support of new technology add-on payment applications.

Response: Because PerfectCLEAN does not meet the requirements specified under § 412.87(c) of our regulations (and was not approved for FY 2012 new technology add-on payments), we are not responding to these public comments in this final rule.

III. 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.'' In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the FY 2012 hospital wage index based on the statistical areas, including OMB's revised definitions of Metropolitan Areas, appears under section III.B. of this preamble.

Beginning October 1, 1993, section 1886(d)(3)(E) of the Act requires that we update the wage index annually. Furthermore, this section of the Act provides that the Secretary base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. The survey must exclude the wages and wage-related costs incurred in furnishing skilled nursing services. 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. The adjustment for FY 2012 is discussed in section II.B. of the Addendum to this final 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 budget neutrality adjustment for FY 2012 is discussed in section II.A.4.b. of the Addendum to this final rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are applying beginning October 1, 2011 (the FY 2012 wage index) appears under section III.C. of this preamble.

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. In accordance with the broad discretion 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 and announced in December 2003 (69 FR 49027). For a discussion of OMB's revised 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).

As with the FY 2011 final rule, and as we proposed, in this FY 2012 final rule, we are providing that hospitals receive 100 percent of their wage index based upon the CBSA configurations. Specifically, for each hospital, we determined a wage index for FY 2012 employing wage index data from hospital cost reports for cost reporting periods beginning during FY 2008 and using the CBSA labor market definitions. We consider CBSAs that are Metropolitan Statistical Areas (MSAs) to be urban, and CBSAs that are Micropolitan Statistical Areas as well as areas outside of CBSAs to be rural. In addition, it has been our longstanding policy that where an MSA has been divided into Metropolitan Divisions, we consider the Metropolitan Division to comprise the labor market areas for purposes of calculating the wage index (69 FR 49029) (regulations at § 412.64(b)(1)(ii)(A)).

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. CMS adopted those changes in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50162), beginning October 1, 2010, and they are reflected in this FY 2012 final rule. In 2013, OMB plans to announce new area delineations based on its 2010 standards (75 FR 37246) and the 2010 Census data.

The OMB bulletin is available on the OMB Web site at *http://www.whitehouse.gov/OMB*—go to ''Agency Information'' and click on ''Bulletins''.

C. Occupational Mix Adjustment to the FY 2012 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Development of Data for the FY 2012 Occupational Mix Adjustment Based on the 2007–2008 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.

For the FY 2010 hospital wage index, we used occupational mix data collected on a revised 2007–2008 Medicare Wage Index Occupational Mix Survey (the 2007–2008 survey) to compute the occupational mix adjustment for FY 2010. (We refer readers to the FY 2010 IPPS final rule (74 FR 43827) for a detailed discussion of the 2007–2008 survey.) Again, for the FY 2011 hospital wage index, we used data from the 2007–2008 survey (including revised data for 45 hospitals) to compute the FY 2011 adjustment.

As we proposed, for the FY 2012 hospital wage index, we again used occupational mix data collected on the 2007–2008 Medicare Wage Index Occupational Mix Survey to compute the occupational mix adjustment for FY 2012. We included data for 3,168 hospitals that also have wage data included in the FY 2012 wage index.

2. New 2010 Occupational Mix Survey for the FY 2013 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 2007–2008 survey to compute the occupational mix adjustment for FY 2010 and the FY 2011 wage index and are using the 2007–2008 occupational mix survey data in this final rule for the FY 2012 wage index. Therefore, a new measurement of occupational mix will be required for FY 2013.

The new 2010 survey (Form CMS–10079 (2010)) provides for the collection of hospital-specific wages and hours data for calendar year 2010 (that is, payroll periods ending between January 1, 2010 and December 31, 2010) and will be applied beginning with the FY 2013 wage index. The 2010 survey was adopted in the **Federal Register** on January 15, 2010 (75 FR 2548) and approved by OMB on February 26, 2010 (OMB control number 0938–0907). The survey is available on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage* and through the fiscal intermediaries/MACs. Hospitals were required to submit their completed 2010 surveys to their fiscal intermediaries/MACs by July 1, 2011. The preliminary, unaudited 2010 survey data will be released in early October 2011, along with the FY 2009 Worksheet S–3 wage data, for the FY 2013 wage index review and correction process.

3. Calculation of the Occupational Mix Adjustment for FY 2012

For FY 2012 (as we did for FY 2011), we calculated the occupational mix adjustment factor using the following steps:

Step 1—For each hospital, determine the percentage of the total nursing category attributable to a nursing subcategory by dividing the nursing subcategory hours by the total nursing category's hours. Repeat this computation for each of the four nursing subcategories: (1) Registered nurses; (2) licensed practical nurses; (3) nursing aides, orderlies, and attendants; and (4) medical assistants.

Step 2—Determine a national average hourly rate for each nursing subcategory by dividing a subcategory's total salaries for all hospitals in the occupational mix survey database by the subcategory's total hours for all hospitals in the occupational mix survey database.

Step 3—For each hospital, determine an adjusted average hourly rate for each nursing subcategory by multiplying the percentage of the total nursing category (from Step 1) by the national average hourly rate for that nursing subcategory (from Step 2). Repeat this calculation for each of the four nursing subcategories.

Step 4—For each hospital, determine the adjusted average hourly rate for the total nursing category by summing the adjusted average hourly rate (from Step 3) for each of the nursing subcategories.

Step 5—Determine the national average hourly rate for the total nursing category by dividing total nursing category salaries for all hospitals in the occupational mix survey database by total nursing category hours for all hospitals in the occupational mix survey database.

Step 6—For each hospital, compute the occupational mix adjustment factor for the total nursing category by dividing the national average hourly rate for the total nursing category (from Step 5) by the hospital's adjusted average hourly rate for the total nursing category (from Step 4).

If the hospital's adjusted average hourly rate is less than the national average hourly rate (indicating the

hospital employs a less costly mix of nursing employees), the occupational mix adjustment factor is greater than 1.0000. If the hospital's adjusted average hourly rate is greater than the national average hourly rate, the occupational mix adjustment factor is less than 1.0000.

Step 7—For each hospital, calculate the occupational mix adjusted salaries and wage-related costs for the total nursing category by multiplying the hospital's total salaries and wage-related costs (from Step 5 of the unadjusted wage index calculation in section III.F. of this preamble) by the percentage of the hospital's total workers attributable to the total nursing category (using the occupational mix survey data, this percentage is determined by dividing the hospital's total nursing category salaries by the hospital's total salaries for ''nursing and all other'') and by the total nursing category's occupational mix adjustment factor (from Step 6 above).

The remaining portion of the hospital's total salaries and wage-related costs that is attributable to all other employees of the hospital is not adjusted by the occupational mix. A hospital's all other portion is determined by subtracting the hospital's nursing category percentage from 100 percent.

Step 8—For each hospital, calculate the total occupational mix adjusted salaries and wage-related costs for a hospital by summing the occupational mix adjusted salaries and wage-related costs for the total nursing category (from Step 7) and the portion of the hospital's salaries and wage-related costs for all other employees (from Step 7).

To compute a hospital's occupational mix adjusted average hourly wage, divide the hospital's total occupational mix adjusted salaries and wage-related costs by the hospital's total hours (from Step 4 of the unadjusted wage index calculation in section III.F. of this preamble).

Step 9—To compute the occupational mix adjusted average hourly wage for an urban or rural area, sum the total occupational mix adjusted salaries and wage-related costs for all hospitals in the area, then sum the total hours for all hospitals in the area. Next, divide the area's occupational mix adjusted salaries and wage-related costs by the area's hours.

Step 10—To compute the national occupational mix adjusted average hourly wage, sum the total occupational mix adjusted salaries and wage-related costs for all hospitals in the Nation, then sum the total hours for all hospitals in the Nation. Next, divide the national occupational mix adjusted salaries and wage-related costs by the national hours. The FY 2012 occupational mix adjusted national average hourly wage is $36.2481.

Step 11—To compute the occupational mix adjusted wage index, divide each area's occupational mix adjusted average hourly wage (Step 9) by the national occupational mix adjusted average hourly wage (Step 10).

Step 12—To compute the Puerto Rico specific occupational mix adjusted wage index, follow Steps 1 through 11 above. The FY 2012 occupational mix adjusted Puerto Rico-specific average hourly wage is $15.4142.

The table below is an illustrative example of the occupational mix adjustment.

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Example of Occupational Mix Adjustment

Hospital A								
			Step 1	Step 2	Step 3	Step 5	Step 6	in Step 7
	Provider Occupational Mix Hours	**Provider Occupational Mix Salaries**	**Provider % by Subcategory**	**National AHWs by Subcategory**	**Provider Adjusted AHW**	**National Adjusted Nurse AHW**	**Nurse Occupa-tional Mix Adjust-ment Factor**	**Provider % by Total**
Registered Nurses	1,642,129	18,125,763	**79.84%**	$40.00	**$31.94**			
Licensed Practical Nurses and Surgical Technologists	67,860	404,822	**3.30%**	$20.00	**$0.66**			
Nursing Aides, Orderlies, & Attendants	259,177	1,762,579	**12.60%**	$13.00	**$1.64**			
Medical Assistants	87,622	577,045	**4.26%**	$12.00	**$0.51**			
Total Nurse Hours and Salaries	**2,056,788**	**20,870,209**			**$34.75**	**$27.00**	**0.7771**	**52.40%**
ALL OTHER	5,000,000	$18,957,010			Step 4			**47.60%**
TOTAL	**7,056,788**	**$39,827,219**						
Wage Data from Cost Report								
Wages (From S-3, Parts II and III)	$83,312,942.55							
Hours (From S-3, Parts II and III)	3,836,299.60							
Hospital A Unadjusted AHW	**$21.72**							
Nurse Occupational Mix Wages	**$33,925,838**	Step 7						
All Other Unadjusted Occupational Mix Wages	**$39,655,400**	Step 7						
Total Occupational Mix Wages	**$73,581,237**	Step 8						
Hospital A Final Occupational Mix Adjusted AHW	**$19.18**	Step 8						

Hospital B								
			Step 1	Step 2	Step 3	Step 5	Step 6	in Step 7
	Provider Occupational Mix Hours	**Provider Occupational Mix Salaries**	**Provider % by Subcategory**	**National AHWs by Subcategory**	**Provider Adjusted AHW**	**National Adjusted Nurse AHW**	**Nurse Occupa-tional Mix Adjustment Factor**	**Provider % by Total**
Registered Nurses	1,142,129	18,125,763	**72.43%**	$30.00	**$21.73**			
Licensed Practical Nurses and Surgical Technologists	67,860	404,822	**4.30%**	$20.00	**$0.86**			
Nursing Aides, Orderlies, & Attendants	279,177	1,762,579	**17.71%**	$13.00	**$2.30**			
Medical Assistants	87,622	577,045	**5.56%**	$12.00	**$0.67**			
Total Nurse Hours and Salaries	**1,576,788**	**20,870,209**			**$25.56**	**$27.00**	**1.0564**	**52.40%**
ALL OTHER	5,000,000	18,957,010			Step 4			**47.60%**
TOTAL	**6,576,788**	**$39,827,219**						
Wage Data from Cost Report								
Wages (From S-3, Parts II and III)	$25,979,714							
Hours (From S-3, Parts II and III)	1,097,585							
Hospital B Unadjusted AHW	**$23.67**							
Nurse Occupational Mix Wages	**$14,381,144**	Step 7						
All Other Unadjusted Occupational Mix Wages	**$12,365,857**	Step 7						
Total Occupational Mix Wages	**$26,747,001**	Step 8						
Hospital B Final Occupational Mix Adjusted AHW	**$24.37**	Step 8						
Note: The numbers in this example are hypothetical, including all National AHW amounts.								

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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 FY 2012 wage index. For the FY 2007–2008 survey, the response rate was 90.8 percent.

In computing the FY 2012 wage index, if a hospital did not respond to the occupational mix survey, or if we determined that a hospital's submitted data were too erroneous to include in the wage index, we assigned the hospital the average occupational mix adjustment for its labor market area. This method has the least impact on the wage index for other hospitals in the area. For areas where no hospital submitted data for purposes of calculating the occupational mix adjustment, we applied the national occupational mix factor of 1.0000 in calculating the area's FY 2012 occupational mix adjusted wage index. In addition, if a hospital submitted a survey, but that survey data could not be used because we determined the survey data to be aberrant, we also assigned the hospital the average occupational mix adjustment for its labor market area. For example, if a hospital's individual nurse category average hourly wages were out of range (that is, unusually high or low), and the hospital did not provide sufficient documentation to explain the aberrancy, or the hospital did not submit any registered nurse salaries or hours data, we assigned the hospital the average occupational mix adjustment for the labor market area in which it is located.

In calculating the average occupational mix adjustment factor for a labor market area, we replicated Steps 1 through 6 of the calculation for the occupational mix adjustment. However, instead of performing these steps at the hospital level, we aggregated the data at the labor market area level. In following these steps, for example, for CBSAs that contain hospitals that did not submit occupational mix survey data, the occupational mix adjustment factor ranged from a low of 0.9246 (CBSA 17780, College Station-Bryan, TX), to a high of 1.0761 (CBSA 19, Rural Louisiana). Also, in computing a hospital's occupational mix adjusted salaries and wage-related costs for nursing employees (Step 7 of the calculation), in the absence of occupational mix survey data, we multiplied the hospital's total salaries and wage-related costs by the percentage of the *area's* total workers attributable to the *area's* total nursing category. For FY 2012, there are five CBSAs (that include six hospitals) for which we did not have occupational mix data for any of its hospitals. The CBSAs are:

- CBSA 36140, Ocean City, NJ (1 hospital)
- CBSA 22140, Farmington, NM (1 hospital)
- CBSA 41900, San German-Cabo Rojo, PR (2 hospitals)
- CBSA 49500, Yauco, PR (1 hospital)
- CBSA 21940, Fajardo, PR (1 hospital)

Since the FY 2007 IPPS final rule, we have periodically discussed applying a hospital-specific penalty to hospitals that fail to submit occupational mix survey data (71 FR 48013 through 48014; 72 FR 47314 through 47315; 73 FR 48580; 74 FR 43832, and 75 FR 50167). During the FY 2008 rulemaking cycle, some commenters suggested a penalty equal to a 1- to 2-percent reduction in the hospital's wage index value or a set percentage of the standardized amount. During the FY 2009 and FY 2010 rulemaking cycles, several commenters reiterated their view that full participation in the occupational mix survey is critical, and that CMS should develop a methodology that encourages hospitals to report occupational mix survey data but does not unfairly penalize neighboring hospitals. We indicated in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule that, while we were not proposing a penalty at that time, we would consider the public comments we previously received, as well as any public comments on the proposed rule, as we developed the FY 2011 wage index.

In the FY 2011 IPPS/LTCH PPS proposed and final rules (75 FR 23943 and 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 will be effective beginning with the new 2010 occupational mix survey (the 2010 survey is discussed in section III.C.2. of this preamble). We will instruct fiscal intermediaries/MACs to begin gathering this information as part of the FY 2013 wage index desk review process. We note that we reserve the right to apply a different approach in future years, including potentially penalizing nonresponsive hospitals.

D. Worksheet S–3 Wage Data for the FY 2012 Wage Index

The FY 2012 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2008 (the FY 2011 wage index was based on data from cost reporting periods beginning during FY 2007).

1. Included Categories of Costs

The FY 2012 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))
- Wage-related costs, including pensions and other deferred compensation costs.

2. Changes to the Reporting Requirements for Pension Costs for the Medicare Wage Index

a. Background

The instructions for determining and reporting costs of qualified defined benefit pension on the cost report for Medicare cost-finding purposes are located in section 2142 of the Provider Reimbursement Manual, Part I (PRM–I). For Medicare wage index purposes, the instructions in section 3605.2 of the Provider Reimbursement Manual, Part II (PRM–II) for Worksheet S–3, Part II, Lines 13 through 20, require hospitals to comply with the requirements in section 2142 of the PRM–I.

Specifically, section 2142.5 of the PRM–I defines the current period liability for pension cost (that is, the maximum allowable pension cost) based on the actuarial accrued liability, normal cost, and unfunded actuarial liability. Under section 2142.4(A) of the PRM–I, these liability measurements are to be computed in accordance with the Employee Retirement Income Security Act of 1974 (ERISA), regardless of whether or not the pension plan is subject to ERISA. Also, section 2142.6(A) of the PRM–I requires the current period liability for pension costs to be funded in order to be allowable. In addition, section 2142.6(C) of the PRM–I allows for funding in excess of

the current period liability to be carried forward and recognized in future periods. We note that, on March 28, 2008, CMS published Revision 436, a technical clarification to section 2142 of the PRM–I.

Under ERISA, the actuarial accrued liability and normal cost are typically determined on an ongoing plan basis using long-term, best-estimate assumptions. The interest assumption reflects the average rates of return expected over the period during which benefits were payable, taking into account the investment mix of plan assets. Pension costs for plans not subject to ERISA (such as church plans and plans sponsored by public sector employers) are also typically based on the actuarial accrued liability and normal cost using long-term, best estimate assumptions.

The Pension Protection Act (PPA) of 2006 (Pub. L. 109–280) amended ERISA. Under the PPA amendments to ERISA, the actuarial accrued liability and normal cost are no longer used as a basis for determining ERISA minimum required or maximum tax deductible contributions. ERISA contribution limits are now based on a ''funding target'' and ''target normal cost'' measured on a settlement basis using the current market interest rates for investment grade corporate bonds that match the duration of the benefit payouts. The Internal Revenue Service (IRS) publishes the applicable interest rate tables on a monthly basis. Because pension liabilities are very sensitive to changes in the interest rate used to discount future benefit payouts, pension costs based on the PPA ''funding target'' and ''target normal cost'' values are expected to be less stable than those based on the pre-PPA traditional long-term, best-estimate assumptions, which change infrequently. Furthermore, plans not subject to the ERISA requirements, as amended by the PPA, are not likely to use the new ''funding target'' and ''target normal cost'' basis for determining pension costs, and ERISA plans are not likely to continue to report costs developed using the actuarial accrued liability and normal cost based on long-term, best estimate assumptions. Accordingly, there is no longer a standard actuarial basis used by all plans.

In response to the PPA amendments to ERISA, we began a review of the rules for determining pension costs for Medicare cost finding and wage index purposes. As an interim measure, we issued a Joint Signature Memorandum (JSM) in November 2009 that contained instructions and a spreadsheet to assist hospitals and Medicare contractors in determining the annual allowable defined benefit pension cost for the FY 2011 wage index (JSM/TDL–10061, 11–20–09, December 3, 2009). Although these instructions were released for purposes of the wage index, they also serve as interim guidance for Medicare cost-finding purposes.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25874 through 25876), we proposed to revise our policy for determining pension cost for Medicare purposes. As mentioned above, due to the ERISA rules, as amended by the PPA, there is no longer a standard actuarial cost basis used by all types of plans. Therefore, we proposed to no longer rely on actuarial computations to determine the maximum annual cost limitation for Medicare. Instead, the general parameters of our policy would maintain the current requirement that pension costs must be funded to be reportable, and would require all hospitals to report the actual pension contributions funded during the reporting period, on a cash basis.

In addition, under this cash basis approach, we proposed separate methodologies for measuring pension costs for Medicare cost-finding purposes (discussed in section IV.M. of this preamble) and for purposes of updating the wage index (discussed below in section III.D.2.b. of this preamble). It is necessary to have two distinct policies in order to address the different goals of determining a hospital's payments and updating the average hourly wage to establish the geographic area wage index. The function of the wage index is to measure relative hospital labor costs across areas. This function is distinct from Medicare payment determinations, where the goal is to measure the actual costs incurred by individual hospitals. These two distinct policies would require separate updated instructions to section 2142 of the PRM–I for Medicare cost-finding purposes and section 3605.2 of the PRM–II for purposes of the wage index. Below is a detailed discussion of our proposal for reporting pension costs under the wage index, as well as our final policy. A full discussion of our new methodology for Medicare cost-finding purposes is discussed in section IV.M. of this preamble, along with a summary of the public comments we received, our responses, and statements of our final policy.

The final policy below reflects our commitment to the general principles of the President's Executive Order released January 18, 2011, entitled ''Improving Regulation and Regulatory Review.''

b. Proposed and Final Policy for Allowable Pension Cost for the Medicare Wage Index

As mentioned above, the function of the Medicare wage index is to measure relative hospital labor costs across all areas. Therefore, while we believe pension costs must be funded in order to be reportable (we refer readers to the August 12, 2010 **Federal Register** (74 FR 47369) for an explanation of this longstanding policy), it also is important for pension costs to be relatively stable from year to year so that there is less volatility in the wage index. Thus, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to include, in the wage index, pension costs equal to a hospital's average actual cash contributions deposited to its defined benefit pension plan over a 3-year period. The use of cash contributions as a measure of the costs incurred is necessary to ensure uniformity among all hospitals, regardless of their tax status or ERISA coverage. The 3-year average is intended to reduce the volatility that often occurs due to timing of contributions. Most pension plan sponsors have flexibility to determine the pension funding for a particular period and their decisions may be based on cash-flow considerations or other factors unrelated to the normal operation of the plan. Furthermore, the funding of current period pension costs may be delayed by almost a full year after the close of the period to which it applies. By using a 3-year average, we hope to enhance the stability of the wage index.

To ensure that the average annual pension cost reflected in the wage index is consistent with the reporting period applicable to all other costs included in the index, we proposed that the 3-year average be centered on the current cost reporting period for the wage index. For example, the 2013 wage index is based on cost reporting periods beginning during Federal Fiscal Year (FFY) 2009 and would therefore reflect the average pension contributions made in hospitals' cost reporting periods beginning during FFYs 2008, 2009, and 2010. Thus, this policy would require pension plan contribution data for the cost reporting periods immediately preceding and immediately following the current cost reporting period for the wage index.

In the proposed rule, we indicated that we do not anticipate that the use of contributions made in the period immediately following the current cost reporting period will create an administrative burden because, even under the existing rule, contributions to

fund current period costs are often deferred until the following period. In addition, trust account statements and general ledger reports to support the contributions should be readily available.

We proposed to apply the above methodology for reporting pension costs for the wage index beginning with the FY 2013 IPPS update. We solicited public comment on this policy proposal and indicated that we were especially interested in receiving comments related to the proposed 3-year averaging period.

Comment: A number of commenters suggested that CMS convene a Medicare Technical Advisory Group (MTAG) before establishing a policy on pension costs.

Response: An MTAG is not required by statute. Engaging in notice and comment rulemaking provides sufficient process for developing a policy on this issue. In addition, timeliness of an updated rule is needed because the actuarial terminology used in section 2142 of the PRM–I is no longer used under ERISA as amended by the PPA. Also, as many commenters noted, there have been numerous appeals related to pension cost adjustments in recent years, and we believe our policy will alleviate the confusion demonstrated by such appeals. Proposing the issue through the notice and comment rulemaking process will allow CMS to address the issue by finalizing the policy effective October 1, 2011.

Comment: Many commenters supporting an MTAG also stated that an MTAG might recommend adoption of Generally Accepted Accounting Principles (GAAP) (with no funding limit) for the wage index. These commenters generally called for CMS to propose a methodology that accurately reflects the total resources hospitals expend over the life of their defined benefit plans and recognizes those costs fully in the wage index. They implied that GAAP could be the most appropriate method to satisfy this goal. One commenter noted that a proposal to base pension expense for both the wage index and cost-finding purposes on a 3-year average of actual funding is inconsistent with the other principles of the cost report relying on GAAP and accrual versus cash-basis accounting.

Response: There is no consistently applied, standardized pension cost accounting methodology that produces a stable measure of the actual cost incurred over the life of a pension plan. Moreover, not all providers are subject to the same GAAP standards, and the rules applicable to pension costs under the various standards are not consistent. Uniformity of costs for the wage index would require all providers to compute pension costs under a particular GAAP standard. This would create an administrative burden for some and would limit transparency.

Even under GAAP as promulgated by the Financial Accounting Standards Board (FASB), significant inconsistencies may exist because the rules allow gains and losses to either be recognized immediately (as a current period cost), or spread over future periods. Until recently, immediate recognition of gains and losses was seldom used because it can cause pension costs to be extremely volatile. For example, those who have adopted immediate recognition of gains and losses are likely to see their GAAP pension costs shift to pension income (negative costs) when interest rates begin to rise.

Finally, the GAAP standards are currently in a state of flux. The Government Accounting Standards Board (GASB) and the International Accounting Standards Board (IASB) are both in the process of reviewing their rules for pension accounting. The FASB and IASB are discussing how U.S. accounting can be reconciled with international accounting. We anticipate changes in GAAP pension rules will reflect the trend towards mark-to-market financial reporting (immediate recognition of gains and losses) and thereby further increase the potential volatility of those cost measurements.

Comment: Most commenters expressed concern that hospitals with prefunded pension plans would be disadvantaged, while those with underfunded plans would be rewarded. A number of these commenters called for a ''true-up'' of costs to ensure absolute equity between past and future periods, similar to the carry forward provision in the current PRM.

Response: We continue to believe that absolute equity between past and future periods is not necessary since the wage index is a relative rather than an absolute measure of costs. However, in response to public comments, we agree that it would be appropriate to allow certain prefunded amounts to be reported as pension costs in future periods. Although most plan sponsors follow a relatively stable pattern of funding over time, accelerated funding may have been required due to stock market losses and declining interest rates in recent years. We are particularly sensitive to the fact that many hospitals were required to make contributions in excess of the amount reportable for Medicare purposes to satisfy ERISA requirements based on the ''current liability.'' We are also aware that some hospitals accelerated their pension plan funding in order to avoid benefit restrictions or other penalties under the PPA amendments to ERISA. As a result, we are finalizing a transition policy based on funding that may have exceeded the amounts reportable for the FY 2007 through FY 2012 wage indexes (cost reports with begin dates during the period of (on or after) October 1, 2002 through (on or before) September 30, 2008). We believe this period is representative of the period when contributions may have exceeded the amounts reportable for Medicare purposes.

Our transition policy will allow providers to establish a prefunding balance equal to (A) minus (B), where (A) is the sum of cash contributions made during a period of consecutive provider cost reporting periods commencing no earlier than October 1, 2002 (the cost reporting period applicable for the FY 2007 wage index), and ending with the cost reporting period applicable for the FY 2012 wage index, and (B) is the sum of pension costs actually reflected in the wage index for the same cost reporting periods. It should be noted that the prefunding balance is not the same as the carry forward amount described in section 2142.6C of the PRM–I since the carry forward amount may include different periods and may include contributions made after the end of the cost reporting period ending immediately prior to the effective date of this new policy.

The transition policy permits a hospital to include 1/10th of the prefunding balance in the wage index pension cost each year commencing with the FY 2013 wage index and ending with the FY 2022 wage index, that is, in 10 equal prefunding installments. Any prefunding installment that is not included in the wage index pension cost for the current cost reporting period cannot be reassigned and added to the wage index pension cost of any subsequent period. To take advantage of all 10 prefunding installments, hospitals must determine and begin claiming the prefunding installment in the pension cost for the FY 2013 wage index. Distributing excess funding over a period of 10 years will ensure that when hospitals have substantial prefunding balances, the amount assigned to any one year will not unduly influence the wage index in that year. An example of how the pension cost (including the prefunding balance) is to be calculated is included in our response to another comment.

For each cost reporting period that a prefunding installment is included in the reported pension cost, the provider must have documentation to support the calculation of the prefunding balance, including the contributions made to the pension plan and pension costs reported in the wage index for each applicable cost reporting period reflected in the calculation. In order to notify the public of this transition policy, we will issue a memorandum to Medicare contractors after the publication of this final policy, requiring them to notify hospitals in writing of these changes. In addition, we plan to post this letter on our Web site and will announce these changes through our regular open door forums.

Comment: A number of commenters expressed support for our proposed rule. One viewed it as a compromise between methods required for private, public, and non-profit entities and thought its simplicity will help to maintain consistency. Another felt it would fairly reflect the actual costs, mitigate year-to-year volatility, and encourage adequate funding. One commenter agreed with our decision to eliminate actuarial based measurements because they were too complex and lead to inconsistency. A number of commenters noted that the Medicare wage index methodology ''should be transparent so that it can be easily reviewed and replicated by providers and other constituents, which allows providers and others to have confidence in the resulting indices.''

Response: We appreciate the commenters' support of our proposal. Our final policy is intended to be one of simplicity that will help maintain consistency. We believe that this final policy will satisfy the objectives of a transparent methodology for including pension costs in the wage index.

Comment: One commenter expressed concern that our proposal would hurt financially strapped hospitals that cannot afford to fund their plans. Another commenter believed that the proposal in the proposed rule would understate wage related costs in periods when a provider was not able to fund, and overstate wage costs in other periods. One commenter was concerned that the proposal in the proposed rule would ''incent a hospital to 'over fund' their plan in a particular year to increase its hourly rate.'' One commenter stated that our policy will penalize good management of investments while rewarding bad management.

Response: Our policy is that costs must be funded to be reportable for Medicare purposes. Some providers have no legal obligation to fund their pension liabilities. There may be organizations that cannot afford to maintain their plan and will ultimately terminate the plan with unfunded liabilities. Moreover, some liabilities reflected in current period costs may never materialize due to future gains or benefit cutbacks.

We understand that the level of funding will vary from one period to the next due to financial constraints or other factors, but believe that the 3-year average will help to limit volatility caused by short-term fluctuations.

We do not believe that Medicare wage index policy will have a material effect on the ultimate level of pension plan funding. Because pension contributions made to a qualified trust are generally irrevocable and most providers have limited financial resources, significant overfunding is not likely to occur solely because of Medicare wage index policy.

Over the long term, pension costs may increase or decrease due to changes in plan coverage, benefit levels, or gains and losses from investment performance or other sources. However, these changes would ultimately affect the level of future pension costs regardless of how those costs have been reported in the past. Thus, we do not expect that providers will choose investments with poor returns or elevate their contribution levels for the sole purpose of increasing their wage index.

Comment: Several commenters requested clarification on technical aspects of the proposed rule on timing or procedural issues. There was confusion regarding the treatment of payments made after the end of a fiscal year but within the 1-year period (or 3 years with extension) permitted under the liquidation of liabilities provision in section 2305 of PRM–I.

Response: The pension cost to be reflected in the wage index will be reported on Worksheet S–3, Part II and will equal the average contributions paid, on a cash basis, over the applicable 3-year period (plus any prefunding installment discussed above). The applicable period for the 3-year average includes the current cost reporting period applicable to the wage index (4 year lag), and the periods immediately preceding and immediately following the applicable wage index reporting period. The 3-year average is reportable even if it exceeds the current period contribution. There is no requirement to demonstrate that the 3-year average, prefunding installment or the amount funded in any particular period are necessary to satisfy a liability under ERISA or any other actuarial basis. Since actuarial measurements are not used to compute pension costs under the final policy, there is no longer a need for a crosswalk between the different terminology used by IRS and GAAP.

For a new plan, the averaging period will be limited to the number of years the plan was in effect. If there is a merger (plan or corporate), contributions should include a provider's pension plan payments made either to a predecessor plan or the current plan during the applicable 3-year period. Increased costs attributable to benefit improvements will be recognized when funded. This is consistent with the amortization of costs associated with plan changes under GAAP and ERISA.

The actual funded amounts for each cost reporting period to be included in the average will not necessarily appear on the cost report for the period in which they were made. We are considering modifications to the cost report to allow for reporting of current period contributions. Instead, provider will be required to obtain contribution data from the pension trustee, insurance carrier, Schedule B or SB of IRS Form 5500, and, if applicable, from accounting records showing the allocation of total plan contributions to each participating provider. These records should be maintained as needed for subsequent periods.

The following is an example of the calculation of pension cost to be included in the FY 2013 wage index calculation for a hospital with a June 30 fiscal year end and a June 30 cost reporting period:

Wage index year	Provider fiscal year		Total pension contributions	Reported wage index pension cost
	Beginning	Ending		
2007	7/1/2003	6/30/2004	$3,200,000	$2,500,000
2008	7/1/2004	6/30/2005	not available	2,800,000
2009	7/1/2005	6/30/2006	1,300,000	800,000
2010	7/1/2006	6/30/2007	2,700,000	3,000,000

Wage index year	Provider fiscal year		Total pension contributions	Reported wage index pension cost
	Beginning	Ending		
2011	7/1/2007	6/30/2008	4,100,000	3,600,000
2012	7/1/2008	6/30/2009	3,000,000	200,000
2013	7/1/2009	6/30/2010	1,000,000	
	7/1/2010	6/30/2011	2,000,000	

Since this hospital can only produce supporting documentation of contributions for the continuous fiscal years beginning 2005 through 2008, the determination of the prefunding balance must exclude contributions from fiscal years beginning (FYB) in 2003 and 2004. The sum of contributions made during FYB in 2005 through 2008 is $11,100,000. The sum of pension costs reflected in the wage index for FYB in 2005 through 2008 is $7,600,000. The prefunding balance is $3,500,000 ($11,100,000—$7,600,000) and the prefunding installment is $350,000 ($3,500,000/10). The $350,000 prefunding installment can be added to the pension costs reported each year for the FY 2013 through FY 2022 wage index.

In this illustration, the hospital determines the 3-year average pension contribution for the FY 2013 wage index is $2,000,000 based on cash contributions made during FYB in 2008, 2009, and 2010. It should report pension costs of $2,350,000 (the sum of the current 3-year average contribution of $2,000,000 [($1,000,000 + $3,000,000 + $2,000,000) 3] plus the prefunding installment of $350,000) on Worksheet S–3, Part II for the FY 2013 wage index. For audit purposes, the hospital must retain and make available its supporting documentation for the 3-year average, the prefunding balance and prefunding installment.

We note that contributions are to be determined on a cash basis rather than an accrual basis. Since there is no recognition of funding which occurs after June 30, 2011, all of the data needed to determine the pension cost for the FY 2013 wage index will be readily available when the reporting process begins in October 2011. Under this final policy, neither section 2142 nor 2305 will be applicable for wage index purposes.

Comment: One commenter believed that we may be ''attempting retroactive rulemaking.'' Another commenter stated that ''if it goes forward with the proposal or a revised version of the proposal, CMS should do so in a prospective manner * * * CMS should apply it only as of the FY 2016 wage index (which would, if using a 3-year rolling average, include pension costs from cost reporting periods beginning during Federal fiscal years 2011, 2012 and 2013).''

Response: We disagree with the commenter that our policy represents retroactive rulemaking. We proposed this change through notice and comment rulemaking and have given the public sufficient time to provide input through public comments before making any policy change concerning the reporting of pension costs under the wage index. The use of data from prior periods to implement prospective policy changes does not constitute retroactive rulemaking. Therefore, we believe we have applied this policy change prospectively.

Comment: One commenter recommended that there should be specific statements in the cost report that pension costs for cost-finding will be treated differently from pension costs for the wage index. The commenter also suggested separate PRM cost reporting instructions for the Medicare cost report versus the Medicare wage index, given that there will be separate methodologies for determining pension costs.

Response: CMS is implementing different pension cost policies for wage index and cost finding purposes. Accordingly, the PRM will be revised to include separate and distinct pension cost provisions for wage index and cost-finding purposes.

We would like to thank the provider community for their public comments on the proposed rule for reporting pension costs for Medicare wage index purposes. After considering their concerns and suggestions, we are finalizing our policy with modifications for reporting pension costs for Medicare wage index purposes. The final policy is effective for the FY 2013 wage index for which the wage index process begins in October 2011.

Under the final policy, the pension cost to be included in the wage index equals a hospital's average cash contributions deposited to its defined benefit pension plan over a 3-year period, or number of years that the hospital has sponsored a defined benefit plan if less than 3 years. Any reversion or other withdrawal of assets from the pension fund or trust is treated as a negative contribution for purposes of measuring the 3-year average. The 3-year average is centered on the base cost reporting period for the wage index. For example, the FY 2013 wage index will be based on Medicare cost reporting periods beginning during FFY 2009 and will reflect the average pension contributions made in hospitals' cost reporting periods beginning during FFYs 2008, 2009, and 2010.

In response to the public comments as discussed above, we are finalizing a transition policy that permits a hospital to determine a ''prefunding balance'' based on pension contributions made but not reflected in the wage index during certain prior periods. Our transition policy will allow providers to establish a prefunding balance equal to (A) minus (B), where (A) is the sum of cash contributions made during a period of consecutive provider cost reporting periods commencing no earlier than October 1, 2002 (the cost reporting period applicable for the FY 2007 wage index), and ending with the cost reporting period applicable for the FY 2012 wage index, and (B) is the sum of pension costs actually reflected in the wage index for the same cost reporting periods.

The transition policy permits a hospital to include 1/10th of the prefunding balance in the wage index pension cost each year commencing with the FY 2013 wage index and ending with the FY 2022 wage index, that is, in 10 equal prefunding installments. Any prefunding installment that is not included in the wage index pension cost for the current year cannot be reassigned and added to the wage index pension cost of any subsequent year.

3. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2011, the wage index for FY 2012 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 FY 2012 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).

4. 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.

E. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2012 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report for cost reporting periods beginning on or after October 1, 2007, and before October 1, 2008. For wage index purposes, we refer to cost reports during this period as the ''FY 2008 cost report,'' the ''FY 2008 wage data,'' or the ''FY 2008 data.'' Instructions for completing Worksheet S–3, Parts II and III are in the Provider Reimbursement Manual (PRM), Part II, sections 3605.2 and 3605.3. The data file used to construct the wage index includes FY 2008 data submitted to us as of June 27, 2011. As in past years, we performed an intensive 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 2012 wage index, we identified and excluded 23 providers with data that was too aberrant to include in the proposed wage index, although we stated that if data elements for some of these providers are corrected, we intended to include some of these providers in the FY 2012 final wage index. We have received corrected data for seven providers, and therefore, we are including the data for these seven providers in the FY 2012 final wage index. However, we have also determined that the data for three additional providers are too aberrant to include in the FY 2012 final wage index. Thus, in total, we are excluding the data of 27 (23 + 7—3) providers from the FY 2012 final wage index.

In constructing the FY 2012 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2008, 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). In the proposed rule, we removed 19 hospitals that converted to CAH status between February 16, 2010, the cut-off date for CAH exclusion from the FY 2011 wage index, and February 15, 2011, the cut-off date for CAH exclusion from the FY 2012 wage index. However, since the issuance of the proposed rule, we have learned of four additional hospitals that have converted to CAH status between February 16, 2010, and February 15, 2011. We have excluded the wage data of these four hospitals as well. After removing hospitals with aberrant data and hospitals that converted to CAH status, the FY 2012 final wage index is calculated based on 3,489 hospitals.

In the FY 2008 final rule with comment period (72 FR 47317) and the FY 2009 IPPS final rule (73 FR 48582), we discussed our policy for allocating a multicampus hospital's wages and hours data, by full-time equivalent (FTE) staff, among the different labor market areas where its campuses are located. During the FY 2011 wage index desk review process, we requested fiscal intermediaries/MACs to contact multicampus hospitals that had campuses in different labor market areas to collect the data for the allocation. The FY 2011 wage index included separate wage data for campuses of three multicampus hospitals.

For FY 2012, as we discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50168), and as we proposed, we are no longer allowing hospitals to use discharge data for the allocation of a multicampus hospital's wage data among the different labor market areas where its campuses are located. The Medicare cost report was updated in May 2008 to provide for the reporting of FTE data by campus for multicampus hospitals (Form CMS–2552–96, Worksheet S–2, lines 61 and 62). The data from cost reporting periods that begin in FY 2008 are now available for calculating the wage index for FY 2012. Therefore, a multicampus hospital will not have the option to use either FTE or discharge data for allocating wage data among its campuses by providing the information from the applicable cost reporting period to CMS through its fiscal intermediary/MAC. Table 2 for the FY 2012 wage index, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, includes separate wage data for campuses of three multicampus hospitals.

F. Method for Computing the FY 2012 Unadjusted Wage Index

1. Steps for Computation

The method used to compute the FY 2012 wage index without an occupational mix adjustment follows:

Step 1—As noted above, we based the proposed FY 2012 wage index on wage data reported on the FY 2008 Medicare cost reports. We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period beginning on or after October 1, 2007, and before October 1, 2008. In addition, we included data from some hospitals that had cost reporting periods beginning before October 2007 and reported a cost reporting period covering all of FY 2008. These data are included because no other data from these hospitals would be available for the cost reporting period described above, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2008 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2008 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2007, and before October 1, 2008), we included wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2—Salaries—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315),

we include Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II for overhead services in the wage index. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation for FY 2011 is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 22.01, 26.01, and 27.01.) In calculating a hospital's average salaries plus wage-related costs, we subtract from Line 1 (total salaries) the GME and CRNA costs reported on Lines 2, 4.01, 6, and 6.01, the Part B salaries reported on Lines 3, 5 and 5.01, home office salaries reported on Line 7, and exclude salaries reported on Lines 8 and 8.01 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. To determine total salaries plus wage-related costs, we add to the net hospital salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 9 and 10), home office salaries and wage-related costs reported by the hospital on Lines 11 and 12, and nonexcluded area wage-related costs (Lines 13, 14, and 18).

We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 18) are excluded if no corresponding salaries are reported for those employees on Line 4.

Step 3—Hours—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2.

Step 4—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ratio of excluded area hours (sum of Lines 8 and 8.01 of Worksheet S–3, Part II) to revised total hours (Line 1 minus the sum of Part II, Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, and Part III, Line 13 of Worksheet S–3). We then compute the amounts of overhead salaries and hours to be allocated to excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Line 13 of Worksheet S–3, Part III. Next, we compute the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) we determine the ratio of overhead hours (Part III, Line 13 minus the sum of lines 22.01, 26.01, and 27.01) to revised hours excluding the sum of lines 22.01, 26.01, and 27.01 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, 8, 8.01, 22.01, 26.01, and 27.01). (We note that for the FY 2008 and subsequent wage index calculations, we are excluding the sum of lines 22.01, 26.01, and 27.01 from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 22.01, 26.01, and 27.01 require that associated wage-related costs be combined with wages on the respective contract labor lines.); (2) we compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 13, 14, and 18; and (3) we multiply the computed overhead wage-related costs by the above excluded area hours ratio. Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2005, through April 15, 2007, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not making any changes to the usage for FY 2012. 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
10/14/2007	11/15/2007	1.03990
11/14/2007	12/15/2007	1.03699
12/14/2007	01/15/2008	1.03402
01/14/2008	02/15/2008	1.03113
02/14/2008	03/15/2008	1.02831
03/14/2008	04/15/2008	1.02555
04/14/2008	05/15/2008	1.02286
05/14/2008	06/15/2008	1.02024
06/14/2008	07/15/2008	1.01766
07/14/2008	08/15/2008	1.01511
08/14/2008	09/15/2008	1.01258
09/14/2008	10/15/2008	1.01015
10/14/2008	11/15/2008	1.00787
11/14/2008	12/15/2008	1.00575
12/14/2008	01/15/2009	1.00375
01/14/2009	02/15/2009	1.00183
02/14/2009	03/15/2009	1.00000
03/14/2009	04/15/2009	0.99820

For example, the midpoint of a cost reporting period beginning January 1, 2008, and ending December 31, 2008, is June 30, 2008. An adjustment factor of 1.01766 would be applied to the wages of a hospital with such a cost reporting period. In addition, for the data for any cost reporting period that began in FY 2008 and covered a period of less than 360 days or more than 370 days, we annualize the data to reflect a 1-year cost report. Dividing the data by the number of days in the cost report and then multiplying the results by 365 accomplishes annualization.

Step 6—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), section 1886(d)(8)(E), or section 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7—We divide the total adjusted salaries plus wage-related costs obtained under both methods in Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage. Using the data as described above, the national average hourly wage (unadjusted for occupational mix) is $36.2784.

Step 9—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10—Following the process set forth above, we develop a separate Puerto Rico-specific wage index for purposes of adjusting the Puerto Rico standardized amounts. (The national Puerto Rico standardized amount is adjusted by a wage index calculated for all Puerto Rico labor market areas based on the national average hourly wage as described above.) We add the total adjusted salaries plus wage-related costs (as calculated in Step 5) for all hospitals in Puerto Rico and divide the sum by the total hours for Puerto Rico (as calculated in Step 4) to arrive at an overall average hourly wage (unadjusted for occupational mix) of $15.3899 for Puerto Rico. For each labor market area in Puerto Rico, we calculate the Puerto Rico-specific wage index value by dividing the area average hourly wage (as calculated in Step 7) by the overall Puerto Rico average hourly wage.

Step 11—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 4D which is listed in section VI. of the Addendum to this final rule and available via the Internet.

In the FY 2012 IPPS/LTCH PPS proposed rule, we made no proposals for changing our policies pertaining to the rural floor provision. However, we received several public comments, particularly regarding the FY 2012 rural floor wage index for Massachusetts, which was discussed in section VI.B.7. of Appendix A (76 FR 26059 and 26060) as part of the regulatory impact analysis for the proposed rule.

Comment: Some commenters stated that CMS had correctly calculated the Massachusetts rural floor wage index in accordance with existing law and regulations. One commenter agreed with the basic policy and premise of the rural floor limit but opined that all hospitals in Massachusetts receiving a significant increase in Medicare revenues as a result of a small hospital converting to an acute care provider is inconsistent with the intent and spirit of the law. The commenter suggested that CMS revisit its regulatory and policy options as it relates to section 4410 of the BBA.

The MedPAC stated that the Massachusetts rural floor situation is suggestive of why a new wage index system is needed, adding that the current system is not equitable because extra payments made to hospitals receiving such exceptions are budget neutral; therefore, all hospitals must absorb the cost. A national hospital association requested that CMS provide a table indicating the state-by-state impact of the rural floor provision for providers in each state, including a schedule of what the area wage indexes would be if the rural floor was not applied. The commenter also suggested that CMS publish this information annually.

Response: Beginning with this FY 2012 IPPS–LTCH final rule, we are including in the impact section of Appendix A of both the proposed and final rules a table indicating State level impacts of the rural floor provision. For FY 2012, this table includes the impacts of both the rural and imputed floors, as discussed under section III.F.2. of this preamble. In addition, we are revising Table 4D of the Addendum, which specifies the wage index for States or urban areas receiving the frontier, rural, or imputed floor, to include a column indicating the pre-floor area wage index. We will consider the commenters' other suggestions as part of our development of the Report to Congress on reforming the wage index, required by section 3137(b) of the Affordable Care Act and due to the Congress by December 31, 2011.

2. Imputed Floor Policy

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25878 and 25879), we discussed the expiration of the imputed floor policy. (We refer readers to FY 2005 IPPS final rule (69 FR 49109 through 49111) for an explanation of CMS' adoption of the ''imputed'' floor as a temporary 3-year regulatory measure to address concerns that hospitals in all-urban States were disadvantaged by the absence of rural hospitals to set a wage index floor in those States; the FY 2008 IPPS final rule with comment period (72 FR 47321) for a discussion of the extension of the imputed floor through FY 2008; and the FY 2009 IPPS final rule (73 FR 48570 through 48574 and 48584) for a discussion of the extension of the imputed floor for an additional 3 years, through FY 2011, due to applying statewide budget neutrality for the rural and imputed floors.) As noted in the FY 2012 IPPS/LTCH PPS proposed rule and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160), section 3141 of the Affordable Care Act replaced the statewide budget neutrality policy and required that budget neutrality for the rural and imputed floor be applied ''through a uniform, national adjustment to the area wage index'' instead of within each State beginning in FY 2011. However, the Affordable Care Act did not include a provision to extend the imputed floor or to make the imputed floor permanent.

As discussed in the FY 2008 IPPS proposed rule and final rule with comment period (72 FR 24786 and 72 FR 47322, respectively), the application of the national budget neutrality requirement for the rural and imputed floors requires a transfer of payments from hospitals in States with rural hospitals but where the rural floor is not applied to hospitals in States where the rural or imputed floor is applied. In the final FY 2012 wage index, the rural floor will apply to 297 hospitals in 29 States. Continuing the imputed floor policy into FY 2012 results in an imputed floor applied for 39 hospitals in New Jersey. In the FY 2012 IPPS/LTCH PPS proposed rule, we did not propose to extend the imputed floor but sought public comments regarding the expiration of the imputed floor.

Comment: Although a few commenters, including a national hospital association, supported CMS making no proposal to extend the imputed floor policy and agreed that this type of floor benefits only one State at the expense of all others, applies even though there are no rural areas in the State, and should apply only when required by statute, several commenters requested that CMS extend the current imputed floor policy. These commenters, including a national hospital association and a few State hospital associations, noted that, absent any new wage index policies that address the original need for the imputed floor, an imputed floor should be continued. Some of the commenters suggested that CMS make the imputed floor policy permanent. They asserted that hospitals in all-urban States suffer financial and competitive disadvantages, and they believed that CMS' permanent adoption of an imputed floor policy would remedy these disadvantages. The commenters stated that other States could potentially benefit from the imputed floor in the future should their circumstances

change, and the fact that only one State currently benefits from the policy should not serve as CMS' rationale for eliminating it. One commenter also suggested that if the imputed floor is to expire, it should be phased out over several years to avoid dramatic cost cutting and elimination of vital services.

Response: In response to commenters' concerns regarding the proposed September 30, 2011 expiration of the imputed floor, we have decided to extend the policy for 2 additional years, for FYs 2012 and 2013 (that is, through September 30, 2013), after which time we will reevaluate the policy. We believe that continuing the current imputed floor policy through FY 2013 is a reasonable accommodation for the hospitals that have benefited from the imputed floor. Also, a 2-year extension period coincides with the requirement under section 3137(c) of Public Law 111–148 that CMS must apply the reclassification average hourly wage comparison standards that were in place during FY 2008 ''until the first fiscal year beginning on or after the date that is one year after the Secretary of Health and Human Services submits a report to Congress on reforming the wage index under 3137(b) of Public Law 111–148.'' (We refer readers to a complete discussion of this requirement in the FY 2011 IPPS/LTCH PPS supplemental proposed rule (75 FR 30919).) The report to Congress is due by December 31, 2011. Therefore, because the first fiscal year beginning after December 31, 2012 (a year after the report to Congress is due) starts on October 1, 2013, CMS cannot make any changes to the reclassification average hourly wage comparison standards before FY 2014. Given our current study of the entire wage index system, including geographic reclassification and the rural and imputed floor policies, we believe it is reasonable to continue the current imputed floor policy through the same evaluation period specified under section 3137(c) of Public Law 111–148.

Therefore, in this FY 2012 final rule, we are providing an extension of the current imputed floor policy, including a national budget neutrality adjustment, through FY 2013 (that is, through September 30, 2013). Accordingly, we also have revised the Medicare regulations in § 412.64(h)(4) to reflect this extension. We note that, although the extension of the imputed floor policy in this final rule is partially based on the due date of the report to Congress under section 3137(b) of Public Law 111–148 and the time period for which CMS is prohibited from making any changes to the FY 2008 reclassification average hourly wage comparison standards, under 3137(c) of Public Law 111–148, this extension of the imputed floor policy is effective through the end of FY 2013, regardless of any changes that may be subsequently made pursuant to these statutory provisions.

Thus, the final FY 2012 wage index and impact tables associated with this final rule and published on CMS' Web site include the application of the imputed floor policy and a national budget neutrality adjustment for the imputed floor. As mentioned above, 39 providers in New Jersey will receive an increase in their FY 2012 wage index due to the imputed floor policy.

3. FY 2012 Puerto Rico Wage Index

We note that, for the FY 2012 wage index, there is one new hospital in rural Puerto Rico when previously there were none. However, this hospital has no cost reporting period beginning during FY 2008 and, therefore, has no wage data for inclusion in the FY 2012 wage index calculation for rural Puerto Rico. We discussed in the FY 2005 IPPS final rule that the imputed floor policy in § 412.64(h)(4) of the regulations does not apply to Puerto Rico hospitals (69 FR 49111). (We note that in this discussion in the FY 2012 IPPS/LTCH PPS proposed rule, we incorrectly stated that the imputed floor policy would apply to Puerto Rico. We have revised the discussion in the preamble of this final rule to accurately reflect our policies.) However, we adopted the policy in the FY 2008 IPPS final rule with comment period (72 FR 47323) that if there are no hospitals' cost report wage data available to calculate a State's rural floor, and the imputed floor policy has expired (or, in the case of Puerto Rico, the imputed floor is not applicable), ''we will use the unweighted average of the wage indices from all CBSAs (urban areas) that are contiguous to the rural counties of the State to compute the State's rural floor. (We define contiguous as sharing a border.)'' Except for Fajardo, Puerto Rico (CBSA 21940), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the FY 2012 rural Puerto Rico wage index is calculated based on the average of the FY 2012 wage indices for the following urban areas: Aguadilla-Isabela-San Sebastián, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayagüez, PR (CBSA 32420); Ponce, PR (CBSA 38660), San Germán-Cabo Rojo, PR (CBSA 41900), San Juan-Caguas-Guaynabo, PR (CBSA 41980), and Yauco, PR (CBSA 49500).

G. Analysis and Implementation of the Occupational Mix Adjustment and the FY 2012 Occupational Mix Adjusted Wage Index

As discussed in section III.C. of this preamble, for FY 2012, we apply the occupational mix adjustment to 100 percent of the FY 2012 wage index. We calculated the occupational mix adjustment using data from the 2007–2008 occupational mix survey data, using the methodology described in section III.C.3. of this preamble.

Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the FY 2012 wage index results in a national average hourly wage of $36.2481 and a Puerto-Rico specific average hourly wage of $15.4142. After excluding data of hospitals that either submitted aberrant data that failed critical edits, or that do not have FY 2008 Worksheet S–3 cost report data for use in calculating the FY 2012 wage index, we calculated the FY 2012 wage index using the occupational mix survey data from 3,168 hospitals. Using the Worksheet S–3 cost report data of 3,489 hospitals and occupational mix survey data from 3,168 hospitals represents a 90.8 percent survey response rate. The FY 2012 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational mix nursing subcategory	Average hourly wage
National RN	$36.075785685
National LPN and Surgical Technician	20.860811964
National Nurse Aide, Orderly, and Attendant	14.619464256
National Medical Assistant	16.443954736
National Nurse Category	30.463606009

The national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $30.463606009. 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 2007–2008 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 44.31 percent, and the national percentage of hospital employees in the all other occupations category is 55.69 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 29.08 percent in one CBSA, to a high of 70.76 percent in another CBSA.

We compared the FY 2012 occupational mix adjusted wage indices for each CBSA to the unadjusted wage indices for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the wage index values for 209 (53.5 percent) urban areas and 32 (66.7 percent) rural areas would increase. One hundred nine (27.9 percent) urban areas would increase by 1 percent or more, and 5 (1.3 percent) urban areas would increase by 5 percent or more. Seventeen (35.4 percent) rural areas would increase by 1 percent or more, and no rural areas would increase by 5 percent or more. However, the wage index values for 182 (46.5 percent) urban areas and 16 (33.3 percent) rural areas would decrease. Eighty-nine (22.8 percent) urban areas would decrease by 1 percent or more, and no urban area would decrease by 5 percent or more. 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 7.83 percent for an urban area and 2.91 percent for a rural area. The largest negative impacts are 4.45 percent for an urban area and 2.78 percent for a rural area. No urban or rural areas are unaffected. These results indicate that a larger percentage of rural areas (66.7 percent) would benefit from the occupational mix adjustment than do urban areas (53.5 percent). While these results are more positive overall for rural areas than under the previous occupational mix adjustment that used survey data from 2006, approximately one-third (33.3 percent) of rural CBSAs would still experience a decrease in their wage indices as a result of the occupational mix adjustment.

The wage index values for FY 2012 (except those for hospitals receiving wage index adjustments under section 1886(d)(13) of the Act) included in Tables 4A, 4B, 4C, and 4F, which are listed in section VI. of the Addendum to this final rule and available via the Internet, include the occupational mix adjustment.

Tables 3A and 3B, which are listed in section VI. of the Addendum to this final rule and available via the Internet, list the 3-year average hourly wage for each labor market area before the redesignation or reclassification of hospitals based on FYs 2010, 2011, and 2012 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 listed in section VI. of the Addendum to this final rule and available via the Internet, includes the adjusted average hourly wage for each hospital from the FY 2006 and FY 2007 cost reporting periods, as well as the FY 2008 period used to calculate the FY 2012 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 average hourly wages in Tables 2, 3A, and 3B, which are listed in section VI. of the Addendum to this final rule and available via the Internet, include the occupational mix adjustment. The wage index values in Tables 4A, 4B, 4C, and 4D also include the national rural and imputed floor budget neutrality adjustment.

H. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General

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 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 of the proximity requirements in the FY 2002 IPPS final rule (66 FR 39874 and 39875).)

Section 1886(d)(10)(D)(v) of the Act provides that, beginning with FY 2001, a MGCRB decision on a hospital reclassification for purposes of the wage index is effective for 3 fiscal years, unless the hospital elects to terminate the reclassification. Section 1886(d)(10)(D)(vi) of the Act provides that the MGCRB must use average hourly wage data from the 3 most recently published hospital wage surveys in evaluating a hospital's reclassification application for FY 2003 and any succeeding fiscal year.

Section 304(b) of Public Law 106–554 provides that the Secretary must establish a mechanism under which a statewide entity may apply to have all of the geographic areas in the State treated as a single geographic area for purposes of computing and applying a single wage index, for reclassifications beginning in FY 2003. The implementing regulations for this provision are located at 42 CFR 412.235.

Section 1886(d)(8)(B) of the Act requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the labor market area to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area under the standards for designating MSAs and if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of *all* contiguous MSAs. In light of the CBSA definitions and the Census 2000 data that we implemented for FY 2005 (69 FR 49027), we undertook to identify those counties meeting these criteria. Eligible counties are discussed and identified under section III.H.5. of this preamble.

2. Effects of Reclassification/Redesignation

Section 1886(d)(8)(C) of the Act provides that the application of the wage index to redesignated hospitals is dependent on the hypothetical impact that the wage data from these hospitals would have on the wage index value for the area to which they have been redesignated. These requirements for determining the wage index values for redesignated hospitals are applicable both to the hospitals deemed urban under section 1886(d)(8)(B) of the Act and hospitals that were reclassified as a result of the MGCRB decisions under section 1886(d)(10) of the Act. Therefore, as provided in section 1886(d)(8)(C) of the Act, the wage index values were determined by considering the following:

- If including the wage data for the redesignated hospitals would reduce the wage index value for the area to which the hospitals are redesignated by 1 percentage point or less, the area wage index value determined exclusive of the

wage data for the redesignated hospitals applies to the redesignated hospitals.

• If including the wage data for the redesignated hospitals reduces the wage index value for the area to which the hospitals are redesignated by more than 1 percentage point, the area wage index determined inclusive of the wage data for the redesignated hospitals (the combined wage index value) applies to the redesignated hospitals.

• If including the wage data for the redesignated hospitals increases the wage index value for the urban area to which the hospitals are redesignated, both the area and the redesignated hospitals receive the combined wage index value. Otherwise, the hospitals located in the urban area receive a wage index excluding the wage data of hospitals redesignated into the area.

• Rural areas whose wage index values would be reduced by excluding the wage data for hospitals that have been redesignated to another area continue to have their wage index values calculated as if no redesignation had occurred (otherwise, redesignated rural hospitals are excluded from the calculation of the rural wage index). The wage index value for a redesignated rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located.

CMS also has adopted the following policies:

• The wage data for a reclassified urban hospital is included in both the wage index calculation of the urban area to which the hospital is reclassified (subject to the rules described above) and the wage index calculation of the urban area where the hospital is physically located.

• In cases where hospitals have reclassified to rural areas, such as urban hospitals reclassifying to rural areas under 42 CFR 412.103, the hospital's wage data are: (a) included in the rural wage index calculation, unless doing so would reduce the rural wage index; and (b) included in the urban area where the hospital is physically located. The effect of this policy, in combination with the statutory requirement at section 1886(d)(8)(C)(ii) of the Act, is that rural areas may receive a wage index based upon the highest of: (1) Wage data from hospitals geographically located in the rural area; (2) wage data from hospitals geographically located in the rural area, but excluding all data associated with hospitals reclassifying out of the rural area under section 1886(d)(8)(B) or section 1886(d)(10) of the Act; or (3) wage data associated with hospitals geographically located in the area plus all hospitals reclassified into the rural area.

In addition, in accordance with the statutory language referring to ''hospitals'' in the plural under sections 1886(d)(8)(C)(i) and 1886(d)(8)(C)(ii) of the Act, our longstanding policy is to consider reclassified hospitals as a group when deciding whether to include or exclude them from both urban and rural wage index calculations.

3. FY 2012 MGCRB Reclassifications

a. FY 2012 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 42 CFR 412.230 through 412.280.

At the time this final rule was constructed, the MGCRB had completed its review of FY 2012 reclassification requests. Based on such reviews, there were 280 hospitals approved for wage index reclassifications by the MGCRB for FY 2012. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2012, hospitals reclassified during FY 2010 or FY 2011 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications. There were 283 hospitals approved for wage index reclassifications in FY 2010 and 294 hospitals approved for wage index reclassifications in FY 2011. Of all of the hospitals approved for reclassification for FY 2010, FY 2011, and FY 2012, based upon the review at the time of this final rule, 659 hospitals are in a reclassification status for FY 2012.

Under 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. CMS became aware that an error was made in the calculation of the proposed wage index out-migration adjustment in Table 4J of the FY 2012 IPPS/LTCH PPS proposed rule. This error in the calculation affected 104 providers that became eligible to receive the out-migration adjustment. We published a correction notice in the **Federal Register** on July 13, 2011 (76 FR 41178), which had a display date of July 11, 2011, announcing the corrections to the tables. Additionally, we issued a letter to hospitals on July 1, 2011, through their fiscal intermediaries/MACs advising that we extended the 45-day deadline and allowed hospitals a 7-day period from the date of display of the correction notice (that is, by July 18, 2011) for hospitals that wished to request a revision to an already submitted withdrawal/termination request under 42 CFR 412.73, or that wished to request a withdrawal of a reclassification or termination of an existing 3-year section 1886(d)(10) reclassification that would be effective in FY 2012. Hospitals also may cancel prior reclassification withdrawals or terminations in certain circumstances. For further information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer the reader to 42 CFR 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887) and the FY 2003 IPPS final rule (67 FR 50065). 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 2012 are incorporated into the wage index values published in the FY 2012 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 2013

Applications for FY 2013 reclassifications are due to the MGCRB by September 1, 2011. We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2011, via the CMS Internet Web site at: *http://cms.hhs.gov/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.

4. 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. Hospitals located in these counties have been known as ''Lugar'' hospitals and the counties themselves are often referred to as ''Lugar'' counties. We provide the FY 2011 chart below with the listing of the rural counties containing the hospitals designated as urban under section 1886(d)(8)(B) of the Act. For discharges occurring on or after October 1, 2011, hospitals located in the rural county in the first column of this chart will be redesignated for purposes of using the wage index of the urban area listed in the second column.

RURAL COUNTIES CONTAINING HOSPITALS REDESIGNATED AS URBAN UNDER SECTION 1886(d)(8)(B) OF THE ACT

[Based on CBSAs and Census 2000 Data]

Rural county	CBSA
Cherokee, AL	Rome, GA.
Macon, AL	Auburn-Opelika, AL.
Talladega, AL	Anniston-Oxford, AL.
Hot Springs, AR	Hot Springs, AR.
Windham, CT	Hartford-West Hartford-East Hartford, CT.
Bradford, FL	Gainesville, FL.
Hendry, FL	West Palm Beach-Boca Raton-Boynton, FL.
Levy, FL	Gainesville, FL.
Walton, FL	Fort Walton Beach-Crestview-Destin, FL.
Banks, GA	Gainesville, GA.
Chattooga, GA	Chattanooga, TN-GA.
Jackson, GA.	Atlanta-Sandy Springs-Marietta, GA.
Lumpkin, GA.	Atlanta-Sandy Springs-Marietta, GA.
Morgan, GA	Atlanta-Sandy Springs-Marietta, GA.
Peach, GA	Macon, GA.
Polk, GA	Atlanta-Sandy Springs-Marietta, GA.
Talbot, GA	Columbus, GA-AL.
Bingham, ID	Idaho Falls, ID.
Christian, IL	Springfield, IL.
DeWitt, IL	Bloomington-Normal, IL.
Iroquois, IL	Kankakee-Bradley, IL.
Logan, IL	Springfield, IL.
Mason, IL	Peoria, IL.
Ogle, IL	Rockford, IL.
Clinton, IN	Lafayette, IN.
Henry, IN	Indianapolis-Carmel, IN.
Spencer, IN	Evansville, IN-KY.
Starke, IN	Gary, IN.
Warren, IN	Lafayette, IN.
Boone, IA	Ames, IA.
Buchanan, IA	Waterloo-Cedar Falls, IA.
Cedar, IA	Iowa City, IA.
Allen, KY	Bowling Green, KY.
Assumption Parish, LA	Baton Rouge, LA.
St. James Parish, LA	Baton Rouge, LA.
Allegan, MI	Holland-Grand Haven, MI.
Montcalm, MI	Grand Rapids-Wyoming, MI.
Oceana, MI	Muskegon-Norton Shores, MI.
Shiawassee, MI	Lansing-East Lansing, MI.
Tuscola, MI	Saginaw-Saginaw Township North, MI.
Fillmore, MN	Rochester, MN.
Dade, MO	Springfield, MO.
Pearl River, MS	Gulfport-Biloxi, MS.
Caswell, NC	Burlington, NC.
Davidson, NC	Greensboro-High Point, NC.
Granville, NC	Durham, NC.
Harnett, NC	Raleigh-Cary, NC.
Lincoln, NC	Charlotte-Gastonia-Concord, NC-SC.
Polk, NC	Spartanburg, SC.
Los Alamos, NM	Santa Fe, NM.
Lyon, NV	Carson City, NV.
Cayuga, NY	Syracuse, NY.
Columbia, NY	Albany-Schenectady-Troy, NY.
Genesee, NY	Rochester, NY.
Greene, NY	Albany-Schenectady-Troy, NY.
Schuyler, NY	Ithaca, NY.
Sullivan, NY	Poughkeepsie-Newburgh-Middletown, NY.
Wyoming, NY	Buffalo-Niagara Falls, NY.
Ashtabula, OH	Cleveland-Elyria-Mentor, OH.
Champaign, OH	Springfield, OH.

RURAL COUNTIES CONTAINING HOSPITALS REDESIGNATED AS URBAN UNDER SECTION 1886(d)(8)(B) OF THE ACT—Continued

[Based on CBSAs and Census 2000 Data]

Rural county	CBSA
Columbiana, OH	Youngstown-Warren-Boardman, OH-PA.
Cotton, OK	Lawton, OK.
Linn, OR	Corvallis, OR.
Adams, PA	York-Hanover, PA.
Clinton, PA	Williamsport, PA.
Greene, PA	Pittsburgh, PA.
Monroe, PA	Allentown-Bethlehem-Easton, PA-NJ.
Schuylkill, PA	Reading, PA.
Susquehanna, PA	Binghamton, NY.
Clarendon, SC	Sumter, SC.
Lee, SC	Sumter, SC.
Oconee, SC	Greenville, SC.
Union, SC	Spartanburg, SC.
Meigs, TN	Cleveland, TN.
Bosque, TX	Waco, TX.
Falls, TX	Waco, TX.
Fannin, TX	Dallas-Plano-Irving, TX.
Grimes, TX	College Station-Bryan, TX.
Harrison, TX	Longview, TX.
Henderson, TX	Dallas-Plano-Irving, TX.
Milam, TX	Austin-Round Rock, TX.
Van Zandt, TX	Dallas-Plano-Irving, TX.
Willacy, TX	Brownsville-Harlingen, TX.
Buckingham, VA	Charlottesville, VA.
Floyd, VA	Blacksburg-Christiansburg-Radford, VA.
Middlesex, VA	Virginia Beach-Norfolk-Newport News, VA.
Page, VA	Harrisonburg, VA.
Shenandoah, VA	Winchester, VA-WV.
Island, WA	Seattle-Bellevue-Everett, WA.
Mason, WA	Olympia, WA.
Wahkiakum, WA	Longview, WA.
Jackson, WV	Charleston, WV.
Roane, WV	Charleston, WV.
Green, WI	Madison, WI.
Green Lake, WI	Fond du Lac, WI.
Jefferson, WI	Milwaukee-Waukesha-West Allis, WI.
Walworth, WI	Milwaukee-Waukesha-West Allis, WI.

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. Affected hospitals were permitted to compare the reclassified wage index for the labor market area in Table 4C (which was listed in section VI. of the Addendum to the proposed rule and available via the Internet) into which they would be reclassified by the MGCRB to the wage index for the area to which they are redesignated under section 1886(d)(8)(B) of the Act. Hospitals could have withdrawn from an MGCRB reclassification within 45 days of the publication of the FY 2012 proposed rule. As discussed in section III.H.3.a. of this preamble, we published a correction notice in the **Federal Register** on July 13, 2011 (76 FR 41178), which had a display date of July 11, 2011, announcing corrections to the FY 2012 proposed out-migration adjustment in Table 4J. Additionally, we issued a letter to hospitals on July 1, 2011, through their fiscal intermediaries/MACs advising that we extended the 45-day deadline and allowed hospitals a 7-day period from the date of display of the correction notice (that is, by July 18, 2011) for hospitals redesignated under section 1886(d)(8)(B) of the Act that also were eligible for an out-migration adjustment to notify CMS that they wished to receive the out-migration adjustment instead of their redesignation under section 1886(d)(8)(B) of the Act. Section 1886(d)(8)(B) hospitals that had already notified CMS that they wished to receive the out-migration adjustment instead of the section 1886(d)(8)(B) redesignation could withdraw such notifications.

5. Reclassifications Under Section 1886(d)(8)(B) of the Act

As discussed in the FY 2009 IPPS final rule (73 FR 48588), Lugar hospitals are treated like reclassified hospitals for purposes of determining their applicable wage index and receive the reclassified wage index for the urban area to which they have been redesignated. Because Lugar hospitals are treated like reclassified hospitals, when they are seeking reclassification by the MGCRB, they are subject to the rural reclassification rules set forth at 42 CFR 412.230. The procedural rules set forth at § 412.230 list the criteria that a hospital must meet in order to reclassify as a rural hospital. Lugar hospitals are subject to the proximity criteria and payment thresholds that apply to rural hospitals. Specifically, the hospital must be no more than 35 miles from the area to which it seeks reclassification (§ 412.230(b)(1)); and the hospital must show that its average hourly wage is at least 106 percent of the average hourly wage of all other hospitals in the area in which the hospital is located (§ 412.230(d)(1)(iii)(C)). In accordance with the requirements of section 3137(c) of the Affordable Care Act, beginning with reclassifications for the FY 2011

wage index, a Lugar hospital must also demonstrate that its average hourly wage is equal to at least 82 percent of the average hourly wage of hospitals in the area to which it seeks redesignation (§ 412.230(d)(1)(iv)(C)).

Hospitals not located in a Lugar county seeking reclassification to the urban area where the Lugar hospitals have been redesignated are not permitted to measure to the Lugar county to demonstrate proximity (no more than 15 miles for an urban hospital, and no more than 35 miles for a rural hospital or the closest urban or rural area for RRCs or SCHs) in order to be reclassified to such urban area. These hospitals must measure to the urban area exclusive of the Lugar County to meet the proximity or nearest urban or rural area requirement. We treat New England deemed counties in a manner consistent with how we treat Lugar counties. (We refer readers to FY 2008 IPPS final rule with comment period (72 FR 47337) for a discussion of this policy.)

6. Reclassifications Under Section 508 of Public Law 108–173

Section 508 of Public Law 108–173 allowed certain qualifying hospitals to receive wage index reclassifications and assignments that they otherwise would not have been eligible to receive under the law. Although section 508 originally was scheduled to expire after a 3-year period, Congress extended the provision several times, as well as certain special exceptions that would have otherwise expired. For a discussion of the original section 508 provision and its various extensions, we refer readers to the FY 2010 notice issued in the **Federal Register** on June 2, 2010 (75 FR 31118). Prior to the enactment of the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309) on December 15, 2010, the extension of the 508 provision was included in sections 3137(a) and 10317 of the Affordable Care Act (Pub. L. 111–148). Section 3137 of the Affordable Care Act extended, through FY 2010, section 508 reclassifications as well as certain special exceptions. The most recent extension of the provision was included in section 102 of the Medicare and Medicaid Extender Act, which extends, through FY 2011, section 508 reclassifications as well as certain special exceptions. The latest extension of these provisions expires on September 30, 2011, and will no longer be applicable effective with FY 2012.

7. Waiving Lugar Redesignation for the Out-Migration Adjustment

We have received several inquiries regarding the effect on a hospital's deemed urban status when a hospital waives its reclassification under section 1886(d)(8) of the Act in order to accept an out-migration adjustment to the wage index under section 1886(d)(13) of the Act. (We refer readers to a discussion of the out-migration adjustment under section III.I. of the preamble of this final rule.) In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25885 and 25886), we clarified that Lugar hospitals will be required to waive their Lugar urban status in its entirety in order to receive the out-migration adjustment. We stated our belief that this represents one permissible reading of the statute, given that section 1886(d)(13)(G) of the Act states that a hospital with an out-migration adjustment is not ''eligible'' for a reclassification under subsection (8). Therefore, beginning with FY 2012, we proposed that an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the DSH payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. (We refer readers to a discussion of DSH payment adjustment under section IV.G. of this preamble.)

In addition, we proposed to make 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 [4]) 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. We made this proposal in response to public comments we received on the FY 2011 IPPS/LTCH PPS proposed rule that discussed the burden of this annual request (74 FR 43840). Thus, under the proposed 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.

Comment: Commenters supported CMS' proposed policy clarification that 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 IPPS purposes. Some of the commenters stated that this policy provides the flexibility necessary to allow hospitals to revert to their true rural status if they wish. Commenters also supported the proposed minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment to automatically waive its urban status for the 3-year period for which its out-migration adjustment is effective. Some commenters asked CMS to clarify whether the procedural change will apply to letters already filed for the FY 2012 update, in which a request was made to waive Lugar redesignation and to instead receive the out-migration adjustment.

Response: Beginning with FY 2012, we are adopting as final the policy that an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has waived its deemed urban status and, thus, is rural for all IPPS purposes. In addition, we are adopting as final the procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment to automatically waive its urban status for the 3-year period for which the out-migration adjustment is effective. This clarified policy and procedural change will be effective beginning with the FY 2013 wage index. Therefore, hospitals that sent requests to waive Lugar status for the out-migration adjustment for FY 2012, and still have 2 or 3 years of eligibility available for the out-migration adjustment, must request again next year for the waiver to apply to the FY 2013 wage index. That request would be effective for the remaining years of its eligibility.

At the time hospitals made their decisions with respect to waiving Lugar status for the out-migration adjustment for FY 2012, the procedural change

[4] 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. As noted in sections III.H.3. and III.H.4. of this preamble, due to the correction of the FY 2012 proposed out-migration adjustment, we extended the 45 day deadline and allowed hospitals a 7-day period from the date of display of the July 13, 2011 correction notice (that is, by July 18, 2011) (76 FR 41178).

allowing a 3-year waiver was not yet in effect. Therefore, those decisions were based on the existing policy in place for the proposed rule, which required annual waivers. As discussed in section III.H.4. of this preamble, counties remain eligible for a consistent out-migration adjustment for a period of 3 years. Each year, we revise the list of counties to (1) add new counties eligible for an adjustment for 3 years; (2) remove counties where 3 years have elapsed and the counties no longer qualify for an adjustment; or (3) revise the adjustment value for counties in cases where 3 years have elapsed and the counties, once again, qualify for an adjustment. Some hospitals may not know whether they are in the first, second, or third year of the out-migration adjustment; and therefore, whether they are able to waive deemed urban Lugar status for 1, 2, or 3 years. For these reasons, beginning with FY 2013, we intend to make available, shortly after we publish the proposed rule, a public use file which will list Lugar/out-migration hospitals (that is, hospitals that have Lugar status and are located in a county that qualifies for an out-migration adjustment), and which will identify whether the hospital is in its first, second, or third year of eligibility for the out-migration adjustment. We will update this file annually and release it to the public after each fiscal year's proposed rule.

Comment: Some commenters expressed concerns with respect to hospitals reclassified from urban to rural under section 1886(d)(8)(E) of the Act (§ 412.103 of the regulations). The commenters expressed concern that a hospital reclassified from urban to rural status under § 412.103 has to cancel this reclassification to return to Lugar status, so that it can then waive its Lugar status to become rural and retain a special rural status (such as SCH or MDH), and also receive the out-migration adjustment. However, a § 412.103 cancellation takes effect only at the beginning of the next cost reporting period, whereas waiving Lugar status is effective on October 1. The commenters indicated that this presents a problem for hospitals that do not have a September 30 cost reporting period end date. The commenters urged CMS to create a process by which hospitals can simultaneously cancel a § 412.103 reclassification and waive Lugar status.

Response: In circumstances where a Lugar hospital has acquired rural status through § 412.103 in order to be classified by Medicare as an SCH or a MDH, we will allow the act of waiving Lugar status for the out-migration adjustment to simultaneously waives the hospital's deemed urban status and cancel the hospital's acquired rural status, thus treating the hospital as a rural provider effective on October 1. (We note that there are special rules that apply to rural referral centers under § 412.103(g)(1) requiring that urban-to-rural status be maintained for a certain period of time, in order to avoid gaming situations. We are not revising these rules for rural referral centers due to these considerations.)

Comment: Some commenters asked for a policy that would allow waivers of Lugar redesignation in all instances—not just when a hospital is eligible for the out-migration adjustment.

Response: The statute provides two methods for a Lugar hospital to be treated as rural for Medicare payment purposes: (1) If the hospital is eligible for an out-migration adjustment under section 1886(d)(13) of the Act; or (2) if the hospital applies for an urban to rural reclassification under section 1886(d)(8)(E) of the Act. There are no other provisions under the Medicare statute that would allow a Lugar hospital to be treated as a rural provider, given that Lugar status is a deemed status.

8. Other Geographic Reclassification Issues

a. Requested Reclassification for Single Hospital MSAs

Section 412.230 of the regulations sets forth criteria for an individual hospital to apply for geographic reclassification to a higher rural or urban wage index area. Specifically, under § 412.230(a)(3)(ii), an individual hospital may be redesignated from an urban area to another urban area, from a rural area to another rural area, or from a rural area to an urban area for the purpose of using the other area's wage index value. Such a hospital must also meet other criteria. One required criterion (under § 412.230(d)(1)(iii)(C) of the regulations) is that the hospital must demonstrate that its own average hourly wage is higher than the average hourly wage of hospitals in the area in which the hospital is located (108 percent for urban hospitals and 106 percent for rural hospitals). In cases in which a hospital wishing to reclassify is the only hospital in its MSA, that hospital is unable to satisfy this criterion because it cannot demonstrate that its average hourly wage is higher than that of the other hospitals in the area in which the hospital is located (because there are no other hospitals in the area). For hospitals in the category described above, our current policy provides an alternative that allows hospitals to seek reclassification using the group reclassification rules under § 412.232 or § 412.234. Specifically, if a hospital is the single hospital in its area for the 3-year period over which the average hourly wage is calculated for the purpose of the comparison under § 412.230(d)(1)(iii)(C), the hospital may apply for geographic reclassification as a single hospital county group in accordance with the procedures set forth at § 412.232 or § 412.234. In addition to specifying the average hourly wage criteria, these regulations state that the county in which the hospital is located must be adjacent to the urban area to which it seeks redesignation. In addition, a certain level of economic integration needs to exist between the two areas. For example, for urban county group reclassifications (for FY 2008 and subsequent periods), § 412.234(a)(3)(iv) states that ''hospitals located in counties that are in the same Combined Statistical Area (CSA) or Core-Based Statistical Area (CBSA) * * * as the urban area to which they seek redesignation qualify as meeting the proximity requirements for reclassification to the urban area to which they seek redesignation.''

Recently, we have been advised of a single hospital MSA scenario of concern to a particular hospital. In this scenario, an urban hospital located in an area in which there was only one other hospital had previously applied for and was granted a reclassification by the MGCRB to an adjacent urban area with a higher wage index. During the 3-year reclassification timeframe, the other hospital in its labor market area closed. After the expiration of its reclassification, the hospital became ineligible for reclassification to that same adjacent urban area with a higher wage index because it was no longer able to satisfy the wage data comparison criteria to reclassify individually under § 412.230(d)(1)(iii)(C). In addition, the hospital could not apply for redesignation under the urban county group regulation at § 412.234 because the hospital was not located in the same CSA or CBSA as the urban area to which it sought reclassification. In this example, the concern that was shared with CMS was that the hospital was competitively disadvantaged in competing for labor with neighboring hospitals where the hospital had a comparable average hourly wage, compared to the other hospitals in its surrounding area, because it receives a lower wage index.

We stated in the proposed rule that we believe that the geographic reclassification regulations should not

be revised to accommodate this situation. We discussed the fact that we have repeatedly rejected special rules to accommodate single hospital MSAs (69 FR 48915, 49109; 71 FR 47869, 48071 and 48072). In these explanations, we have highlighted the fact that hospitals in single hospital MSAs not only may be eligible for out-commuting adjustments, but that they also may apply to an adjacent MSA within the same CSA using the group reclassification rules without meeting the 108-percent test. We explained that each year we propose to adopt the OMB's statistical area definitions (75 FR 50162), so if a hospital in a single hospital MSA cannot meet group reclassification criteria because of the CSA standard, it means that OMB has determined that there is not a sufficient degree of employment interchange to suggest that the areas compete for the same labor. In addition, we explained that when we originally adopted the 108-percent test, we noted that ''with respect to single hospital MSAs, a hospital in such an MSA receives a wage index value that is based entirely on its own wage data and, therefore, its actual wage levels. Because such a hospital is clearly not disadvantaged by its inclusion in a labor market area where its wage index is determined based on its own wage levels, it is appropriate under this guideline that a hospital should not be reclassified if it is the only one in its area'' (57 FR 39746). In the proposed rule, we expressed concern that allowing a hospital representing 100 percent of its area's wages to be exempt from the wage data comparison test could undermine the 108-percent test for hospitals in other circumstances where the standard cannot be met. Finally, we referred to section 3137(c) of the Affordable Care Act, which prohibits us from altering average hourly wage comparison criteria for FY 2012. That provision states that ''notwithstanding any other provision of law,'' the MGCRB is required to use the ''average hourly wage comparison criteria used in making such decisions as of September 30, 2008,'' until the first fiscal year beginning on the date that is one year after the Secretary submits a report to Congress.

In the proposed rule, we solicited public comments on this issue. In particular, we invited comments on the types of regulatory solutions that could be made available to a hospital in this type of situation.

Comment: Commenters suggested that, among other solutions to this issue, the 108 percent test should be waived for hospitals that are the single hospital in the MSA, as it is mathematically impossible to be 108 percent of your own average hourly wage. In addition, commenters suggested that establishing one's own wage index or being eligible for an out-migration adjustment may not result in adequate compensation for a hospital's services. Commenters also noted that, despite the existing remedies of the out-migration adjustment and county group reclassification, a hospital may still be at a disadvantage and unable to compete for labor with a neighboring labor market area that receives a higher wage index. Commenters believed that Congress did not intend to exclude a hospital in a single hospital MSA from the ability to reclassify to another labor market area. Commenters further stated that recognizing county boundaries does not always accurately reflect labor markets, which is why in 1989 Congress established the reclassification process. Therefore, commenters believed the very purpose of Congress creating the reclassification process, that is, to give hospitals an opportunity to be included in a labor market area in which they compete for labor, is not being fulfilled by excluding a hospital in a single hospital MSA the ability to seek reclassification.

Response: While we continue to be concerned regarding the precedent that might be set by exempting a category of hospitals from the 108 percent test, we agree that the current policies for geographic reclassification are disparate for hospitals located in single hospital MSAs compared to hospitals located in multiple hospital MSAs. We acknowledge the commenters' views that this disparity is sometimes a disadvantage because hospitals in single hospital MSAs have fewer options for qualifying for geographic reclassification than hospitals in multiple hospital MSAs. To address the concerns of the commenters, in this final rule, we are making a change in our policy in order to waive a hospital in a single hospital MSA from the average hourly wage comparison criterion under § 412.230(d)(1)(iii)(C) beginning with applications for geographic reclassification for the FY 2013 wage index. That is, a hospital in a single hospital MSA will be exempt from meeting the 108 percent average hourly wage criterion. Accordingly, we are amending our regulation at § 412.230 by adding a new paragraph (d)(5) to reflect this exception for single hospital MSAs. We note that section 3137(b) of Public Law 111–148 requires CMS to submit a report on reforming the wage index to Congress by December 31, 2011. As a result of this statutory requirement, we are currently studying of the entire wage index system, including geographic reclassification. Although we are adopting this new policy for hospitals in single hospital MSAs for reclassification applications starting with FY 2013, we may reevaluate this policy as we formulate a plan to reform the wage index system under the requirements of section 3137(b).

b. Requests for Exceptions to Geographic Reclassification Rules

Over the last several years, CMS has received numerous requests for exceptions to current Medicare law and regulation regarding geographic reclassification or requests to revise the existing regulations in order to allow a hospital or group of hospitals the ability to reclassify to a labor market area with a higher wage index. Section 3137(b) of the Affordable Care Act requires the Secretary to submit a report to Congress that includes a ''plan to reform the hospital wage index.'' This report to Congress is due by December 31, 2011. As part of our efforts in this regard, in the FY 2012 IPPS/LTCH PPS proposed rule, we solicited public comments, to be considered only as part of our report to Congress and not to be addressed in the FY 2012 IPPS/LTCH PPS final rule, on ways to redefine the geographic reclassification requirements to more accurately define labor markets.

I. FY 2012 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. Such adjustments to the wage index are effective for 3 years, unless a hospital requests to waive the application of the adjustment. A county will not lose its status as a qualifying county due to hospital wage index changes during the 3-year period, and counties will receive the same wage index increase for those 3 years. However, a county that qualifies in any given year may not necessarily qualify

after the 3-year period, or it may qualify but receive a different adjustment to the wage index level. Hospitals that receive this adjustment to their wage index are not eligible for reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act. Adjustments under this provision are not subject to the budget neutrality requirements under section 1886(d)(3)(E) of the Act.

Hospitals located in counties that qualify for the wage index adjustment are to receive an increase in the wage index that is equal to the average of the differences between the wage indices of the labor market area(s) with higher wage indices and the wage index of the resident county, weighted by the overall percentage of hospital workers residing in the qualifying county who are employed in any labor market area with a higher wage index. Beginning with the FY 2008 wage index, we use post-reclassified wage indices when determining the out-migration adjustment (72 FR 47339).

For the FY 2012 wage index, we calculated the out-migration adjustment using the same formula described in the FY 2005 IPPS final rule (69 FR 49064), with the addition of using the post-reclassified wage indices, to calculate the out-migration adjustment. This adjustment is calculated as follows:

Step 1—Subtract the wage index for the qualifying county from the wage index of each of the higher wage area(s) to which hospital workers commute.

Step 2—Divide the number of hospital employees residing in the qualifying county who are employed in such higher wage index area by the total number of hospital employees residing in the qualifying county who are employed in any higher wage index area. For each of the higher wage index areas, multiply this result by the result obtained in Step 1.

Step 3—Sum the products resulting from Step 2 (if the qualifying county has workers commuting to more than one higher wage index area).

Step 4—Multiply the result from Step 3 by the percentage of hospital employees who are residing in the qualifying county and who are employed in any higher wage index area.

These adjustments will be effective for each county for a period of 3 fiscal years. For example, hospitals that received the adjustment for the first time in FY 2011 will be eligible to retain the adjustment for FY 2012. For hospitals in newly qualified counties, adjustments to the wage index are effective for 3 years, beginning with discharges occurring on or after October 1, 2011.

Hospitals receiving the wage index adjustment under section 1886(d)(13)(F) of the Act are not eligible for reclassification under sections 1886(d)(8) or (d)(10) of the Act unless they waive the out-migration adjustment. Consistent with our FYs 2005 through 2011 IPPS final rules, we are specifying that hospitals redesignated under section 1886(d)(8) of the Act or reclassified under section 1886(d)(10) of the Act are deemed to have chosen to retain their redesignation or reclassification. Hospitals that reclassified under section 1886(d)(10) of the Act that wished to receive the out-migration adjustment, rather than their reclassification adjustment, had to follow the termination/withdrawal procedures specified in 42 CFR 412.273 and section III.H.3. of the preamble of the FY 2012 proposed rule. Otherwise, they were deemed to have waived the out-migration adjustment. Hospitals redesignated under section 1886(d)(8)(B) of the Act were deemed to have waived the out-migration adjustment unless they explicitly notified CMS within 45 days from the publication of the FY 2012 proposed rule that they elected to receive the out-migration adjustment instead. As noted in sections III.H.3.a. and III.H.4. of this preamble, due to the correction of the FY 2012 proposed outmigration adjustment, we extended the 45-day deadline and allowed hospitals a 7-day period from the date of display of the July 13, 2011 correction notice (that is, by July 18, 2011) (76 FR 41178).

Table 4J, which is listed in section VI. of the Addendum to this final rule and available via the Internet, lists the out-migration wage index adjustments for FY 2012. Hospitals that are not otherwise reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act will automatically receive the listed adjustment. In accordance with the procedures discussed above, redesignated/reclassified hospitals will be deemed to have waived the out-migration adjustment unless CMS was otherwise notified within the timeframe stated above. In addition, hospitals eligible to receive the out-migration wage index adjustment and that withdrew their application for reclassification will automatically receive the wage index adjustment listed in Table 4J, which is listed in section VI. of the Addendum to this final rule and available via the Internet.

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 2012 wage index were made available on October 4, 2010, through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional public use file on our Web site that reflects the actual data that are used in computing the proposed wage index. The release of this new file does not alter the current wage index process or schedule. We notified 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 encouraged hospitals to sign up for automatic notifications of information about hospital issues and the scheduling of the Hospital Open Door forums at: *http://www.cms.hhs.gov/OpenDoorForums/.*

In a memorandum dated October 13, 2010, 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 4, 2010 wage and occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its fiscal intermediary/MAC by December 6, 2010. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted on the preliminary wage index data files on the Internet, through the October 13, 2010 memorandum referenced above.

In the October 13, 2010 memorandum, we also specified that a hospital requesting revisions to its occupational mix survey data was to copy its record(s) from the CY 2007–2008 occupational mix preliminary files posted to our 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 6, 2010.

The fiscal intermediaries/MACs notified the hospitals by mid-February 2011 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 2011. CMS published the proposed wage index public use files that included hospitals' revised wage index data on February 22, 2011. Hospitals had until March 7, 2011, 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 13, 2011. The deadline for a hospital to request CMS intervention in cases where the hospital disagrees with the fiscal intermediary's (or, if applicable, the MAC's) policy interpretations was April 20, 2011.

Hospitals were given the opportunity to examine Table 2, which is listed in section VI. of the Addendum to the proposed rule and available via the Internet. Table 2 contained each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2008 data used to construct the proposed FY 2012 wage index. We noted that the hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by March 2011.

We released the final wage index data public use files in early May 2011 on the Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp.* The May 2011 public use files were 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 13, 2011). If, after reviewing the May 2011 final public use files, a hospital believed that its wage or occupational mix data were incorrect due to a fiscal intermediary/MAC or CMS error in the entry or tabulation of the final data, the hospital had to send a letter to both its fiscal intermediary/MAC and CMS that outlined why the hospital believed an error existed and provided 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) had to receive these requests no later than June 6, 2011.

Each request also had to be sent to the fiscal intermediary/MAC. The fiscal intermediary/MAC reviewed requests upon receipt and contacted CMS immediately to discuss any findings.

After the release of the May 2011 wage index data files, changes to the wage and occupational mix data were only 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 approved 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 13, 2011.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 22, 2011 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 6, 2011) were incorporated into the final wage index in the FY 2012 IPPS/LTCH PPS final rule, which will be effective October 1, 2011.

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 2012 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the 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. (See *W. A. Foote Memorial Hospital* v. *Shalala,* No. 99–CV–75202–DT (E.D. Mich. 2001) and *Palisades General Hospital* v. *Thompson,* No. 99–1230 (D.D.C. 2003).) 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 had access to the final wage index data by early May 2011, they had 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 2012 wage index by August 2011, and the implementation of the FY 2012 wage index on October 1, 2011. If hospitals availed 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 6, 2011, 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 6 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), 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: (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 6, 2011 deadline for the FY 2012 wage index); and (3) CMS agreed 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 6, 2011 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 other situations where our policies would allow midyear corrections, 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 FY 2012 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.'' We believe that this reflected Congressional intent that hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43850 through 43856), we rebased and revised the hospital market basket for operating costs. We established a FY–2006-based IPPS hospital market basket to replace the FY 2002-based IPPS hospital market basket, effective October 1, 2009. In that final rule, we presented our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY 2010. We also recalculated a labor-related share of 68.8 percent, using the FY 2006-based IPPS market basket, for discharges occurring on or after October 1, 2009. In addition, we implemented this revised and rebased labor-related share in a budget neutral manner, but consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0 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. In this final rule, as we proposed, we are not making any further changes to the national average proportion of operating costs that are attributable to wages and salaries, fringe benefits, contract labor, the labor-related portion of professional fees, administrative and business support services, and all other labor-related services (previously referred to in the FY 2002-based IPPS market basket as labor-intensive).

Therefore, for FY 2012, we are continuing to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2011. Tables 1A and 1B, which are published in section VI. of the Addendum to this final rule and available via the Internet, reflect this 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 all IPPS hospitals whose wage indices are less than 1.0000, we applied 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, we applied the wage index to a labor-related share of 68.8 percent of the national standardized amount. For Puerto Rico hospitals, the national labor-related share will always be 62 percent because the national wage index for all Puerto Rico hospitals is less than 1.0. As we proposed, in this final rule, we are continuing to use a labor-related share for the Puerto Rico-specific standardized amounts of 62.1 percent for discharges occurring on or after October 1, 2011. This Puerto Rico labor-related share of 62.1 percent was also adopted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43857) at the time the FY 2006-based hospital market basket was established, effective October 1, 2009. Consistent with our methodology for determining the national labor-related share, we added the Puerto Rico-specific relative weights for wages and salaries, fringe benefits, contract labor, the labor-related portion of professional fees, administrative and business support services, and all other labor-related services (previously referred to in the FY 2002-based IPPS market

basket as labor-intensive) 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. The labor-related share of a hospital's Puerto Rico-specific rate will be either the Puerto Rico-specific labor-related share of 62.1 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, we will set the hospital's rates using a labor-related share of 62.1 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 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 Puerto Rico labor-related share of 62.1 percent for FY 2012 is reflected in the Table 1C, which is published in section VI. of the Addendum to this final rule and available via the Internet.

IV. Other Decisions and Changes to the IPPS for Operating Costs and GME Costs

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. Overview

CMS is seeking to promote higher quality and more efficient healthcare for Medicare beneficiaries. This effort is supported by the adoption of an increasing number of widely-agreed upon quality measures. CMS has worked with relevant stakeholders to define measures of quality in almost every setting and measures various aspects of care for almost all Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and, increasingly, outcomes.

CMS has implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, CMS implemented the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). In addition, CMS has implemented quality reporting programs for hospital outpatient services, the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)), and for physicians and other eligible professionals, the Physician Quality Reporting System (formerly referred to as the Physician Quality Reporting Program Initiative (PQRI)). CMS has also implemented quality reporting programs for home health agencies and skilled nursing facilities that are based on conditions of participation, and an end-stage renal disease quality incentive 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 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.

We also are implementing a Hospital Value-Based Purchasing (VBP) Program under section 1886(o) of the Act. Earlier this year, we issued a final rule (76 FR 26490 through 26547) (the Hospital Inpatient VBP Program final rule) that implemented the Hospital VBP Program. We proposed additional policies for the Hospital VBP Program in section IV.B. of the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25926 through 25928) and in section XVI. of the CY 2012 OPPS/ASC proposed rule (76 FR 42354 through 42365). In the Hospital Inpatient VBP Program proposed rule (76 FR 2454 through 2491), we proposed that hospitals would 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 specified under the Hospital IQR Program. The Hospital VBP Program will apply to payments for discharges occurring on or after October 1, 2012, in accordance with section 1886(o) of the Act.

The Hospital IQR Program is intertwined with the Hospital VBP Program because the measures and reporting infrastructure for both programs will overlap. We view the Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare into an active purchaser of quality health care for its beneficiaries. As we stated in the Hospital Inpatient VBP Program proposed rule (76 FR 2455), in developing that proposed rule as well as other value-based payment initiatives, we applied the following principles for the development and use of measures and scoring methodologies:

Purpose:

- We view value-based purchasing as 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.

Use of Measures:

- 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 that effort, we will continuously seek to align our measures with the adoption of meaningful use standards for health information technology (HIT), so 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 invited public comment on these principles.

Comment: Many commenters supported CMS' measure selection principles for the Hospital IQR Program and the Hospital VBP Program. The commenters believed that these principles reflect the efficacy of quality measure reporting, reduce data collection burdens and facilitate alignment of measures across Medicare programs. Furthermore, the commenters applauded CMS' overarching goal of

improving the quality and cost-effectiveness of care provided in health care institutions.

Response: We appreciate the commenters' support. We will continue implementing these principles to reach our goal to foster quality improvement, establish strong and effective quality standards, and systematically link quality to payment in various healthcare settings.

Comment: Many commenters overwhelmingly supported our efforts to enhance healthcare quality transparency through the public reporting of quality measures.

Response: We appreciate the commenters' support of public reporting of quality measures.

Comment: Many commenters stated that with the increasing number of measures across the Medicare and Medicaid programs, CMS should align the measures adopted for various Medicare programs whenever possible to reduce the hospital reporting burden. One commenter further suggested that future measure reporting alignment across payers would reduce the burden of quality reporting and also allow for the meaningful comparison of healthcare quality.

Response: We recognize that the addition of manually chart-abstracted measures to the Hospital IQR Program over time has increased the reporting burden on hospitals. Aligning and harmonizing measures across Medicare programs and implementing electronic measure reporting are high priority goals for us, and we seek to further these goals as we select measures for our programs. We agree with the commenters regarding the importance of measure alignment across our programs in order to provide meaningful comparative information for beneficiaries, and we have sought to collect and utilize all-patient data for the measures used in our programs wherever possible. Currently, we collect all-patient data for all of the chart-abstracted and survey-based measures for the Hospital IQR, and Hospital OQR Programs. We also agree that alignment of measure reporting requirments across payers would also reduce burden among providers responding to multiple reporting requirements. CMS has adopted many measures that are in widespread use in the industry and by other payers, and will continue to do so when feasible and practicable.

Comment: One commenter encouraged CMS to articulate the relationship between the measures selected for the Hospital IQR Program and the framework laid out in the National Quality Strategy.

Response: In March 2011, HHS issued a Report to Congress entitled ''National Strategy for Quality Improvement in Health Care [National Quality Strategy].'' The National Quality Strategy was developed with input from stakeholders across the health care system, including Federal and State agencies, local communities, provider organizations, clinicians, patients, businesses, employers, and payers. The National Quality Strategy is located at: *http://www.healthcare.gov/center/reports/nationalqualitystrategy032011.pdf.*

The purpose of the National Quality Strategy is to provide a strategic plan for improving health care, of which measurement is an integral component. The National Quality Strategy promotes three overarching aims—Better Care (improving overall quality by making health care more patient-centered reliable, accessible and safe), Healthy People/Healthy Communities (improving the health of the U.S. population by supporting proven interventions to address behavioral, social and, environmental determinants of health in addition to delivering higher-quality care), and Affordable Care (reducing the cost of quality health care for individuals, families, employers, and government). The NQS also lists six priorities to target in furthering these goals: (1) Making care safer by reducing harm caused in the delivery of care; (2) ensuring that each person and family are engaged as a partner in their care; (3) promoting effective communication and coordination of care; (4) promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease; (5) working with communities to promote wide use of best practices to enable healthy living; and (6) making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.

Our measure selection activity for the Hospital IQR Program directly addresses the first five of these six priorities. For example, the selection of Hospital Acquired Condition (HAC) measures, Healthcare-Associated Infection (HAI) measures, and AHRQ Patient Safety Indicators (PSIs) and Inpatient Quality Indicators (IQIs) addresses the first priority of safer healthcare, and reduction of harm. The selection of the HCAHPS survey addresses the second priority of patient/family engagement. The risk-adjusted 30-day readmission and 30-day mortality measures address effective coordination of care. The current process of care measures for AMI, HF, PN, and Surgical Care address effective prevention and treatment practices. Lastly, the structural measures adopted for the Hospital IQR Program address encouragement of best practices. To the extent that the measures we have adopted for Hospital IQR are used in CMS value-based purchasing programs, alternative payment demonstrations, and the evaluation of new delivery system models, the measures also address the sixth priority area of the National Quality Strategy.

Comment: One commenter expressed concern about the overlap in the use of the same HACs in the Hospital IQR and Hospital VBP Programs. The commenter suggested that CMS adopt mutually exclusive HAC measures so that hospitals are not penalized for the same HAC measures adopted for various Medicare programs.

Response: We do not agree with the commenter's view that the implementation of the same HAC measures in both the Hospital VBP and Hospital IQR Programs would penalize hospitals twice with respect to these measures. Under section 1886(o)(1)(C)(ii)(I) of the Act, a hospital that is subject to the payment reduction under the Hospital IQR Program with respect to a fiscal year is excluded from the Hospital VBP Program for that year.

Also, as we stated in the Hospital Inpatient VBP Program final rule (76 FR 26504), we view the program authorized by section 3008 of the Affordable Care Act and the Hospital VBP Program as being related but separate efforts to reduce HACs. Although the Hospital VBP Program is an incentive program that provides incentive-based payments to hospitals based on quality performance, the program established by section 3008 of the Affordable Care Act creates a payment adjustment resulting in payment reductions for the lowest performing hospitals.

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, although we intend to monitor the various interactions of programs authorized by the Affordable Care Act and their overall impact on providers and suppliers.

Comment: A few commenters suggested that CMS should adopt NQF-endorsed measures whenever possible. A commenter further noted that if CMS adopts non-NQF-endorsed measures, these measures should be formally tested prior to their inclusion in the Hospital IQR Program. Another commenter stated that if CMS considers

adopting measures that are endorsed by organizations other than the NQF, CMS should ensure that such organizations demonstrate strong consensus activities from consumers, healthcare organizations, physicians and other relevant professionals, purchasers and payers, and the organizations should have demonstrated expertise in healthcare quality measurement. A commenter suggested that CMS seek expedited NQF review of non-NQF-endorsed measures under consideration.

Response: We thank the commenters for all their suggestions for measure endorsement. We have generally adopted NQF-endorsed measures whenever possible. For non-NQF endorsed measures developed by CMS, we use a consensus-based measure development process that includes broad stakeholder input, and as part of this development process, we test feasibility, validity, and reliability whenever feasible and practicable.

Section 3001(a)(2) of the Affordable Care Act amended section 1886(b)(3)(B)(viii) of the Act to provide a different standard for quality measures included in the Hospital IQR Program for payments beginning with FY 2013. Under the amended provision of the Act, for payments beginning with FY 2013, each measure specified by the Secretary must be endorsed by a consensus entity that has a contract with the Secretary under section 1890(a) of the Act (currently the NQF), except in certain circumstances. Specifically, 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 entity, the Secretary may specify a measure that is not endorsed by the consensus entity if due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We thank the commenters for suggesting that we attempt to expedite NQF review of non-NQF-endorsed measures under consideration for the Hospital IQR Program, and we will consider doing so for measures for which CMS is the steward.

Comment: One commenter expressed concerns about the sufficiency of the risk-adjustment methods for the proposed process of care and outcome measures. The commenter recommended that CMS and AHRQ convene an expert panel to develop risk-adjustment for the measures used in the Hospital IQR, Hospital Readmissions Reduction and Hospital VBP Programs. Commenters stated that risk-adjustments should include patient demographic factors (for example, age, sex, race, and socioeconomic status), severity of illness, and types of services being provided.

Response: The current 30-day outcome measures and AHRQ PSIs and IQIs in the Hospital IQR Program are NQF-endorsed, and are risk adjusted using NQF-endorsed risk adjustment methodologies that include clinical risk factors. The current NQF policy for risk adjustment does not encourage risk adjustment for non-clinical patient demographic factors, because doing so may obscure disparities in care provided by hospitals to disadvantaged groups. The risk adjustment methodology employed in the NQF-endorsed outcome measures adopted for the Hospital IQR Program, therefore, would follow these principles.

Most of the outcome measures used in these programs are restricted to a specific condition or procedure, and therefore do not need to be adjusted for the type of service being provided as suggested by one of the commenters. Other outcome measures, such as the HACs, assess ''never events'' or serious reportable events that would not be appropriate to risk adjust for either clinical or demographic factors. CMS and AHRQ both participate in Measure Application Partnership workgroups convened by the NQF. These workgroups are tasked with issuing recommendations to HHS on various aspects of measurement (such as appropriate risk adjustment) for consideration in HHS' programs.

Comment: Some commenters urged CMS to focus heavily on outcome measures.

Response: We agree with the commenters. The adoption of outcome measures has always been and will remain as a priority goal for the Hospital IQR and Hospital VBP Programs.

We thank the commenters for their comments on our measure development principles, and we will consider these comments as we develop and select measures in the future.

b. Statutory History and 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) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180) for detailed discussions of the history of the Hospital IQR Program, including the statutory history and the measures we have adopted for the Hospital IQR measure set through FY 2014.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25891), we sought comments on an option that would allow us from time to time to consider a range of consensus endorsement entities or bodies that can assist us with our measure development process. We believe that this approach would provide for a diverse endorsement process and the best body of evidence to support measures used in our quality programs.

Comment: Several commenters recommended that CMS use the NQF as the sole consensus entity. These commenters stated that the NQF, which is composed of healthcare stakeholders, has developed a robust measurement evaluation system for the measure's importance, scientific acceptability, feasibility and usability, and their endorsed measures are gold standards. Other commenters recommended the NQF, Hospital Quality Alliance (HQA), and Measure Application Partnership (MAP) as consensus endorsement entities for assisting CMS in the measure development process. These commenters considered these organizations as the primary consensus groups for hospital quality reporting. These commenters believed that the HQA, composed of public and private partners, can appropriately select NQF-endorsed measures that best assess quality in high priority areas. These commenters also pointed out that the MAP was created under the Affordable Care Act, and aimed to recommend a coordinated set of measures for acute hospital, physician and long-term care hospital quality reporting. One commenter requested clarification as to which other entities are being considered by CMS for inclusion in its list(s) of consensus endorsement entities.

Response: We thank the commenters for their suggestions. Under section 1886(b)(3)(B)(viii)(IX) of the Act, for payments beginning with FY 2013, each measure specified by the Secretary under the Hospital IQR Program must be endorsed by the entity with a contract under section 1890(a) of the Act, except in certain circumstances. This contract is currently held by the NQF, and for this reason, we generally look to the NQF for endorsement of the measures we are considering for the Hospital IQR Program. However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the consensus entity, the Secretary may specify a measure that is not endorsed by the consensus entity if due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We also note that we give consideration to suggestions from other organizations such as the HQA, and the newly convened MAP, as well as from public comment received through rulemaking. As stated in the proposed rule, we strive to align measures where possible and appropriate across programs.

c. 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 Specifications Manual for National Hospital Inpatient Quality Measures (Specifications Manual). This Specifications Manual is posted on the CMS QualityNet Web site at *https://www.QualityNet.org.* We maintain the technical specifications by updating this Specifications Manual semiannually, or more frequently in unusual cases, and include detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. These semiannual updates are accompanied by notifications to users, providing sufficient time between the change and the effective date in order to allow users to incorporate changes and updates to the specifications into data collection systems.

The technical specifications for the HCAHPS patient experience of care survey are contained in the current HCAHPS *Quality Assurance Guidelines* manual, 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.

Comment: One commenter requested that CMS exercise its administrative authority to add the new FDA-approved Fidaxomicin off-cycle via Release Note to the current Specification Manual for National Hospital Inpatient Quality Measures (3.3a), Medication List—Appendix C—Table 2.1 ''Antimicrobial Medications—for hospital discharges as of April 1, 2011.''

Response: We convene Technical Expert Panels (TEPs) for measure development and maintenance in order to ensure that our measures reflect current science, evidence-based clinical practice guidelines, and best practices. We will take this suggestion under consideration during our measure maintenance process, which informs changes to the Specification Manual.

d. 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. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25891 through 25892), we proposed to display information regarding the measures (such as names of measures for which data will be displayed in the future) on the *Hospital Compare* Web site under this provision, and invited public comment on this proposal. We will continue our current practice 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.hhs.gov,* 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, and structural 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/.* Publicly reporting the information in this manner, though 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 e-mail blasts, 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.*

Comment: Many commenters overwhelmingly supported the increasing transparency in public reporting and appreciated CMS's principles for selecting measures. The commenters believed that these principles reflect practical aspects of quality data reporting such as reducing the burden of data collection on providers as well as aligning measures across programs. The commenters stated that CMS should ensure that this performance measure information is meaningful in improving patient care outcomes. Some commenters stated that more consumer education on performance measure data displayed on *Hospital Compare* is needed for meaningful interpretation of the data and identification of opportunities to improve patient outcomes.

Response: We greatly appreciate the commenters' support of public quality reporting and agree that consumer education is an ongoing process. We continuously strive to improve the user-friendliness of *Hospital Compare* Web site design and educate Medicare beneficiaries in understanding healthcare quality and healthcare trends. For example, we conduct periodic consumer testing to find out consumer preference for measure domains, understanding of measures and associated explanatory text. We believe that the reporting of various hospital quality metrics incentivizes hospitals to assess their patient care performance and identify opportunities to improve patient outcomes. In addition, the healthcare information released on *Hospital Compare* has become a popular resource for beneficiaries when they need to make decisions regarding their healthcare.

Comment: A few commenters opposed our intention to display measure names for which data will be displayed in the future on the *Hospital Compare* Web site. The commenters believed that the display of more descriptive information on future measures would help consumers better understand what the future measures are. The commenters believed that displaying only the measure names would not be helpful to consumers who need to choose a hospital for medical care.

Response: We use the *Hospital Compare* ''spotlight'' section to

highlight upcoming changes to the site, including the addition of new measures, topics, and future potential Hospital VBP Program measures. The measure names alone are not intended to drive consumer choice regarding which hospital to select, but we believe that highlighting names of measures to be added to Hospital Compare introduces possible new topic areas that consumers can discuss with their physicians in choosing a hospital. We also provide information about why the new measure topic may be important to know about.

Comment: Some commenters stated that data display on *Hospital Compare* should cater to consumers who visit *Hospital Compare* for information related to short-term healthcare decisions.

Response: We interpret the commenters' statements to mean that the information displayed on the *Hospital Compare* should provide information to help consumers to make informed decisions regarding inpatient acute care services (for example, treatments, tests, procedures or surgeries) that may be provided by a hospital. *Hospital Compare* is designed to be a consumer-oriented Web site where consumers can obtain information on how well hospitals provide care to their patients. The Web site displays quality data on process of care and outcome measures for heart attack, heart failure, pneumonia and surgical care as measured by the Surgical Care Improvement Project (SCIP). In the future, we will display data on other topics, such as Hospital-Associated Infections (HAIs) and complications of care. We will continue to post data to the Web site in a manner that is easy for consumers of the data to understand.

Comment: A few commenters opposed CMS' current practice of publishing performance measure information on Web sites other than *Hospital Compare* for 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.* The commenters were concerned that it would be difficult for providers and consumers to navigate and track information on multiple sites and supported *Hospital Compare* as the sole source for public display of quality reporting. The commenters recommended *Hospital Compare* be the sole Web site for display of quality data and supported continued improvement in the *Hospital Compare* Web site to make its data comprehensive and meaningful to consumers.

Response: We believe that *Hospital Compare* should be the primary vehicle for displaying hospital quality data reported for the Hospital IQR Program. As we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), the data we display on Web sites other than *Hospital Compare* is displayed on a temporary basis because of pending display design and other unresolved issues so as to not confuse beneficiaries who intend to use data in making healthcare decisions. Once an appropriate display mechanism has been determined, the information is added to the *Hospital Compare* Web site.

Comment: One commenter noted that results displayed on *Hospital Compare* should always exclude results based on a small number of cases or those results that may be misinterpreted by consumers.

Response: Currently, hospital-level process of care measures based on fewer than 25 cases are displayed with a footnote indicating that the number of cases may be too few for meaningful comparisons to be made. Hospital-level risk-adjusted outcome measure rates based on fewer than 25 cases are not displayed at all. This minimum case threshold may be subject to change in the future to match the minimum case threshold for the various measures established for the Hospital VBP Program. We thank the commenter for this suggestion.

Comment: One commenter suggested the standalone display of the PSI–12 Post-operative PE and DVT measure due to its significance as an indicator of hospital quality for Medicare beneficiaries undergoing surgeries that may put them at risk for thromboembolism.

Response: We appreciate this comment. We have not finalized the display options for the AHRQ PSI and IQI composite measures, in which PSI–12 is included. We will take this suggestion into consideration for the display of the AHRQ measures.

Comment: One commenter suggested that public reporting should be presented in different formats to meet the needs of consumers, healthcare providers and researchers.

Response: We are exploring options as to how best meet the needs of our multiple stakeholders, including beneficiaries and researchers. A new Web site, *http://www.data.medicare.gov,* allows researchers and other interested parties to view and manipulate multiple data sources, including downloadable databases from hospitals, nursing homes and dialysis facilities.

Comment: One commenter asked whether the data displayed on *Hospital Compare* included data from Medicare Advantage affiliated hospitals.

Response: Section 1886(b)(3)(B)(viii)(VII) of the Act requires that the Secretary establish procedures for making information regarding measures submitted under the Hospital IQR Program available to the public. The Hospital IQR Program applies to subsection (d) hospitals, many of which treat beneficiaries enrolled in Medicare Advantage (MA) plans. With respect to the process of care measures, the data are collected, and subsequently displayed, on all patients, including these MA beneficiaries. However, the claims-based measures are currently calculated using only Medicare Part A fee for service claims and do not, for that reason, capture MA beneficiary data. In the future, we hope to collect outcome measure data on all patients.

After consideration of the public comments we received, we are finalizing our proposal to display information regarding the measures (such as names of measures for which data will be displayed in the future) on the *Hospital Compare* Web site.

2. Retirement of Hospital IQR Program Measures

a. Considerations in Retiring Quality Measures From the Hospital IQR Program

We generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets. We previously retired one ''topped out'' measure, PN–1: Oxygenation Assessment for Pneumonia, from the Hospital IQR Program on the basis of high unvarying performance among hospitals, because measures with very high performance among hospitals present little opportunity for improvement, and do not provide meaningful distinctions in performance for consumers.

We also have retired one 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 retire such a measure, confirm

the retirement in the next IPPS rulemaking cycle, and notify hospitals and the public of the decision to promptly retire measures through the usual hospital and QIO communication channels used for the Hospital IQR Program. These channels include memos, e-mail notification, and QualityNet Web site postings.

As we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), among the criteria that we consider when determining whether to retire Hospital IQR Program measures are the following: (1) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made; (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. These criteria were suggested by commenters during rulemaking, and we agreed that these criteria should be among those considered in evaluating Hospital IQR Program measures for retirement.

b. Retirement of Hospital IQR Program Measures for the FY 2014 Payment Determination and Subsequent Years

In order to reduce the reporting burden on hospitals, and in particular, the burden associated with reporting chart-abstracted measures, we have considered options to accommodate the expansion of the measure set through the retirement of additional Hospital IQR measures. Specifically, we have considered retiring one or more of the measures suggested by various commenters that were listed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43865). We noted in that final rule that commenters recommended for retirement 11 Hospital IQR Program chart-abstracted measures. Seven of these 11 measures were recommended by commenters for retirement based on their performance being uniformly high nationwide, with little variability among hospitals (topped-out measures). Based on our own analysis, we concluded that these measures are topped out and for this reason, we proposed not to include them in the FY 2013 Hospital VBP Program measure set (76 FR 2460). These measures are listed below:

- AMI–1 Aspirin at arrival
- AMI–3 ACEI/ARB for left ventricular systolic dysfunction
- AMI–4 Adult smoking cessation advice/counseling
- AMI–5 Beta-blocker prescribed at discharge
- HF–4 Adult smoking cessation advice/counseling
- PN–4 Adult smoking cessation advice/counseling
- SCIP INF–6 Appropriate Hair Removal

The methodology we used to determine that these measures are topped out is detailed in the Hospital VBP Program proposed rule (76 FR 2460). In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25892), we proposed to retire these topped out measures from the Hospital IQR measure set. In addition, we proposed to not include an eighth measure in the FY 2013 Hospital VBP Program measure set because we believe that inclusion of this measure would result in the unintended consequence of inappropriate antibiotic use (76 FR 2462). This measure is PN–5c Timing of receipt of initial antibiotic following hospital arrival. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25892), we also proposed to retire this measure from the Hospital IQR Program because of the potential for this negative unintended consequence.

For these reasons, we proposed to retire these eight measures from the Hospital IQR measure set for FY 2014 and subsequent years, and that hospitals would no longer be required to submit data on these measures starting with January 1, 2012 discharges. We invited public comment on this proposal.

Comment: Several commenters supported the CMS measure retirement criteria and the proposed retirement of the 8 proposed topped out measures to reduce burden. The commenters encouraged CMS to replace process measures with comparable outcome measures whenever possible.

Response: We thank the commenters for their support and agree with the suggestion that, when possible, process measures should be replaced by suitable outcome measures.

Comment: A few commenters suggested that CMS should proceed cautiously in its decisions whether to retire topped-out measures or measures no long supported by scientific evidence. Some commenters recommended the continuation of data collection for topped out measures because they were concerned that there may be unintended consequences, such as a deterioration of the standard of care, if data collection and monitoring are discontinued.

Response: We believe it is appropriate to retire measures based on our measure retirement criteria. Retirement using these criteria also meets our goals of minimizing the reporting burden, and staying current with the latest scientific evidence. Furthermore, we believe that in many cases, the proposed topped out measures have been integrated into standard hospital clinical practices and for this reason, we believe it is unlikely that the types of beneficiary care addressed by these measures would deteriorate as a result of their retirement from the Hospital IQR Program measure set. However, as explained below, we have decided not to retire four of the eight measures we proposed to retire. Instead, we will retain these measures in the Hospital IQR Program but suspend data collection on them. We believe this will address the commenters' concern that we proceed cautiously when deciding whether to retire measures.

Comment: A few commenters opposed the retirement of the quality measures that have been deemed clinically meaningful or that were part of long-standing measure sets. A commenter suggested that CMS consider including topped out measures in composite measures. Commenters were concerned that the retirement of these measures may disrupt quality improvement efforts in hospitals. A commenter noted that quality measurement in general has the optimal impact on quality of care and patient outcomes when multiple related metrics are used. Another commenter believed that topped out measures that are NQF-endorsed should stay in the Hospital IQR Program until the NQF has retired them.

Response: While we are dedicated to the care and safety of our beneficiaries, we are also concerned with the burden placed on hospitals in order to collect data for the Hospital IQR Program. We do not believe we should continue collecting measures simply because they are part of a long standing measure set or that it would be generally meaningful to combine topped out measures into a composite topped out measure. Our decision to retire a measure from the Hospital IQR Program would not preclude a hospital from continuing to improve its own performance on the measure. Moreover, as discussed below, we are keeping four of the measures we proposed for retirement in the Hospital IQR Program, but are suspending the data submission requirements for these

measures. This approach will reduce data collection burdens on hospitals, but will enable us to resume data collection should we observe abrupt declines in adherence to these measures.

Comment: A few commenters supported the retirement of AMI–4, HF–4, and PN–4 because they are topped out. A few commenters stated that these 3 measures and the PN–5c measure do not meet the The Joint Commission accountability measure criteria and should be retired. Another commenter requested clarification on the reason for retiring PN–5c since this measure has been a high priority in hospitals which have geared up training efforts for this measure.

Response: We thank the commenters for supporting our proposal to retire these four measures, and we are finalizing our proposal to retire these measures beginning with January 1, 2012 discharges. The three adult smoking cessation counseling measures (AMI–4, HF–4, and PN–4) are no longer NQF-endorsed. They are also topped out, which provides us with some assurance that these processes have been incorporated into routine hospital care. With respect to the PN–5c measure, we believe that the continued collection of this measure might lead to the unintended consequence of antibiotic overuse, which is a practice that could negatively affect beneficiary health and one that should not be incentivized through the Hospital IQR Program. Should we decide in the future that the clinical evidence supports the re-adoption of one or more of these measures into the Hospital IQR Program measure set, we will propose to re-adopt the measure(s) in rulemaking.

Comment: One commenter suggested that CMS establish policies to retire a quality measure midyear if the measure is found to have unintended serious consequences.

Response: We appreciate this suggestion. Our current policy is to immediately suspend collection of a measure when there is reason to believe that continued collection of the measure raises patient safety concerns. In these circumstances, we will take action outside of the rulemaking cycle, and then confirm the retirement in the next IPPS rulemaking cycle. We will also disseminate this information to hospitals and the public through the usual hospital and QIO communication channels used for the Hospital IQR Program, including the QualityNet Web site, e-mail blasts, memos and other information postings as needed.

Comment: One commenter recommended that the following four measures also be considered for retirement: HF–1 (because it is a ''check the box'' measure and is not related to the quality of the discharge process), SCIP–Inf–2 (because it is a process measure which can be replaced by its outcome measure which is the Surgical Site Infection measure scheduled for implementation for FY 2014), SCIP–INF–VTE–1 and SCIP–VTE–2 (because these 2 proposed VTE measures are already included in the VTE measure set for FY 2015) and PN–3b (because of the incompatible EHR integration with the clinical workflow).

Response: We thank the commenter for these recommendations and will evaluate them in our measure review for future rulemaking.

Comment: Many commenters agreed that the retirement of all eight measures would result in a reduction in chart abstraction burden for hospitals. However, a few commenters were particularly concerned about retiring AMI–1, AMI–3, AMI–5, and SCIP Infection–6 because they have been designated as accountability measures by The Joint Commission.[5] The commenters agreed that these measures should not be used in the Hospital VBP Program but urged CMS to keep these measures in the Hospital IQR Program and continue their display on *Hospital Compare* in order to prevent a decline in adherence to the important care processes assessed by these measures that are clinically associated with better outcomes. Commenters supported the cessation of data collection for these measures that we proposed for retirement (AMI–1, AMI–3, AMI–5, and SCIP INF–6) in order to ease the data collection burden.

Response: We have been persuaded by these commenters that it might be premature to retire these measures (AMI–1, AMI–3, AMI–5 and SCIP INF–6) from the Hospital IQR Program. As the commenters pointed out, these measures, unlike the other four measures we proposed to retire, have been defined by The Joint Commission as measures of accountability. In addition, these measures, unlike three of the other four measures, are currently still endorsed by the NQF.

We are sensitive, however, to comments noting how the continued adoption of chart-abstraction measures over time has increased the burden to hospitals. Therefore, in an effort to balance our goal to incentivize high quality care with the goal to work where possible to minimize the data collection burden for hospitals, we have decided to retain these measures in the Hospital IQR Program but to suspend data collection on them until such time that the evidence shows that hospital adherence to these practices has unacceptably declined. In these circumstances, we would resume data collection using the same form and manner and on the same quarterly schedule that we finalized for these and other chart abstracted measures for the applicable period of collection, providing at least 3 months of notice prior to resuming data collection. Hospitals would be notified of this via CMS listservs, CMS e-mail 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 4 measures.

In summary, based upon the public comments we received, we are retiring the following four measures beginning with January 1, 2012 discharges:

- AMI–4 Adult smoking cessation advice/counseling
- HF–4 Adult smoking cessation advice/counseling
- PN–4 Adult smoking cessation advice/counseling
- PN–5c Timing of receipt of initial antibiotic following hospital arrival

We are suspending data collection for the following four measures beginning with January 1, 2012 discharges:

- AMI–1 Aspirin at arrival
- AMI–3 ACEI/ARB for left ventricular systolic dysfunction
- AMI–5 Beta-blocker prescribed at discharge
- SCIP INF–6 Appropriate Hair Removal

3. Measures for the FY 2014 and FY 2015 Hospital IQR Payment Determinations

a. Considerations in Expanding and Updating Quality Measures Under the Hospital IQR Program

In general, we seek to adopt measures for the Hospital IQR Program that promote better, safer, more efficient care. Our measure development and selection activities for the Hospital IQR Program take into account national priorities, such as those established by the National Priorities Partnership, HHS Strategic Plan, the National Strategy for Quality Improvement in Healthcare, as well as other widely accepted criteria established in medical literature. (We refer readers to the following Web sites regarding these priorities: *http://*

[5] Accountability measures are defined by the Joint Commission as measures that: (1) Support a strong link between the measure and improved outcomes; (2) accurately assess the relevant clinical process; and (3) have minimal unintended adverse consequences if implemented.

www.nationalprioritiespartnership.org/ (National Priorities Partnership); *http://www.hhs.gov/secretary/about/priorities/priorities.html* (HHS Strategic Plan); and *http://www.healthcare.gov/center/reports/quality03212011a.html* (National Strategy for Quality Improvement in Healthcare)). To the extent practicable, we have sought to adopt measures which have been endorsed by a national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers and other stakeholders. Because measures for the Hospital VBP Program must be selected from the measures specified for the Hospital IQR Program, the measures to be selected for inclusion in the Hospital VBP Program also reflect these priorities. In addition, we believe it is important to expand the pool of measures to include measures that are directed toward improving patient safety. This goal is supported by at least two Federal reports documenting that tens of thousands of patients do not receive safe care in the nation's hospitals.[6] [7]

Section 3001(a)(2) of the Affordable Care Act amended the Act by adding a new section 1886(b)(3)(B)(viii)(VIII) of the Act. This section states that, ''[e]ffective for payments beginning with fiscal year 2013, with respect to quality measures for outcomes of care, the Secretary shall provide for such risk adjustment as the Secretary determines to be appropriate to maintain incentives for hospitals to treat patients with severe illnesses or conditions.'' Section 3001(a)(2) of the Affordable Care Act also added new sections 1886(b)(3)(B)(viii)(IX)(aa) and (bb) of the Act. These sections state that ''* * * effective for payments beginning with fiscal year 2013, each measure specified by the Secretary under this clause shall be endorsed by the entity with a contract under section 1890(a) [of the Act],'' and ''[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical 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 2011 IPPS/LTCH PPS final rule, we established that all of the measures adopted in that rule for the FY 2013 and FY 2014 payment determinations meet these standards (75 FR 50200).

We have previously acknowledged the data collection burden for hospitals participating in the Hospital IQR Program, and reiterated our desire to expand the Hospital IQR Program measure set while minimizing burden and seeking to provide alternative mechanisms for data submission (75 FR 50189). We also stated that in future expansions and updates to the Hospital IQR Program measure set, we would be taking into consideration several important goals. These goals include: (a) Expanding the types of measures beyond process of care measures to include an increased number of outcome measures, efficiency measures, and patients' experience of care measures; (b) expanding the scope of hospital services to which the measures apply; (c) considering the burden on hospitals in collecting chart-abstracted data; (d) harmonizing the measures used in the Hospital IQR Program with other CMS quality programs to align incentives and promote coordinated efforts to improve quality; (e) seeking to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims databases; and, (f) weighing the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital IQR Program.

Specifically, we give priority to measures that assess performance on: (a) Conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and, (c) conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. We have used and continue to use these criteria to guide our decisions regarding what measures to add to the Hospital IQR Program measure set. In addition, in selecting measures, we seek to address the six quality aims of effective, safe, timely, efficient, patient-centered, and equitable healthcare. Current and long term priority topics include: prevention and population health; safety; chronic conditions; high cost and high volume conditions; elimination of health disparities; HAIs and other adverse healthcare outcomes; improved care coordination; improved efficiency; improved patient and family experience of care; effective management of acute and chronic episodes of care; reduced unwarranted geographic variation in quality and efficiency; and adoption and use of interoperable HIT.

Hospital IQR Program measures were initially based solely on a hospital's submission of chart-abstracted quality measure data. However, in recent years we have adopted measures that do not require chart abstraction, including structural measures and claims-based measures that we can calculate using other data sources. This approach supports our goal of expanding the measures for the Hospital IQR Program while minimizing the burden on hospitals and, in particular, without significantly increasing the chart abstraction burden.

In addition to structural measures and claims-based measures, we previously noted that registries are potential alternative sources of hospital data for the Hospital IQR Program. (A registry is a collection of clinical data for purposes of assessing clinical performance, quality of care, and opportunities for quality improvement.) We envisioned that instead of requiring hospitals to submit the same data to CMS that many hospitals are already submitting to registries, we would collect the data directly from the registries. This could enable the expansion of the Hospital IQR Program measure set without increasing the burden of data collection for those hospitals participating in the registries. We have previously adopted structural measures of registry participation, and we continue to evaluate the feasibility of leveraging registry-based data collection mechanisms for the Hospital IQR Program.

We also stated our intention to explore mechanisms for data submission using electronic health records (EHRs) (73 FR 48614; 74 FR 43866, 43892; and 75 FR 50189). Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and 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 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

[6] OEI–06–09–00090, ''Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries.'' Department of Health and Human Services, Office of Inspector General, November 2010.

[7] 2009 National Healthcare Quality Report, pp. 107–122. ''Patient Safety,'' Agency for Healthcare Research and Quality.

[8] McKibben L, Horan T, Guidance on public reporting of healthcare-associated infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005; 33:217–26

to hospitals. We believe that automatic collection and reporting of data through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs and that at a future date, currently targeted to be FY 2015, hospitals will be able to switch solely to EHR-based reporting of data that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We reiterate our commitment to pursue our goals to expand and update quality measures under the Hospital IQR Program and also to minimize burden. We note that in addition to the input we described above, we take into consideration the measures adopted by the Hospital Quality Alliance (HQA) as well as an array of input from the public. The HQA is a national public-private collaboration that is committed to making meaningful, relevant, and easily understood information about hospital performance accessible to the public and to informing and encouraging efforts to improve quality. We appreciate HQA's integral efforts to improve hospital quality of care and its support of our public quality reporting programs.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50191 through 502192), we finalized our proposal to adopt measures for the Hospital IQR Program for three consecutive payment determinations. The intent of this policy was to provide greater certainty for hospitals to plan to meet future reporting requirements and implement related quality improvement efforts. In addition to giving hospitals more advance notice in planning quality reporting, this 3-year approach also provides more time for us to prepare, organize and implement the infrastructure needed to collect data on the measures and make payment determinations. We indicated, however, that these preliminary measure sets could still be updated through the rulemaking process should we need to respond to agency and/or legislative changes.

Finally, in section IV.A.5.a.(2) of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50219 through 50220), we adopted a proposal to make Hospital IQR Program payment determinations beginning with FY 2013 using one calendar year of data for chart-abstracted measures. We will use this approach, which synchronizes the quarters for which data on these measures must be submitted during each year with the quarters used to make payment determinations with respect to a fiscal year beginning with January 1, 2011 discharges. However, it will not affect our payment determinations until FY 2013.

Section 1886(o)(2)(A) of the Act requires the Secretary to select measures, other than readmission measures, for the Hospital VBP Program from the measures specified under the Hospital IQR Program. Section 1886(o)(2)(B)(i)(I) of the Act states that, for FY 2013, the selected measures must cover at least the following five specified conditions or procedures: Acute myocardial infarction (AMI), Heart failure (HF), Pneumonia (PN), Surgeries, as measured by the Surgical Care Improvement Project (SCIP), and HAIs, as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections [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).

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework of the Hospital VBP Program. We will focus on selecting measures that we believe will also meet the Hospital VBP Program measure inclusion criteria and advance the goals of the Hospital VBP Program by targeting hospitals' ability to improve patient care and patient outcomes.

In addition, in order to support HHS priorities such as patient safety, reduction of HAIs, and readmissions, and to meet more of the widespread goals of the Affordable Care Act in terms of improving the quality of care provided to Medicare beneficiaries, in the FY 2012 IPPS/LTCH PPS proposed rule we proposed to adopt measures for the FY 2014 and FY 2015 Hospital IQR payment determinations. However, we noted that the final measure sets to be used for these years' payment determinations could be changed via future rulemaking. This allows us the flexibility to accommodate changes in program needs and legislative changes. We invited public comment on these proposals.

Comment: Some commenters were pleased to see CMS's move to align measures used for various Medicare programs in order to reduce the reporting burden. Some commenters supported the alignment of all new measures with the objectives of the National Priorities Partnership, the HHS Strategic Plan, and the National Strategy for Quality Improvement in Healthcare, while other commenters recommended aligning reporting approaches across payers to reduce the burden of quality reporting and to also allow for meaningful comparisons across payers.

Response: We appreciate the commenters' support of our ongoing alignment strategy. We may consider an approach to align measures across payers in the future.

Comment: Many commenters strongly opposed the adoption of additional chart-abstracted measures because they believed these measures would increase hospital burden. One commenter urged CMS to limit its adoption of new chart-abstracted measures to a maximum of three per payment determination. Some commenters recommended that CMS either: stop adopting additional new chart-abstracted measures altogether; propose to adopt new chart-abstracted measures only if it simultaneously proposes to retire the same number of measures; or retire chart-abstracted measures when related outcome measures could instead be used.

A commenter suggested that CMS should monitor whether the adoption of new measures for the Hospital IQR Program would create redundancy in terms of what data is being collected. This commenter cited the following measures and measure topics included in the table of measures and topics under consideration for future implementation (76 FR 25899 through 25901) which was included the FY 2012 IPPS/LTCH PPS proposed rule as examples of potentially duplicative measures: Timing of Antibiotic Prophylaxis; Selection of Antibiotic Prophylaxis; Pre-Operative Beta Blockade; and Duration of Prophylaxis.

A few commenters cited several other examples of measures that they believed are already duplicative. Specifically, these commenters believed that the 30-day mortality rate and 30-day readmission rate measures for AMI, HF, and PN were duplicative of the 9 chart-abstracted process measures currently included in the Hospital IQR measure set for these 3 conditions, and that for this reason, the chart-abstracted measures could be retired. Commenters further noted that the periodic evaluation of measures for redundancy would significantly reduce the administrative burden for hospitals while maintaining incentive for hospitals to focus on their quality improvement efforts.

Commenters also suggested that the HAC measure (Vascular Catheter-Associated Infections) is so similar to the CLABSI measure that it is redundant for CMS to include both of these measures in the Hospital IQR Program measure set. These commenters believed that it is unnecessary and potentially confusing and inefficient to

collect data on these two measures simultaneously.

Response: We agree that chart-abstracted measures are burdensome for hospitals to collect. As soon as we can obtain quality data from EHRs, we intend to limit the adoption of chart-abstracted measures for future payment determinations. To ease the burden before then, we are finalizing our proposal to retire four chart-abstracted measures beginning with January 1, 2012 discharges. Additionally, we are finalizing a policy in this final rule under which the collection of data on four chart-abstracted measures will be suspended until such time that the clinical evidence indicates that hospital adherence to these practices has unacceptably declined. We also continuously seek to harmonize and align measure specifications where applicable in an effort to reduce the incidence of duplicative measures both within and across programs. We also seek to reduce redundancy in measurement. We will carefully consider whether the measures cited by commenters significantly overlap with each other and, for that reason, whether some of the measures cited should be retired.

Comment: One commenter suggested that for initial transition into EHR reporting, CMS should limit the number of electronic measures that could be collected via EHR technology.

Response: We are mindful of the potential challenges that could be faced by hospitals during a transition to EHR-based reporting. We will keep these challenges in mind as we develop our proposals for adopting measures that can be reported through EHRs.

Comment: In response to our projected timeframe for transitioning to EHR-based data collection, a commenter noted that given the slow progress of EHR software development, it was premature to anticipate that Hospital IQR Program measures could be collected via EHRs by 2015.

Response: We believe FY 2015 is a reasonable transition date for switching from chart-abstracted measures to EHR-based reporting for the Hospital IQR Program because that is the year when certain hospitals will become subject to payment adjustments if they do not demonstrate meaningful use of certified EHR technology. For this reason, we believe that these hospitals will be EHR-technology-ready by FY 2015.

Comment: A few commenters supported using registries and the EHR reporting mechanism to ease burden and to obtain robust clinical data. Some commenters believed that registries assist hospitals in managing specific patient populations more effectively. A commenter noted that reporting to a registry is not the long term solution to advance the reporting of the increasingly complex quality data, but could be an interim solution. A few commenters opposed using registries and believed that registry-based measures would create an extra burden for hospitals. These commenters explained that many registries require data collection from the medical record only, whereas other registries require the collection and submission of a significant number of data elements. Another commenter noted that registry-based reporting would not be meaningful when EHR-based reporting becomes more common in FY 2015.

Response: We believe that registries, in general, hold promise for less burdensome quality reporting, and that is why we adopted several structural measures that monitor participation in systematic clinical database registries for the Hospital IQR Program. We agree that registry requirements may vary. We also agree that registries could serve as an interim solution until we implement wide-spread EHR-based reporting for the Hospital IQR Program.

Comment: Some commenters encouraged CMS to consistently evaluate the relevancy and need to modify quality measures in its quality reporting expansion efforts, for small rural hospitals with limited resources.

Response: We thank the commenter for this suggestion. In general, we seek to adopt measures that are broadly applicable to all hospitals, including small rural hospitals. However, we are mindful of the challenges faced by small rural hospitals with limited resources.

In summary, we will continue to pursue goals regarding the expansion and updating of quality measures under the Hospital IQR Program while minimizing burden. We will take into account the public comments we received on this issue, including the possible uses of EHRs and registries in the Hospital IQR Program. We also note that in accordance with the policy we are finalizing in this final rule to suspend data collection on four measures (AMI–1, AMI–3, AMI–5, and SCIP–6), the measure set for FY 2014 and/or FY 2015 that we finalize in this final rule might change if we resume the collection of data on one or more of these measures.

b. Hospital IQR Program Measures for the FY 2014 Hospital IQR Payment Determination

(1) Retention of 56 Hospital IQR Program Measures Finalized in the FY 2011 IPPS/LTCH PPS Final Rule for the FY 2014 Payment Determination

We previously finalized 60 measures for the FY 2014 Hospital IQR Program measure set. In general, we retain measures used in prior payment determinations for subsequent payment determinations unless otherwise stated. However, as we discussed above, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25892), we proposed to retire 8 measures from the FY 2014 measure set and to retain the remaining 52 of the 60 quality measures finalized in the FY 2011 IPPS/LTCH PPS final rule for the FY 2014 payment determination. We invited public comment on our proposal to retain these 52 measures for the FY 2014 payment determination. We note that in this final rule we are finalizing a policy under which we will retain four of the eight measures we proposed to retire and will retain but suspend data collection for the other four measures.

Comment: One commenter was concerned about the burden of chart-abstraction of two Hospital IQR measures: ED–1: Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital; and ED–2: Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status. To reduce the chart-abstraction burden for these measures, the commenter suggested that patients with principal diagnosis codes unrelated to the cause for the ED visit be excluded from the denominator.

Response: We share the commenter's concern regarding the burden hospitals face to collect data on Hospital IQR measures. We acknowledge that patients seek medical attention in the hospital ED for a variety of reasons, some of which may not appear to be linked with a discharge diagnosis. We will consider whether it is appropriate to modify the ED throughput measures to exclude patients with a principal diagnosis code seemingly unrelated to the cause for the ED visit in the denominator. In such case, we will seek an NQF ad hoc review to have the new specifications endorsed. However, we believe that all patients, regardless of chief complaint or discharge diagnosis, should have access to timely and efficient care.

Comment: One commenter recommended that for the Surgical Site Infection (SSI) measure that was

finalized in the FY 2011 IPPS/LTCH final rule for the FY 2014 payment determination, CMS should limit the surgical procedures to not more than two and increase the number of surgical procedures gradually in the future.

Response: We thank the commenter for the suggestion. In the measure Specifications Manual, there are currently 395 SCIP procedures summed up into 6 stratifications: cardiac surgery, other cardiac surgery, hip arthroplasty, colon surgery, hysterectomy and vascular surgery. We are working with CDC on the collection of the Surgical Site Infection data. The data collection is consistent with the specifications, and as recommended by the CDC, we will be collecting data on 2 surgical procedure categories. This will not only reduce burden, but will allow the CDC to collect data in a phased roll out. Consistent with current NQF harmonization efforts underway for this measure, and based on recommendations by CDC, we will be collecting Surgical Site Infection data only for colon and abdominal hysterectomy procedures via NHSN for the FY 2014 payment determination.

Comment: A commenter stated that current mortality and readmissions outcome measures in the Hospital IQR Program pose challenges for hospitals. Other commenters stated that the hierarchical regression model on which these measures are based includes a risk-adjustment methodology that hospitals cannot replicate or validate. These commenters believed that this hampered hospitals from generating internal reports to assess performance and that hospitals have to wait for CMS to provide the information annually.

Response: Although it provides some challenges to hospitals, we believe that there are several reasons supporting our conclusion that hierarchical modeling, which is NQF-endorsed, is the appropriate statistical approach for calculating the hospital outcome measures: 30-day risk-adjusted all-cause readmission and mortality measures. This conclusion is based on the structure of the data and the underlying assumption that hospital quality of care influences 30-day mortality/readmission rates. First, patients are clustered within hospitals and, therefore, have a shared exposure to the hospital quality and processes. The use of hierarchical modeling accounts for the clustering of patients within hospitals. Second, hierarchical models distinguish within-hospital variation and between-hospital variation to estimate the hospital's contribution to the risk of mortality or readmission. This allows for an estimation of the hospital's influence on patient outcomes. Finally, within hierarchical models we can account for both differences in case mix and sample size to fairly profile hospital performance. If we did not use hierarchical modeling we could overestimate variation and potentially misclassify hospitals' performance.

This approach to calculating the numerator, therefore, although more complex than that used for logistic regression, is more statistically accurate and fairer to hospitals. We agree that hospitals currently cannot replicate the RSMRs or RSRRs independently. Although hospitals have access to the inclusion/exclusion criteria and risk-adjustment coefficients used; the model requires the input of patient longitudinal data across care settings and data from the entire national sample to estimate the hospital-specific effects used in the calculations. We will consider whether it is operationally possible to provide these data to hospitals and whether sharing these data would be consistent with patient privacy considerations.

Comment: A few commenters opposed the retention of the HAC measure: Manifestations of Poor Glycemic Control and the two Global Immunization measures (Immunization for Influenza and Immunization for Pneumonia) because they believed that these measures are more appropriate to collect at the physician level.

Response: We disagree with the commenters' belief that the measures are better suited for the physician office. The HAC measure, manifestation of poor glycemic control, has ICD–9 codes that are specific to a secondary diagnosis in the hospital, not to ambulatory settings. Certain acute illnesses and procedures, such as influenza or surgery, can cause blood glucose to become uncontrolled in some patients. In these instances, a patient may react to high or low blood sugar with adverse events such as coma, or a secondary illness or infection. In response to the comments on the two Global Immunization measures, we believe that the acute care setting offers a unique opportunity to assess a patient's immunization status and offer a service they may not otherwise receive.

Comment: A commenter stated that the current AMI and HF measures adopted for the FY 2014 payment determination are not well-aligned with current evidence and treatment guidelines for AMI or HF that are reflected in the current performance measures developed by the American Heart Association/American College of Cardiology/Physician Consortium for Performance Improvement. The commenter also stated that the HF–1 discharge instruction measure does not have a valid process outcome link.

Response: We are interested in the heart failure measure set referenced by the commenter, and we included these measures in our list of measures under future consideration for this program. However, the AMI and HF measures proposed for retention in the Hospital IQR measure set were developed using the most up to date clinical evidence. The CMS TEP convened as part of our measure maintenance work for these measures includes members and guideline authors from both the American Heart Association and the American College of Cardiology. We look to TEPs to inform us of vital changes to the guidelines, assuring our measures are scientifically credible. We believe that the processes assessed by the HF–1 measure, which assesses whether discharge instructions for heart failure patients were issued, are vital in assuring that patients are appropriately informed of activities and behaviors that promote health and positive outcomes.

Comment: A commenter recommended that CMS separate the IQI–11 Abdominal aortic aneurysm (AAA) mortality rate (with or without volume) measure into two distinct measures: one measure for those patients undergoing elective repair and one measure for those undergoing emergency or urgent repair. The commenter believed that this measure should be stratified by open surgical and endovascular repair, and that the risk-adjustment model should be tested prospectively for accuracy.

Response: We thank the commenter for this suggestion. AAA repair is a technically difficult procedure with a relatively high mortality rate (we refer readers to *http://www.qualityindicators.ahrq.gov/modules/iqi_resources.aspx*). We have adopted the measure as it is currently specified by the Agency for Healthcare Research and Quality, and endorsed by the NQF which includes both elective and emergent cases and is not stratified. We believe that the measure is appropriately risk-adjusted to account for differences in risk factors in the elective and emergent populations undergoing this procedure.

After consideration of the public comments we received, we are finalizing the retention of 56 measures that we finalized in the FY 2011 IPPS/LTCH PPS final rule for the FY 2014 payment determination. We note that this number includes the four measures which, as discussed above, we are also

retaining but on which we are suspending data collection.

(2) Additional Hospital IQR Program Measures for the FY 2014 Payment Determination

(A) CDC/NHSN-Based Healthcare-Associated Infection (HAI) Measures

HAIs are among the leading causes of death in the U.S. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths per year.[8] 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 healthcare costs.

HAIs are largely preventable with widely publicized interventions such as better hygiene and advanced scientifically tested techniques for surgical patients. Therefore, the public reporting of HAIs has been of great interest to many healthcare consumers and advocacy organizations because it promotes awareness and permits health care consumers to choose the hospitals with lower HAI rates, as well as gives hospitals an incentive to improve infection control efforts. To maximize the efficiency and improve the coordination of HAI prevention efforts across the Department, HHS established in 2008 a senior-level Steering Committee for the Prevention of Healthcare-Associated Infections. In 2009, the Steering Committee, along with scientists and program officials across the government, developed the HHS Action Plan to Prevent HAIs providing a roadmap for HAI prevention in acute care hospitals. In the first iteration of the Action Plan, the Steering Committee chose to focus on infections in acute care hospitals because the associated morbidity and mortality was most severe in that setting and the scientific information on prevention and the capacity to measure improvement was most complete. Thus, prevention of HAIs in acute care hospitals became the first phase of the Action Plan and it focuses on six high priority HAI-related areas.

In addition, the Steering Committee included in the Action Plan five-year goals for nine specific measures of improvement tied to the six HAI prevention priority areas. Since the release of the first Action Plan in June 2009, the Steering Committee has been developing a successor plan in collaboration with public and private partners which is expected to incorporate advances in science and technology and expand the scope to the outpatient environment. The successor plan is also expected to address the health and safety of healthcare personnel, as well as the risks of influenza transmission from healthcare personnel to patients. The second Action Plan is due for publication in 2011.

We also note that the House Committee on Appropriations asked in a 2009 Report that CMS include in its ''pay for reporting'' system two infection control measures developed by the Hospital Quality Alliance (HQA)—Central line-associated bloodstream infections and a surgical site infection rate (H. Rep. No. 111–220, at 159 (2009)). In the report, the Committee stated that ''if the measures are included in *Hospital Compare,* the public reporting of the data is likely to reduce HAI occurrence, an outcome demonstrated in previous research.''

In the FY 2011 IPPS/LTCH PPS final rule, we adopted the two HAI measures identified by the House Committee on Appropriations in its 2009 report: Central Line [catheter] Associated Blood Stream Infection (CLABSI) measure, and Surgical Site Infection (SSI) measure. The CLABSI measure is currently being collected as part of the FY 2013 Hospital IQR measure set, and data submission on the measure began with January 2011 events.[9] The Surgical Site Infection (SSI) measure is currently part of the FY 2014 Hospital IQR measure set, and data submission on the measure will begin with January 2012 events.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25894 through 25896), we proposed to adopt two additional HAI measures for the FY 2014 Hospital IQR measure set. These measures are: (1) Central Line Insertion Practices, or CLIP (which is NQF # 298 and operationalized by the CDC for collection through the NHSN); and (2) Catheter Associated Urinary Tract Infection (CAUTI) (NQF # 138). Both measures are high priority HAI measures that are included among the prevention metrics established in the HHS Action Plan To Prevent HAIs which, as we noted above, underscores the importance of reducing HAIs. As detailed below, both measures also meet Hospital IQR Program statutory requirements for measure selection.

Furthermore, both measures are currently collected by the NHSN, which is a secure, Internet-based surveillance system maintained and managed by the CDC, and can be used by all types of healthcare facilities in the U.S., including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and long term care facilities. The NHSN enables healthcare facilities to collect and use data about HAIs, adherence to clinical practices known to prevent HAIs, the incidence or prevalence of multidrug-resistant organisms within their organizations, and other adverse events. Some States use NHSN as a means for healthcare facilities to submit patient-level data on the measures mandated through their specific State legislation. Currently, 28 States require hospitals to report HAIs using NHSN, and CDC provides support to more than 4,000 hospitals that are using NHSN. NHSN data collection occurs via a Web-based tool hosted by CDC provided free of charge to providers. In addition, data submission for HAI measures through EHRs may be possible in the near future.

Comment: A commenter encouraged CMS to include only those HACs that could reasonably be prevented. A commenter requested clarification on how the proposed HAI measures differ from the ''never events'' currently being reported.

Response: In our selection of HACs, we have to meet the requirements under section 1886(d)(4)(D) of the Act. Section 1886(d)(4)(D) of the Act specifies that by October 1, 2007, the Secretary was required to select, in consultation with the 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. Under this provision, the HACs we select must be reasonably preventable. Many of the HACs also are ''never events'' or serious reportable events defined by the NQF. The HAI measures, unlike the HACs, are designed to look at more than ICD codes. The CDC criteria for the HAIs rely on chart-abstracted and point of care assessments to identify HAIs. Many of these infections can be identified during the acute stay, before hospital discharge, thereby providing a more real time view of the patient.

Comment: A commenter suggested that CMS should propose to adopt only outcome HAI measures rather than

[8] McKibben L, Horan T, Guidance on public reporting of healthcare-associated infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005; 33:217–26

[9] The CDC captures HAI data based on the onset of an event, rather than based on the discharge date.

process HAI measures. Furthermore, the commenter recommended that CDC should streamline the amount of information required for collection within HAI modules to ease the data collection burden for providers.

Response: We agree with the commenters regarding the preference for outcome measures over process of care measures. For example, we discuss below our decision to not finalize the proposed CLIP measure because we have been persuaded by commenters that the CLABSI measure already adopted for the Hospital IQR Program is sufficiently related and captures the outcome of the process of care. We have shared the comment regarding streamlining data collection with the CDC.

(i) Central Line Insertion Practice Adherence Percentage (CLIP)

Central line associated blood stream infections (CLABSIs) can be prevented through proper management of the central line. The CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) *Guidelines for the Prevention of Intravascular Catheter-Related Infections* recommends evidence-based central line insertion practices known to reduce the risk of subsequent central line-associated bloodstream infection.[10] These include hand-washing by inserters, use of maximal sterile barriers during insertion, proper use of a skin antiseptic prior to insertion, and allowing that skin antiseptic to dry before catheter insertion. Despite the scientific evidence supporting these practices, several reports suggest that adherence to these practices remains low in United States hospitals. The proposed CLIP process measure is a companion measure to the previously adopted CLABSI measure, and it assesses the extent to which a facility employs practices consistent with CDC/HICPAC recommendations that are known to reduce CLABSI. There are 2 States that currently require facilities to report to NHSN at least one month of CLIP data.

The CLIP measure is used in State reporting initiatives and is an NQF-endorsed measure (NQF # 298) that is operationalized for collection by the CDC via the NHSN. Therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. This CLIP prevention metric is also listed in the HHS Action Plan To Prevent HAIs and, as we detailed above, has been widely identified as a high priority for public reporting.

Comment: A few commenters strongly believed that the CLABSI measure in the Hospital IQR Program is a valid, well-constructed, and risk-adjusted outcome measure. These commenters pointed out that the decreasing incidence of central line-associated infections was attributed to the implementation of this measure in early 2011 in conjunction with other ongoing patient safety infection initiatives. Some commenters noted the current CLABSI rates have been excellent.

Commenters opposed the adoption of the CLIP measure because they believed that it is labor-intensive to collect, hard to validate, and does not address the need for quick removal of the central line which is the key to reducing CLABSI. Based on these reasons, the commenters opposed the adoption of the proposed CLIP measure, which is a process measure, because the outcome itself (CLABSI) is being already reported by hospitals. Furthermore, one commenter suggested that if CMS adopts the measure, it should clarify that the measure is only applicable to high risk units such as ICUs where central lines are generally placed and should only apply to hospitals with bad CLABSI outcomes. A commenter suggested that the measure be risk-adjusted based on the morbidity of the patient at the time of admission. A few commenters recommended delaying the adoption of the proposed CLIP measure until FY 2015 to allow time to refine its specifications. Some commenters requested the removal of the CLABSI HAC claims measure if the CLIP measure is implemented. A commenter believed that the proposed time frame to begin data collection does not allow proper time for hospitals to assure the collection of these elements for all the central line insertions.

Response: We agree with the commenters that the existing CLABSI outcome measure is preferable because it captures the outcome that the process of care measure (CLIP) is designed to prevent. Therefore, by measuring the outcome, we are inherently assessing the effectiveness of central line insertion and maintenance processes being employed by the facility. Consistent with our goal to shift toward outcome measures, we are not finalizing our proposal to adopt the CLIP measure for the Hospital IQR measure set.

Comment: A few commenters asked CMS for clarification whether the CLIP measure developed by the Institute for Healthcare Improvement (IHI) or the CDC/NHSN CLIP measure is being proposed for adoption into the Hospital IQR measure set.

Response: We proposed to adopt the CDC CLIP measure, and we believe that it is an operationalization of the NQF-endorsed CLIP measure (NQF # 0298) for which IHI (not CDC) is the steward. Although the NQF-endorsed CLIP measure was developed by the IHI, it is based upon the CDC prevention guidelines for preventing Central Line Associated Blood Stream Infections. However, the CDC specifications for the measure do not require that the hospital report its daily monitoring of central lines. For the reasons stated previously, we will not be adopting the proposed CLIP measure for the Hospital IQR Program at this time.

(ii) Catheter Associated Urinary Tract Infection (CAUTI)

The urinary tract is the most common site of HAI, accounting for more than 30 percent of infections reported by acute care hospitals.[11] Healthcare-associated urinary tract infections (UTIs) are commonly attributed to catheterization of the urinary tract. CAUTI can lead to such complications as cystitis, pyelonephritis, gram-negative bacteremia, prostatitis, epididymitis, and orchitis in males and, less commonly, endocarditis, vertebral osteomyelitis, septic arthritis, endophthalmitis, and meningitis in all patients. Complications associated with CAUTI cause discomfort to the patient, prolonged hospital stay, and increased cost and mortality. Each year, more than 13,000 deaths are associated with UTIs.[12] Prevention of CAUTIs is discussed in the CDC/HICPAC document, *Guideline for Prevention of Catheter-associated Urinary Tract Infections.* The NQF-endorsed CAUTI measure we proposed is currently collected by the NHSN as part of State-mandated reporting and surveillance requirements for hospitals. There are 3 States that require facilities to report to NHSN at least one month of CAUTI data.

Section 1886(b)(3)(B)(viii)(IX)(aa) of the Act requires that effective for payments beginning with FY 2013, each measure specified by the Secretary for inclusion in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless the exception set forth in section 1886(b)(3)(B)(viii)(IX)(bb) of the

[10] O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, *et al.,* Guidelines for the Prevention of Intravascular Catheter-Related Infections. MMWR 2002; 51 (No. RR–10:1–26).

[11] Klevens RM, Edward JR, et al., Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. Public Health Reports 2007; 122:160–166.

[12] Wong ES., Guideline for Prevention of Catheter-Associated Urinary Tract Infections. Infect Control 1981; 2:126–30.

Act applies. The NQF currently holds the contract under section 1890(a) of the Act, and the NQF has endorsed this CAUTI measure (NQF # 138). For this reason, we believe that this measure satisfies the endorsement requirement applicable to the Hospital IQR Program. This proposed measure is currently risk stratified, and therefore is consistent with section 1886(b)(3)(B)(viii)(VIII) of the Act. Risk stratification means that it is calculated using different categories of patients with varying risk of developing an infection. At the time of the FY 2012 IPPS/LTCH PPS proposed rule, this CAUTI measure (NQF # 138) was undergoing measure maintenance review by the NQF and we note that the review may result in changes to the specifications. We invited public comment on our proposal to adopt these two HAI measures into the Hospital IQR Program for the FY 2014 payment determination. We proposed that hospitals would begin submitting data on these measures beginning with events that occur on or after January 1, 2012. We also proposed that hospitals use the NHSN infrastructure and protocols, as well as the specifications (available at *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf*) to report the measures for Hospital IQR Program purposes. The proposed reporting mechanism for these HAI measures is discussed in greater detail in section IV.A.5.i. of the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25919 through 25920).

Comment: Many commenters supported the CAUTI measure and suggested that CMS monitor a CAUTI project initiative that is underway to test the effects of collecting data for both device days and patient days, each of which might have different implications for the urinary tract infection rate. Several commenters cautioned against using device days as the measure denominator because that might have the unintended consequence of artificially inflating the UTI rate.

Response: We thank the commenters for the suggestions. We will monitor this project as suggested by the commenter. Currently, we seek to adopt the measures targeted in the 2009 HHS Action Plan To Prevent HAIs. These measures include the proposed NQF-endorsed CAUTI measure and that measure is based on device days. We do not believe that reporting a measure by device days would have a negative effect on patient care or result in patient harm.

Comment: A commenter remarked that the measure might encourage hospitals to reduce the CAUTI incidence rate, but would not completely bring the rate down to zero. The commenter also noted that it would be difficult to diagnose every UTI at the time of admission without increasing the volume of potentially unnecessary screenings. The commenter believed that the pressure to remove catheters quickly in the ICU and post-surgery can have unintended consequences and complications. Several commenters stated that the CAUTI measure should have exclusions for patients considered to be high-risk to avoid unintended consequences (for example, removal of catheter too quickly). Commenters believed that this measure should also include a data capture point for catheter reinsertion to collect the rate of repeat instrumentation and infection risk for those with early catheter removal.

Response: We thank the commenters for these suggestions. As stated above, UTI is the leading cause of HAIs in the acute care setting, and significantly reducing UTIs is a component of the HHS Action Plan To Prevent HAIs, and we have proposed to use the metric that is listed in the Action Plan. We do not believe that the screening of catheterized patients according to the NQF-endorsed specifications for this measure will cause undue treatment or patient harm. To date, there are no published studies that we are aware of that recommend a urinary catheter be maintained in ICU and post-surgical patients. We also thank the commenters' suggestions for a catheter reinsertion measure. However, we are not aware of such NQF-endorsed measure. We are adopting the measure as currently specified in order to support the reduction efforts of the HHS Action Plan. However, we have forwarded these suggestions to the CDC.

Comment: A few commenters recommended that CMS delay the adoption of this proposed measure to FY 2015 or until: (1) The CDC has addressed the validation and implementation issues; (2) all hospitals have attested to the installation of fully functional EHR systems; (3) hospitals and States have had enough time to develop the proper infrastructure to report these data (only 3 States currently require hospitals to report these data); and (4) the measure is risk-adjusted based on the morbidity of the patient at the time of admission.

Response: We disagree with these recommendations. The measure is NQF-endorsed with appropriate risk-stratification as previously described. We have been working in collaboration with the CDC, and are assured that the measure is ready for implementation in the Hospital IQR Program beginning with January 1, 2012 discharges. The data are collected via the NHSN, and hospitals do not need a fully functional EHR system in order to submit data to the NHSN.

Comment: A commenter suggested that CMS retire the current claims-based Catheter-Associated Urinary Tract Infection HAC measure once the proposed CAUTI measure is adopted for the Hospital IQR Program.

Response: We agree that the claims-based CAUTI measure and the NHSN CAUTI measure may overlap. However, because the topic of HAIs is of great importance, and a large quantity of data for the NHSN version of the measure will not be available to CMS for some time, we will continue to utilize the claims-based measure until such time as the NHSN version is available to CMS. We will seek an appropriate time to retire the claims-based version of the measure, taking into account the needs of and impact on other programs, such as the Hospital VBP Program.

After consideration of the public comments we received, we are finalizing the CAUTI measure that we proposed to adopt for the FY 2014 payment determination.

(B) New Claims-Based Measure

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25896 through 25897), we proposed to add the following new claim-based measure to the Hospital IQR Program measure set for the FY 2014 payment determination: Medicare Spending per Beneficiary. The details of this measure are discussed below.

(i) Medicare Spending per Beneficiary Measure

Healthcare costs consume an ever-increasing amount of our Nation's resources, straining family, business, and government budgets. Healthcare costs take up a growing share of Federal and State budgets and imperil the governments' long-term fiscal outlooks. In the U.S., the sources of inefficiency that are leading to rising healthcare costs include payment systems that reward medical inputs rather than outcomes. Medicare is transforming from a system that rewards volume of service to one that rewards efficient, effective care and reduces delivery system fragmentation.

In order to further this transformation and help address the critical issue of health care costs, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25896 through 25897) we proposed to add a measure of Medicare spending per beneficiary to the Hospital IQR Program measure set for the FY 2014 payment determination. This proposed Medicare

spending per beneficiary measure addressing the cost of care is a type of measure that is not currently included in the Hospital IQR Program. We are not aware that the NQF or any other consensus organizations under section 1886(b)(3)(B)(viii)(IX) of the Act have currently endorsed any Medicare spending per beneficiary measures. We will give due consideration under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act to any Medicare spending per beneficiary measures that become endorsed in the future. It is important that the cost of care be explicitly measured so that, in conjunction with other quality measures included in the Hospital IQR Program, we can recognize hospitals that are involved in the provision of high quality care at lower cost.

We proposed that this Medicare spending per beneficiary measure would be calculated using claims data for hospital discharges occurring between May 15, 2012 and February 14, 2013. Therefore, the addition of this proposed measure would not increase the data submission burden on hospitals. We outline below the methodology that we proposed to use to calculate the measure.

- The Medicare Spending per Beneficiary Episode

As we stated in the proposed rule, in order to calculate the Medicare spending per beneficiary for each hospital, we believe that it is necessary to determine: (1) The timeframe, or length of the ''spending per beneficiary episode'' during which Medicare payments would be aggregated; (2) the types of Medicare payments to be aggregated over this timeframe; and (3) how to adjust or standardize these payments across hospitals (for example, risk adjustment).

- Length of the Medicare Spending per Beneficiary Episode

Encouraging delivery of coordinated care in an efficient manner is an important goal which can best be achieved through inclusion of Medicare payments made outside the timeframe of the hospital inpatient stay. We proposed to use an episode that runs from three days prior to an inpatient PPS hospital admission (the index admission) through 90 days post hospital discharge.

We also sought public comment on an alternative 30-day time period for the initial implementation of this measure that would be more consistent with the 30-day time period currently in use for some outcome measures.

We received numerous public comments on the proposed length of the Medicare spending per beneficiary episode.

Comment: The majority of commenters stated an episode spanning 90 days post-discharge was too long to represent factors which are within hospitals' control, and that a shorter period would focus on factors which are more directly influenced by the hospital. Commenters noted physician care and patient compliance with post-discharge instructions as examples of factors which are outside the hospital's control. Several commenters suggested a 30-day post-discharge period would be more appropriate. Several commenters noted that a 30-day post-discharge period would be consistent with the measures used in the Hospital Readmissions Reduction Program. One commenter noted that it would be consistent with the bundling pilot included in the Affordable Care Act. Many commenters suggested a 15-day post-discharge period, and a few suggested a 7- or 15-day post-discharge period. Three commenters suggested no more than 14 days, with one suggesting that this shorter period would simplify separation of episodes for complex patients.

Response: We are accepting the suggestions that we align the length of the spending per beneficiary episode with other agency initiatives, including the post-discharge period that applies to the readmission measures under the Hospital IQR Program and the one we are adopting in this final rule for the readmission measures we are finalizing for the Hospital Readmissions Reduction Program, for the initial implementation of this measure. We also believe that a shorter length will allow hospitals to gain experience with this measure while we consider whether it would be appropriate to propose to hold them accountable for coordinating services over a longer post-discharge period. Therefore, we are adopting a shorter length of the Medicare spending per beneficiary episode than we proposed for the Medicare spending per beneficiary measure to be included in the FY 2014 Hospital IQR Program. We also believe that a shorter Medicare spending per beneficiary episode will enable us to include a larger number of episodes in the measure calculation because admissions occurring more than 30 days after a discharge will now represent new index admissions, rather than having the Medicare payments associated with them attributed back to the first index admission. This will potentially allow more opportunity for hospitals to improve their performance on the measure.

We are finalizing a Medicare spending per beneficiary episode which spans from 3 days prior to hospital admission through 30 days post hospital discharge, for the initial implementation of this measure. Our intent is to revisit the episode length in future rulemaking as we gain more experience with this measure and as hospitals gain more experience in redesigning care processes and coordinating patient care in the post-hospital discharge period, and we will strongly consider lengthening the Medicare spending per beneficiary episode.

Comment: A few commenters suggested that a 90-day post-discharge period was not long enough. One commenter suggested that an episode of 1 year or more post-discharge would be required in order to realize savings achieved by selection of treatment alternatives which are more costly initially. Another commenter suggested that a minimum of 6 months would be necessary to recognize system-wide cost savings across all Part A and Part B payments and stated that a 90-day post-discharge period, if adopted, should only count inpatient hospital costs, in recognition that other provider types do not have similar incentives and that readmissions could likely be reduced over 90 days.

Response: We acknowledge that including a longer post-discharge period in the Medicare spending per beneficiary episode could recognize system-wide cost savings. However, we are going to implement a 30-day post-discharge period for the measure for the FY 2014 Hospital IQR Program for the reasons discussed above. We intend to revisit the episode length in the future in order to determine whether a longer Medicare spending per beneficiary post-discharge window would be appropriate for incentivizing greater efficiency, care coordination, and care transitions.

Comment: One commenter expressed strong support for the 90-day post-discharge period, noting that it encourages the teamwork and care coordination that is necessary to achieve the delivery of high quality, efficient healthcare.

Response: We agree that a 90-day episode would encourage teamwork and cooperation for the provision of quality care to Medicare beneficiaries. However, we are finalizing a 30-day post discharge window in order for hospitals to gain experience with the measure, and work toward redesign of care processes, while we consider whether it would be appropriate to propose to hold them accountable for coordinating services over a longer post-discharge period.

Comment: Several commenters requested clarification as to whether the spending per beneficiary measure was intended to measure general per-beneficiary spending or to measure the per-beneficiary spending of specific hospitals. These commenters suggested that a 90-day post discharge period was appropriate for inclusion in an episode to measure general per-beneficiary spending, but that if that spending was to be attributed to a specific hospital, then a shorter period, such as 7 or 15 days would be more appropriate.

Response: The intent of the Medicare spending per beneficiary measure is to measure hospital-specific Medicare spending per beneficiary, as compared to the median Medicare spending amount across all hospitals nationally. We believe that a comparison of individual hospitals' spending to hospital spending on a national level will best allow hospitals to recognize where opportunities for improved efficiencies exist. We do not believe that display of general per beneficiary spending would achieve this intent, because it would not indicate to hospitals how their individual Medicare spending per beneficiary amount compares to other hospitals.

After consideration of all public comments we received on the length of the Medicare spending per beneficiary episode, we are finalizing a Medicare spending per beneficiary episode, spanning from 3 days prior to hospitalization through 30-days post discharge. We are finalizing the policy that only discharges occurring within 30 days before the end of the performance period will be counted as index admissions for purposes of calculating episodes. We intend to revisit the length of the Medicare spending per beneficiary episode as we gain more experience with the use of this measure and as hospitals increasingly focus on working to redesign care processes and to coordinate with other providers of care, in the interest of providing the highest-quality, most efficient coordinated care possible to the beneficiaries they serve.

- Medicare Payments Included in the Spending per Beneficiary Episode

In order to calculate the Medicare spending per beneficiary, it is necessary to define the Medicare payments included in the spending per beneficiary episode. Subject to the adjustments described below, we proposed to include all Medicare Part A and Part B payments made for services provided to the beneficiary during the episode, including payments made by beneficiaries that we can determine using our claims data, such as Part B deductibles and coinsurance amounts. We believe that this comprehensive inclusion of Medicare Part A and Part B spending emphasizes the importance of care coordination in improving patient care. Encouraging delivery of coordinated care in an efficient manner over an extended time period is an important goal which can best be achieved through the inclusion of comprehensive Medicare Part A and Part B spending.

We also proposed that transfers, readmissions, and additional admissions that began during the post discharge period of an index admission would be included in the episode used for calculating the measure.

We proposed to exclude from the Medicare spending per beneficiary calculation episodes where at any time during the episode the beneficiary is not enrolled in both Medicare Part A and Medicare Part B, including if the beneficiary is enrolled in a Medicare Advantage plan at any time during the episode or becomes deceased. We also proposed to exclude any episodes where the beneficiary is covered by the Railroad Retirement Board, and where Medicare is a secondary payer. We also proposed to exclude episodes where the beneficiary is not enrolled in both Medicare Part A and Medicare Part B, for the 90 days prior to the episode, because we would not be able to capture all the data necessary for the severity of illness adjustment discussed later in this preamble. The rationale for exclusion of these episodes from the calculation of the Medicare spending per beneficiary is that we do not have full payment data to identify and standardize spending which would otherwise be attributable to these episodes.

We received numerous public comments on the payments proposed for inclusion in the Medicare spending per beneficiary measure.

Comment: Almost half of the commenters requested clarification of the proposed handling of transfer cases, and many requested clarification of the proposed handling of readmissions. One commenter requested clarification of the proposed handling of cases in which the beneficiary's primary insurance becomes Medicaid during the episode, due to exhaustion of Medicare Part A benefits.

Response: We proposed to include in the spending per beneficiary episode all Medicare Part A and Part B payments made for services provided to the beneficiary during the episode that we can determine using our claims data. Readmissions and transfers would have been attributed to the hospital at which the index hospitalization occurred as long as they occurred during the post-discharge window of the index admission. For example, Medicare payments for any of the following which happened during the hospital stay or the post-discharge window would have been included in the Medicare spending per beneficiary episode: A beneficiary was transferred from the subsection (d) hospital to another subsection (d) hospital for the purposes of receiving inpatient services; a beneficiary was transferred from the subsection (d) hospital to a post-acute care setting, such as a SNF, LTCH, or home; a beneficiary was readmitted to the same subsection (d) hospital; and/or the beneficiary was admitted to a different subsection (d) hospital. As noted above, we are finalizing a Medicare spending per beneficiary episode, spanning from 3 days prior to hospitalization through 30-days post discharge, in response to public comment.

Based on public comment, however, we have reconsidered the proposed handling of transfers from one subsection (d) hospital to another, as discussed below. We also note that, in response to public comment, we have reconsidered whether statistical outliers should be included in the Medicare spending per beneficiary amount, and we will exclude them, as discussed below. To clarify our proposal regarding beneficiaries whose primary insurance becomes Medicaid during the episode, due to exhaustion of Medicare Part A benefits, we will not include Medicaid payments made for services rendered to those beneficiaries during the episode, because this is a measure of Medicare spending per beneficiary, not Medicaid spending. We will include all Medicare Part A payments made before benefits are exhausted and all Medicare Part B payments made during the episode, consistent with our policy for inclusion of all Medicare Part A and Part B payments, with the exception of statistical outliers, as discussed below, in the calculation of hospitals' Medicare spending per beneficiary amounts in all cases. We intend to analyze the impact of including episodes in which beneficiaries' primary insurance changes to Medicaid in this measure and will consider refinements to this policy in the future. We will also include Medicare payments made for services rendered to beneficiaries who are eligible for both Medicare and Medicaid in the Medicare spending per beneficiary amount.

Comment: Several commenters stated that inclusion of Medicare payments for all Part A and Part B services occurring

during the post-discharge period would penalize hospitals for ensuring that patients receive necessary post-discharge follow-up care.

Response: We do not believe that inclusion of all Part A and Part B Medicare spending during the Medicare spending per beneficiary episode will penalize hospitals for ensuring that beneficiaries receive needed post-discharge care. The measure's purpose is to assess the amount of payments Medicare makes surrounding an inpatient hospital stay at a subsection (d) hospital, as compared to a national benchmark. We believe that hospitals which provide quality inpatient care and appropriate discharge planning and work with providers and suppliers on appropriate follow-up care will realize efficiencies and perform well on the measure, because the Medicare beneficiaries they serve will have a reduced need for excessive post-discharge services. We believe that including a 30-day post-discharge period, as compared to a shorter post-discharge period, such as 7 or 14 days, will further reduce the risk that hospitals might delay needed post-discharge care.

Comment: Six commenters expressed the opinion that readmissions should be excluded from the measure, and four of those commenters believed that the Affordable Care Act prohibits inclusion of readmissions in this measure. Two of those commenters noted that readmissions are addressed in other measures. One commenter suggested that readmissions should not be attributed to the hospital at which the index admission occurred, and another commenter suggested that readmissions should not be treated as index admissions, for the purposes of creating new, distinct episodes. Six commenters suggested that unrelated readmissions should be excluded, and one commenter suggested that unrelated readmissions should not be attributed to the hospital where the index hospitalization occurred.

Response: We disagree with the interpretation that the inclusion of Medicare spending for readmissions is contrary to the intent of the Affordable Care Act that the Hospital VBP Program may not include measures of readmissions. The Medicare spending per beneficiary measure is not a measure of readmission rates, but rather it is a measure of total Medicare spending per beneficiary, relative to a hospital stay. A Medicare spending per beneficiary measure is required by the Affordable Care Act to be included in the Hospital VBP Program, and therefore, in the Hospital IQR Program. We believe that the Medicare payments made for readmissions must be attributable to the index hospital stay, in order: to fully capture Medicare spending relative to a hospital stay; to encourage the provision of comprehensive inpatient care, discharge planning, and follow-up; and to strengthen incentives to reduce readmissions.

With regard to exclusion of unrelated readmissions, we acknowledge the commenters who suggested that unforeseen events which are unrelated to the hospital stay could occur. However, we note that the measure is consistent with all cause readmission measures and that determinations of the degree of relatedness of each subsequent hospital stay to an initial hospitalization could be subjective and prohibitively complex. We believe that inclusion of all readmissions in the episode attributable to the index hospital stay is the best way to encourage quality inpatient care, care coordination, and care transitions. We note that all hospitals will be subject to the same method of calculation of their Medicare spending per beneficiary amounts, as compared to the median Medicare spending per beneficiary amount across all hospitals, so we do not believe that inclusion of all readmissions will notably disadvantage any individual hospital. We also note that, in response to public comment, we will exclude statistical outliers from the calculation of the Medicare spending per beneficiary amount, as discussed below.

We agree with the commenter who suggested that a readmission occurring during a Medicare spending per beneficiary episode should not represent a new index hospitalization, for the purpose of generating a new Medicare spending per beneficiary episode. We also acknowledge the importance of aligning payment initiatives across CMS. Based on our consideration of the comments we received, we are shortening the proposed post-discharge period included in the Medicare spending per beneficiary episode to 30 days in this final rule, which is consistent with the Hospital Readmissions Reduction Program.

Comment: One commenter stated that no services for conditions unrelated to the index hospitalization should be attributed to the hospital at which that hospitalization occurred.

Response: We acknowledge the fact that health events which are unrelated to the hospital stay could occur and require treatment post-discharge, during the Medicare spending per beneficiary episode. However, we believe that determinations of the degree of relatedness of each subsequent hospital stay to an initial hospitalization would be subjective and prohibitively complex. In order to capture the potential efficiencies which hospitals might achieve through provision of comprehensive, high-quality inpatient care, discharge planning, and care transitions, we believe that it is necessary to capture all Part A and Part B Medicare payments which occur during the Medicare spending per beneficiary episode surrounding the hospital stay. We also note that all hospitals will be subject to the same method of calculation of their Medicare spending per beneficiary amounts, as compared to the median Medicare spending per beneficiary amount across all hospitals, so we do not believe that inclusion of all post-discharge follow-up care will notably disadvantage any individual hospital. Again, we note that, in response to public comment, we will exclude statistical outliers from the calculation of the Medicare spending per beneficiary amount, as discussed below.

Comment: Four commenters stated that transfer cases should be excluded, in order to avoid penalizing hospitals often called upon to receive transfers, because follow-up care may be received in a region outside the influence of the hospital receiving the transfer, and for consistency with the Hospital Readmissions Reduction Program.

Response: The comments regarding attribution of Medicare payments for hospitalizations resulting in acute to acute transfers, and specifically, the potential impact on hospitals who transfer patients to another subsection (d) hospital or those who receive large numbers of transfers, have persuaded us that that the attribution of Medicare payments for hospitalizations resulting in acute to acute transfers requires further consideration. At this time, we will exclude cases involving acute to acute transfers from being considered index admissions. A case involving an acute to acute transfer will therefore not generate a new Medicare spending per beneficiary episode. This means that neither the hospital which transfers a patient to another subsection (d) hospital, nor the receiving subsection (d) hospital will have an index admission attributed to them for an acute-to-acute transfer case. The rationale for exclusion of these acute to acute transfer cases as index admissions is that CMS wishes to perform further analysis of hospital impacts and explore potential unintended consequences of attribution of the Medicare spending per beneficiary episode relative to the cases

to either the transferring or the receiving hospital. Therefore, at this time we will exclude acute-to-acute transfer cases from being counted as index admissions, and these cases will not create a new Medicare spending per beneficiary episode. However, if a patient is readmitted during the post-discharge window and then transferred to another acute care hospital, we will attribute these costs to the hospital where the original index admission occurred.

For example, if a beneficiary is hospitalized in a subsection (d) hospital (Hospital A), then discharged from that hospital to home or to another subacute level of care, such as a SNF, then that hospitalization would represent an index admission, and the Medicare Part A and Part B payments (with the exception of statistical outliers) which are made during the Medicare spending per beneficiary episode spanning from 3 days prior to admission through 30 days post discharge (including payments to a subacute facility) would be included in the Medicare spending per beneficiary amount attributed to Hospital A. We would also include, in the total Part A and Part B payments attributed to hospital A, any Medicare payments made for the beneficiary's readmission to the same or a different subsection (d) hospital during the 30 day post-discharge window, including any case where during that subsequent hospitalization, the beneficiary is transferred to another subsection (d) hospital.

Comment: Several commenters offered their views regarding the importance of looking at Medicare spending concurrently with other measures of quality, and potential unintended consequences of a measure which is specific to Medicare spending. These commenters stated that the scope of the measure should not be Medicare spending alone, but that spending data should be tied to other measures. One commenter suggested that the measure should assess conformity toward an endorsed care process. Several commenters stated that an efficiency measure should measure cost concurrently with quality or outcomes measures, and three commenters stated that Medicare spending data could be misinterpreted in the absence of quality data.

One commenter stated that the measure should be implemented for FY 2014, but should be adjusted to tie in a new HCAHPS measure of care transitions. Three commenters stated that a spending-only measure could result in the unintended consequence of efforts to cut cost by limiting needed care, and another commenter suggested that it could result in a risk of hospital avoidance of complex patients. One commenter stated that the measure would penalize hospitals that work to keep all but the sickest patients out of the hospital. One commenter stated that the measure would result in physicians placing more patients into inpatient care, post hospital discharge, in order to assure proper care transitions, and one commenter questioned the measure's inclusion in a quality reporting program when it does not inherently measure quality.

Response: We agree with the commenters that it is useful to view a measure of Medicare spending per beneficiary in conjunction with other quality measures. We will provide explanatory language on *Hospital Compare,* in order to assist beneficiaries in interpreting the Medicare spending per beneficiary measure data. We also note that we developed this measure with the intent of including it in the Hospital VBP Program, where it will represent the first measure in a new Efficiency domain. Under that program, we will weight and combine the Efficiency domain with the other, individual domain scores, in order to calculate each hospital's Total Performance Score (TPS). This procedure for calculating a TPS ensures that spending per beneficiary makes up only a portion of the TPS, and that the remainder is based on hospitals' performance on the other measures.

We disagree that Medicare spending per beneficiary should be tied to a new HCAHPS measure. The Affordable Care Act requires the inclusion of efficiency measures, and specifically the inclusion of a measure of Medicare spending per beneficiary, in the Hospital VBP Program, which in turn, means that the measure must also be adopted for the Hospital IQR Program. We believe the intent of this statutory mandate is for Medicare spending to be independently measured.

The data for the Medicare spending per beneficiary measure will be posted on *Hospital Compare,* along with the other hospital quality measure data available on that Web site. We will also provide explanatory language, in order to assist beneficiaries in interpreting the Medicare spending per beneficiary measure data. We appreciate the commenters' concerns regarding unintended consequences of a spending per beneficiary measure, and will monitor for any utilization changes which may result from this measure.

We disagree that the measure will penalize hospitals that work to keep all but the sickest beneficiaries out of the hospital. We proposed to utilize the primary diagnoses and comorbidities from claims submitted during the 90-days preceding the Medicare spending per beneficiary episode to risk-adjust Medicare payments made for services provided to beneficiaries during an inpatient hospital stay and during the Medicare spending per beneficiary episode surrounding the stay. We believe that this will adequately account for hospital treatment of complex patients. We also disagree with the comment that the measure provides an incentive for increased discharges from hospitals to other inpatient settings. We believe that hospitals will have an incentive to coordinate care and discharge beneficiaries to the most appropriate setting, including utilizing less-costly outpatient levels of care for post-discharge care. With regard to inclusion of the Medicare spending per beneficiary in a quality reporting program, we disagree with the comment that it does not belong in the program. We believe that hospitals' provision of quality, coordinated care will result in more efficient and effective delivery of care for Medicare beneficiaries and provides an incentive to eliminate unnecessary services. Therefore, we believe that a measure of Medicare spending per beneficiary is a measure of quality.

Comment: Two commenters objected to the use of an episode in the Medicare spending per beneficiary measure because they believed that it did not meet the intent of the Affordable Care Act to measure spending per beneficiary.

Response: The Affordable Care Act requires that the Hospital VBP Program include measures of efficiency, including Medicare spending per beneficiary. As we expand the Hospital VBP Program Efficiency domain, we will consider adding additional measures of efficiency, which could include measures of internal hospital efficiencies, through future rulemaking.

Comment: One commenter suggested that spending for Medicare Advantage beneficiaries should be included in the measure, because non-managed care beneficiaries are costlier.

Response: We do not have evidence that managed care beneficiaries are less expensive. In order to minimize burden on hospitals, CMS has proposed the Medicare spending per beneficiary measure as a claims-based measure. Therefore, we cannot include spending for managed care beneficiaries in the measure calculation since we do not have fee-for-service claims for these patients. In order to fairly compare hospitals' spending, we have proposed

to exclude from the measure any episodes in which we do not have complete Medicare FFS claims data, such as those enrolled in Medicare Advantage plans. We will account for the complexities and resulting costs associated with caring for Medicare beneficiaries who have complex conditions by risk-adjusting for beneficiary age and severity of illness.

Comment: One commenter suggested that Medicare payments for drugs should be included, because expenditure on a new technology, for example, could offset future costs for drugs.

Response: We appreciate this comment and will take it into consideration in future rulemaking for the Medicare spending per beneficiary measure. At this time, we are able to include Part A and Part B payments, so payments for Part B drugs will be included in the Medicare spending per beneficiary amount. We will consider whether to propose to include Medicare payments made under the Medicare Part D drug payment system in the future.

Comment: Two commenters stated that a hospital cost efficiency measure should be limited to hospital resource use, such as resources used to treat HAIs and falls, or provision of appropriate lengths of stay.

Response: We disagree with these comments. The Affordable Care Act requires that the Hospital VBP Program include measures of efficiency, including Medicare spending per beneficiary. We do not believe that a measure of hospital resource use, rather than Medicare payments, as suggested by the commenters, would meet the intent of the law that we include a measure of Medicare spending per beneficiary. As we expand the Hospital VBP Program Efficiency domain, we will consider adding additional measures of efficiency, which could include measures of internal hospital efficiencies, through future rulemaking.

Comment: One commenter stated that CMS policies should not punish the most efficient states and that CMS should seek savings from providers and regions that use the highest levels of respurces to care for patients.

Response: We agree that efficient providers should not be penalized, and we believe they will be incentivized under this measure. We are finalizing our proposal to calculate hospitals' Medicare spending per beneficiary ratios as compared to the median spending across all hospitals; therefore, we believe that hospitals who demonstrate efficiencies in the provision of care for their patients will perform well on the measure, regardless of where the hospital is located.

Comment: Two commenters stated that there was no scientific or evidentiary support for the measure.

Response: We recognize that this Medicare spending per beneficiary measure is a new type of measure for the Hospital IQR and Hospital VBP Programs. A measure of Medicare spending per beneficiary is is mandated by the Affordable Care Act, so we developed a measure to capture Medicare payments made in an episode surrounding a hospital stay, in order to compare hospitals' individual spending to spending across all hospitals. We considered many factors in developing the measure and outlined in detail our methodology in the proposed rule. We believe that this measure will provide an incentive to hospitals to redesign care systems in order to better coordinate and provide high-quality, cost-efficient care to Medicare beneficiaries. As we gain more experience with the use of this new type measure for the Hospital IQR Program, we will continue to analyze and refine the measure as appropriate, based on that experience.

Comment: Several commenters recommended that the scope of Medicare payments included in the Medicare spending per beneficiary be narrowed. MedPAC suggested focus on a subset of episode costs associated with the stay, such as the stay itself and post acute care provided during a shortened post-discharge period. Two commenters suggested use of condition-specific measures to address costs associated with diagnoses such as acute myocardial infarction (AMI), heart failure (HF), or pneumonia. One commenter suggested that the measure should be better targeted, consistent with the Hospital Readmissions Reduction Program and the bundling pilot, and another commenter suggested that the measure should use criteria similar to those required for the bundling pilot. One commenter suggested that the measure be limited to inpatient hospital spending over 90 days, in an effort to reduce readmissions through care coordination, but with the recognition that other types of providers do not have the same incentives to reduce Medicare spending.

Response: We appreciate the commenters suggestion that the Medicare spending per beneficiary measure should be aligned with measures used in other Medicare payment incentive programs. We believe that inclusion of Medicare spending for all Part A and Part B services in the calculation of the hospital's Medicare spending per beneficiary amount aligns with the aim of reducing readmissions under the Hospital Readmissions Reduction Program. We also note that the bundling pilot is under development and we will seek to align the Hospital VBP Program with that program as it develops.

We appreciate the comments regarding the use of targeted or condition-specific measures in the interest of aligning with other CMS-initiatives. While the Affordable Care Act does not limit the Secretary to adopting only one efficiency measure, it does specify that the efficiency measures must include a measure of Medicare spending per beneficiary, not per condition. At this time, we believe that inclusion of Medicare spending related to hospital stays for all diagnoses is the best approach to enable hospitals identify where opportunities for improved coordination and efficiency exist, by measuring hospitals' individual Medicare spending per beneficiary amount, as compared to Medicare spending per beneficiary on a national basis. We will consider adding condition-specific measures to the Hospital IQR Program and to the Efficiency domain in the Hospital VBP Program in the future, through rulemaking. We have shortened the post-discharge period during which Medicare payments will be included in the calculation of the Medicare spending per beneficiary amount in order to more closely align the measure with the Hospital Readmissions Reduction Program and other related initiatives.

We disagree with the comment that only inpatient payments should be counted toward the Medicare spending per beneficiary amount. As we explained above, we do not believe that inclusion of inpatient hospital payments only will sufficiently address the need for care coordination and care transitions across all settings, in the interest of providing the highest-quality, most efficient care to Medicare beneficiaries.

Comment: Some commenters stated that CMS should collect more data regarding the impact of inclusion of spending for post-acute care services in the measure, due to variability in access across different geographic areas, prior to including spending for these services in the measure. Two commenters suggested that no post-discharge services should be included in the measure, and expressed their belief that post-discharge services are not within a hospital's control. A few commenters stated that the measure should address processes or outcomes which are under

hospital control, and that all Medicare spending within a 90-day post-discharge period is not under hospital control. A few commenters expressed that post-discharge payments depend more on physician management, beneficiary compliance with care planning, and community resources than they depend on care coordination by the hospital.

Response: We acknowledge the comments that geographic variability in access to post-acute care services exists. However, we believe that hospitals have a responsibility to encourage the highest-quality, most coordinated and efficient care for the beneficiaries they serve, regardless of their geographic location.

We disagree with commenters who stated that Medicare spending for post-discharge services is outside the hospitals' control, even within a 90-day post-discharge period. (As previously discussed, we are finalizing a 30-day post-discharge period for the initial implementation of this measure.) We believe that as hospitals focus on working to redesign care systems and to coordinate with other providers of care they can have a significant impact on the quality and efficiency of services provided to the Medicare beneficiaries they serve. As a result, we plan to revisit the issue of expanding the episode duration by lengthening the period of time post discharge in future rulemaking. We acknowledge that physician management, beneficiary compliance with post-discharge instructions, and availability of community resources contribute to Medicare spending after hospital discharge. However, we believe that hospitals have a significant influence on Medicare spending during the episode surrounding a hospitalization, through the provision of appropriate, high-quality care before and during inpatient hospitalization and through proper hospital discharge planning, care coordination, and care transitions. We believe that this measure will add an additional incentive for hospitals to apply this influence in ways that will promote the provision of the highest quality, most efficient care for hospitalized Medicare beneficiaries.

After consideration of all public comments we received on our proposals regarding which Medicare payments we will include in the Medicare spending per beneficiary episode, we are finalizing the inclusion of Medicare payments for all Part A and Part B services rendered to Medicare beneficiaries during the Medicare spending per beneficiary episode, with the exception of statistical outliers, in the Medicare spending per beneficiary amount, which we will attribute to the hospital at which the index admission occurred. We will exclude cases involving acute to acute transfers from being counted as index admissions. A case involving an acute to acute transfer will therefore not generate a new Medicare spending per beneficiary episode. This means that neither the hospital which transfers a patient to another subsection (d) hospital, nor the receiving subsection (d) hospital will have an index admission attributed to them for purposes of creating a Medicare spending per beneficiary episode. However, if a patient is readmitted during the post-discharge window and then transferred to another acute care hospital, we will attribute these costs to the hospital where the original index admission occurred.

We will attribute Medicare payments for acute to subacute transfers, such as discharges from a subsection (d) hospital to a SNF, IRF, or LTCH, to the index admission, as proposed.

- Adjusting the Medicare Payments Included in the Spending per Beneficiary Episode

Section 1886(o)(2)(B)(ii) of the Act requires that a Medicare spending per beneficiary measure adopted for the Hospital VBP Program be ''adjusted for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate.'' Consistent with these statutory requirements, we proposed to adjust the proposed Medicare spending per beneficiary measure for age and severity of illness. We proposed to adjust for severity of illness based on the hierarchical condition categories (HCCs) for the period 90 days prior to the episode and based on the MS–DRG during the index admission. Adding the MS–DRG to the use of the HCC improves the severity of illness adjustment and better standardizes the data, allowing for more valid comparisons of Medicare spending per beneficiary amounts across hospitals. Note that we would exclude episodes where the beneficiary is not enrolled in both Medicare Part A and Medicare Part B, for the 90 days prior to the episode because we would not be able to capture all the data necessary for the severity of illness adjustment.

We did not propose to adjust the Medicare spending per beneficiary for sex and race, consistent with our understanding of NQF's position strongly discouraging adjusting measures based on these factors.

In addition, we proposed to exclude geographic payment rate differences (for example, based on the wage index and geographic practice cost index) in order to standardize the spending per beneficiary. We did not propose to adjust for geographic differences in spending that are unrelated to geographic payment rate differences. However, we sought comment on whether there are geographic factors other than payment rate differences that should be considered in the spending per beneficiary measure. We also proposed to standardize spending by excluding the portion of IPPS payments resulting from the payment differentials caused by hospital-specific rates, IME, and DSH. We did not propose to exclude spending for hospitals that are paid Hospital-Specific Rates, rather we proposed to exclude the differential additional spending that results from the use of the hospital-specific rates. Making these adjustments allows for more valid comparisons of Medicare spending per beneficiary amounts across hospitals. For example, without adjusting for geographic payment rate differences, a hospital might have higher or lower spending per beneficiary amounts compared to other hospitals based on its wage index and not its performance.

Comment: The majority of commenters supported the proposal to adjust for beneficiary age and severity, as well as for geographic and hospital-specific payment differences. Many commenters suggested that payment standardization should also go further, to adjust for beneficiary demographic and socioeconomic factors, including sex, race, working status, disability status, and Medicaid eligibility.

Response: We appreciate the comments supporting the severity of illness and age adjustments proposed. We disagree with the comments that risk-adjustment for the Medicare spending per beneficiary measure should include further adjustment for socioeconomic factors. Consistent with NQF's position on not adjusting for potential demographic (sex or race) or socioeconomic factors, we believe that the best adjustment for a payment measure is based on the beneficiaries' underlying health status, not demographic or socioeconomic factors. We intend to further analyze the implications of risk-adjustment for additional factors; however at this time, we feel that for initial implementation, consistency with the NQF position is the best approach to risk-adjusting the Medicare spending per beneficiary measure. As we proposed, we will take into account the underlying health status and acuity levels for all patients before the episode in risk-adjusting

because these factors reflect the complexities these patients may present.

Comment: Three commenters suggested that physician services should be risk-adjusted, as well as the hospital services.

Response: We agree with these commenters. We intend to adjust total Medicare Part A and Part B payments for services received during hospitalization as well as for those received during the episode surrounding the hospital stay.

Comment: One commenter stated that there is little evidence that the use of the diagnosis categories used for hierarchical condition category (HCC) scores accurately quantify severity. Three commenters suggested that HCCs should look back further than 90 days, and one stated that they should factor in not only primary diagnoses, but also comorbities.

Response: First, we are clarifying that we are not applying the HCCs in a hierarchical manner, in which some diagnoses would in effect cancel others out. Rather, we are utilizing the diagnosis codes, both primary diagnoses and comorbidities, from the 90 days preceding the Medicare spending per beneficiary episode to risk adjust the Medicare Part A and Part B payments for services received during the Medicare spending per beneficiary episode. We believe that this approach is sensitive to all of the diagnoses most directly affecting the hospital stay. In addition, we will perform a risk adjustment for the beneficiary's age. We are open to future refinements to the risk-adjustment methodology, including potentially looking back further than 90 days for risk adjustment to the Medicare spending per beneficiary episode calculation, in future rulemaking.

Comment: Some commenters suggested that CMS should also exclude from the calculation of the Medicare spending per beneficiary measure any payment differences resulting from other policy or incentive payments, including payment differences for physician services rendered in Federally-qualified health centers (FQHC), rural health center (RHC), and Outpatient PPS (OPPS) settings, new technology add-ons, sole community providers, and Medicare-dependent hospitals, as well as incentives from the Hospital VBP Program, meaningful use under the EHR Incentive Program, PQRS, or other current or future incentive payment adjustments.

Response: We agree with the commenters that Medicare payment incentives, including the Hospital VBP Program, meaningful use under the EHR Incentive Program, PQRS, should not be factored in to the Medicare spending per beneficiary amount. They will not be included, in order to avoid penalizing high-quality and efficient hospitals. Likewise, we will exclude hospital-specific rates from the Medicare spending per beneficiary amount, so payment differentials for sole community hospitals and Medicare-dependent hospitals would not be included. We are excluding these payment adjustments from the calculation of the Medicare spending per beneficiary amount because we believe that they represent differences in the Medicare payments made to these types of hospitals, rather than differences resulting from hospitals' choices in provision of care or coordination of post-discharge services.

We disagree with the comment that the Medicare spending per beneficiary amount should be adjusted for the differential amount paid for physician services rendered in RHCs, FQHCs, or OPPS setting. First, we believe that adjustment for these ''site of services'' differences would undermine the ability of this measure to meaningfully capture differences in Medicare spending per beneficiary related to inpatient hospitalizations. Also, we do not believe that adjusting out such differences would result in a significant impact to any hospital's Medicare spending per beneficiary amount or their subsequent value-based incentive payment amount. Physician services make up only a portion of the Medicare payments which are summed to calculate a hospital's Medicare spending per beneficiary amount, so the differential impact of physician services on the measure would be further minimized. In addition we are moving to a 30-day post-discharge period, which we believe will further reduce the impact of any payment differentials resulting from the receipt of physician services in various settings.

We are therefore not adjusting out differential payments made for physician services based on site of service such as RHCs, FQHCs, or OPPS settings. We appreciate the comments on adjusting for the new-technology add-on payment. We intend to address this payment through future rulemaking, prior to the implementation of the FY 2014 Hospital VBP Program payment adjustment, and we will seek to align with other CMS incentive programs in addressing new technology add-on payments.

Comment: Four commenters stated that CMS should adjust for hospital case mix, in order to avoid penalizing hospitals serving specific populations, such as transplant centers or areas with high levels of chronic illness. One commenter suggested that CMS could adjust for underuse, or hospitals' failure to provide needed care, in order to avoid setting a benchmark reflecting underuse, and for overuse, or excessive use of healthcare services, due to poverty by stratifying the beneficiaries into cohorts reflecting disability status and Medicaid eligibility status.

Response: We disagree that an additional adjustment should be made to the Medicare spending per beneficiary amount to account for hospital case mix. As we proposed, we are applying a severity adjustment on a per-beneficiary basis, so hospitals serving large proportions of Medicare beneficiaries with complex conditions will not be disadvantaged.

We appreciate the comment regarding stratifying beneficiaries according to disability and Medicaid eligibility status, as a method to avoid setting benchmarks and making comparisons which are not appropriate for all populations. At this time, we are implementing this measure with adjustments for beneficiary age and severity of illness, which is consistent with NQF's position on not risk-adjusting potential race, socioeconomic, or gender disparities. Stratification of beneficiaries is an approach which we may consider in future refinements to the risk adjustment methodology, through future rulemaking. We intend to analyze the risk-adjustment methodology, as we gain experience with this measure, for potential changes to the methodology we are finalizing for the initial implementation.

Comment: Two commenters suggested that CMS convene a panel to determine the best risk-adjustment strategy. One commenter suggested that no further risk adjustment beyond what was proposed should be undertaken without further analysis.

Response: We agree that a panel may be a useful tool in achieving consensus on a strategy. We are open to suggestions for future refinements to the Medicare spending per beneficiary measure, for future fiscal years' payment adjustments. However, at this time convening a panel would delay implementation of this important measure emphasizing coordination and efficiency in the delivery of health care services to Medicare beneficiaries.

After considering all public comments we received on our proposals for adjusting the Medicare payments included in the Medicare spending per beneficiary episode, we are finalizing our proposal to adjust the Medicare spending per beneficiary amount for beneficiary age and severity of illness,

as calculated by applying the hierarchical condition categories which apply to the beneficiary during the 90 days preceding the Medicare spending per beneficiary episode. We will also adjust for geographic payment differences such as wage index and geographic practice cost differences. We will further adjust for Medicare payment differences resulting from hospital-specific rates, IME and DSH payments, as proposed. In addition, in response to public comment as discussed above, we will exclude statistical outliers and Medicare payment incentives, including the Hospital VBP Program, meaningful use under the EHR Incentive Program, and PQRS incentives, from the calculation of the Medicare spending per beneficiary amount.

- Calculating a Hospital's Medicare Spending per Beneficiary Amount

For each subsection (d) hospital participating in the Hospital IQR Program, we proposed to add together all the adjusted Medicare Part A and Part B payments, as defined above, with the exception of statistical outliers, included in all the Medicare spending per beneficiary episodes, as defined above, for that hospital. We would then divide this sum by the total number of Medicare spending per beneficiary episodes for that hospital. The resulting amount would constitute the hospital's Medicare spending per beneficiary amount for the period. The discharge period that we proposed to apply the proposed measure for the FY 2014 Hospital IQR Program is May 15, 2012 through February 14, 2013.

Comment: A few commenters questioned whether CMS has sufficient internal controls to ensure accurate calculation of a complex measure spanning time and service areas. Three commenters expressed concern that outliers would skew the calculation.

Response: We acknowledge that a Medicare spending per beneficiary measure is new to the Hospital IQR Program. However, we will have in place internal checks to ensure that calculations are complete and accurate. Hospitals wil also have an opportunity to review and correct any information made public about them, with respect to this measure. We agree with the commenters' suggestion that statistical outliers should be excluded, so that low-volume hospitals are not potentially disadvantaged by one or two anomalous high-cost outliers having a significant impact on their Medicare spending per beneficiary amount. We will exclude them from the calculation of individual hospitals' Medicare spending per beneficiary amount and from the calculation of the median Medicare spending per beneficiary amount across hospitals.

Comment: Nine commenters requested that the data used to calculate the Medicare spending per beneficiary amount be made public in time for public comment, and so that hospitals and advocacy groups could check CMS' calculations. One commenter suggested that a relative-value unit (RVU) system be used for simplicity and transparency in calculating standardized payment amounts.

Response: We appreciate the suggestion that an RVU system could be used for the calculation of a Medicare spending per beneficiary amount and may consider such an approach for future refinements through rulemaking. We understand the importance of hospital access to data used to calculate the Medicare spending per beneficiary measure. In response to these comments, we intend to make a public use file available, so that hospitals can determine their own historical Medicare spending per beneficiary amounts and identify the drivers of those amounts.

After considering the public comments received on our proposals for calculating a hospital's Medicare spending per beneficiary amount, we are finalizing calculation of a Medicare spending per beneficiary amount which is inclusive of most Medicare Part A and Part B payments made for services provided to Medicare beneficiaries during the Medicare spending per beneficiary episode. In addition to the exclusions we identified above, we will exclude statistical outliers from the calculation of individual hospitals Medicare spending per beneficiary amounts and from the calculation of the median Medicare spending per beneficiary amount across hospitals. We intend to make a public use file available so that hospitals may determine their own historical Medicare spending per beneficiary amounts.

- Calculating a Hospital's Medicare Spending per Beneficiary Ratio

We proposed to calculate a hospital's Medicare spending per beneficiary ratio as the hospital's Medicare spending per beneficiary amount divided by the median Medicare spending per beneficiary amount across all hospitals.

As noted above, we also proposed to adopt this proposed measure for the Hospital VBP Program FY 2014 measure set. The proposed method for scoring and incorporating this Medicare spending per beneficiary ratio into the hospital's TPS for the Hospital VBP Program, as part of a new Efficiency domain, is fully described in section IV.B.3.b.(3)(C) of the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25928) and the method we are adopting is fully described in section IV.B.3.b.(3)(C) of this final rule. The proposed weighting for the Efficiency domain is proposed in the FY 2012 OPPS/ASC proposed rule.

Comment: One commenter suggested that CMS use the mean, rather than the median spending per beneficiary amount for the purposes of calculating the Medicare spending per beneficiary ratio, stating that the mean is less sensitive to being skewed by outliers.

Response: We disagree with the comment that the median is more sensitive to being skewed by outliers than the mean is. That is why we proposed to use the median for the purposes of comparison and calculation of the Medicare spending per beneficiary ratio. Furthermore, we are finalizing our proposal to exclude outliers from the calculations.

Comment: MedPAC suggested that CMS should align incentives for hospitals and post-acute care providers to reduce readmissions, toward an end goal of alignment of incentives across the sectors, in order to improve the quality and reduce the cost of episodes of care, and to reduce the number of unnecessary inpatient episodes.

Response: We agree that alignment of incentives is an important goal. We will keep that goal in mind as we work to refine the Medicare spending per beneficiary measure. However, we acknowledge that this measure alone would not be a sufficient vehicle to fully accomplish that goal.

After consideration of the public comments received on our proposal for calculating a hospital's Medicare spending per beneficiary ratio, we are finalizing our proposal to calculate individual hospitals' Medicare spending per beneficiary ratios as their individual Medicare spending per beneficiary amount divided by the median Medicare spending per beneficiary amount across all hospitals.

In summary, after consideration of all public comments we received, we are finalizing the following policies related to the inclusion of the Medicare spending per beneficiary measure in the Hospital IQR Program.

We are finalizing a Medicare spending per beneficiary episode, spanning from three days prior to hospitalization through 30-days post discharge. We are finalizing the policy that only discharges occurring within 30 days before the end of the performance period will be counted as index admissions.

We are finalizing the inclusion of all Medicare Part A and Part B payments for services rendered to Medicare beneficiaries during the Medicare spending per beneficiary episode, with the exception of statistical outliers, in the Medicare spending per beneficiary amount, which we will attribute to the hospital at which the index admission occurred. We are finalizing that cases involving acute to acute transfers will be excluded from being counted as index admissions and that those cases will not generate new Medicare spending per beneficiary episodes.

We are finalizing our proposal to adjust the Medicare spending per beneficiary amount for beneficiary age and for severity of illness, as calculated by applying the hierarchical condition categories which apply to the beneficiary during the 90 days preceding the Medicare spending per beneficiary episode. We are finalizing our proposal to adjust for geographic payment differences such as wage index and geographic practice cost differences. We are finalizing our proposal to adjust for Medicare payment differences resulting from hospital-specific rates, IME and DSH payments, and to adjust for Medicare payment incentives, including Hospital VBP Program, meaningful use under the EHR Incentive Program, and PQRS.

We are finalizing calculation of a Medicare spending per beneficiary amount which is inclusive of all Medicare Part A and Part B payments made for services provided to Medicare beneficiaries during the Medicare spending per beneficiary episode surrounding an index hospitalization, excluding statistical outliers. We intend to make a public use file available so that hospitals may determine their own historical Medicare spending per beneficiary amount.

We are finalizing our proposal to calculate individual hospitals' Medicare spending per beneficiary ratios as their individual Medicare spending per beneficiary amount divided by the median Medicare spending per beneficiary amount across all hospitals.

We note that after consideration of the comments, this measure is also being finalized for inclusion in the Hospital VBP Program, and this discussion is located in section IV.B.3.b. of this final rule.

(C) New Web-Based Structural Measure

Structural measures assess the characteristics and capacity of the provider to deliver quality health care. In the FY 2009 IPPS final rule, we finalized the ''Participation in a Systematic Database Registry for Cardiac Surgery'' measure (73 FR 48609) for the FY 2010 payment determination. This measure does not require the hospital to actually participate in a cardiac surgery registry, instead, it only requires the hospital to report whether or not it participates in a cardiac surgery registry. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43871 and 43872), we adopted two more structural measures: Participation in a Systematic Clinical Database Registry for Stroke Care; and Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care under the Hospital IQR Program for the FY 2011 payment determination. Based on public comments, we collect these structural measures once annually.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25897 through 25898), we proposed to include a new structural measure, Participation in a Systematic Clinical Database Registry for General Surgery, in the Hospital IQR Program beginning with the FY 2014 payment determination. The Participation in a Systematic Clinical Database Registry for General Surgery measure would require each hospital that participates in Hospital IQR Program to indicate whether it is participating in a Systematic Clinical Database Registry for General Surgery and, if so, to identify the registry. This measure, like two of the previously adopted structural measures on registry participation (Participation in a Systematic Clinical Database Registry for Stroke Care; and Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care), is an application of an NQF-endorsed measure (NQF # 0493) ''Participation by a physician or other clinician in a systematic clinical database registry that includes consensus endorsed quality measures'' to the inpatient facility.

We recognize that the NQF has endorsed this measure for the physician/clinician setting, but believe that this measure is highly relevant to the hospital setting, in that participation in a systematic clinical database registry for various topics is quite common in hospitals. Therefore, we previously adopted the Stroke and Nursing Sensitive Care registry participation measures as applications of the measure appropriate to the hospital inpatient setting. We reviewed the NQF's consensus endorsed measures, as well as measures endorsed or adopted by other organizations, and were unable to identify any other measures specifically for participation in a systematic clinical database registry for general surgery that have been endorsed for the hospital inpatient setting. Having given due consideration to other measures that have been endorsed or adopted by a consensus entity, we proposed to adopt an application of this non-NQF endorsed measure under the Secretary's authority to select non-NQF endorsed measures where such measures do not exist for a specified topic or medical topic. We proposed to adopt the measure under the exception authority provided in section 1886(b)(3)(B)(IX)(bb) of the Act. Additionally, we believe that, for the same reasons, the previously adopted structural measures for Stroke and Nursing Sensitive Care registries also meet the requirements under this authority and proposed to continue collecting them on that basis.

We proposed that annual data submission for this proposed structural measure via a Web-based collection tool would occur between April 1, 2013 and May 15, 2013 with respect to the time period January 1, 2012, through December 31, 2012. This collection period and time period were included in a correction notice to the FY 2012 IPPS/LTCH proposed rule published at (76 FR 34633).

We believe that participation in a registry provides hospitals with valuable ongoing quality improvement information and demonstrates a commitment to improve. Many registries also collect outcome data and provide feedback to hospitals about their performance. We invited public comment on this proposal to include this structural measure for the FY 2014 payment determination.

Comment: Some commenters did not support the adoption of the proposed structural measure because they believed that the measure is neither tightly linked to improving the quality of patient care, nor is it NQF-endorsed or adopted by the HQA.

Response: This measure is an application of an NQF-endorsed measure for the hospital inpatient setting. We believe that structural measures are backbones to quality care as they assess whether infrastructure or conditions conducive to providing high quality care are present.

Comment: Some commenters did not support the adoption of this structural measure because they believed that registry participation might create a false assumption among beneficiaries that the quality of a hospital can be judged by its participation or non-participation in the registry. The commenters also objected because they felt they would be required to participate in a registry and incur fees, and believed that registry participation should be voluntary. Furthermore, the

commenters stated that the addition of another registry measure is not meaningful given CMS' goal of establishing an EHR-based quality data reporting program by 2015.

Response: We understand the commenters' concerns. We want to clarify that the structural registry measure that we are finalizing does not require participation in any registry. To meet the reporting requirements for the structural measure, hospitals only have to answer yes or no to a question about whether they participate in a systematic clinical database registry for general surgery, and if so to indicate the registry. We do not believe adoption of a structural measure is incompatible with our goal to switch to EHR-based reporting by 2015, because many registries accept data from EHRs. After consideration of the public comments received, we are finalizing the proposed structural measure for FY 2014 payment determination.

In summary, after consideration of the public comments received, we are finalizing the retirement of 4 measures from the FY 2014 measure set that was finalized in the FY 2011 IPPS/LTCH PPS final rule, suspending collection for 4 measures beginning with January 1, 2012 discharges, and adding 3 new measures to the measure set for the FY 2014 payment determination: 1 HAI measure (CAUTI) collected through the NHSN, 1 claims-based measure (Medicare Spending Per Beneficiary), and 1 structural measure (Participation in a Systematic Clinical Database Registry for General Surgery). As a result, there will be a total of 59 measures in the FY 2014 Hospital IQR measure set, but we will only be collecting data on 55 of those measures for purposes of the FY 2014 payment determination. The 59 measures are listed below, and the 4 measures for which we will not be collecting data are designated with the word ''SUSPENDED.''

Topic	Hospital IQR program measures for FY 2014 payment determination reflecting retirement of 4 measures, suspension of data collection for 4 measures and adoption of 3 new measures
Acute Myocardial Infarction (AMI)	• AMI–1 Aspirin at arrival [SUSPENDED]. • AMI–2 Aspirin prescribed at discharge. • AMI–3 ACEI/ARB for left ventricular systolic dysfunction [SUSPENDED]. • AMI–5 Beta-blocker prescribed at discharge [SUSPENDED]. • AMI–7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival. • AMI–8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI). • AMI–10 Statin Prescribed at Discharge.
Heart Failure (HF)	• 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.
Pneumonia (PN)	• 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).	• 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–6 Appropriate Hair Removal [SUSPENDED]. • 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 INF—VTE-1: Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered. • 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	• HCAHPS survey.
Readmission Measure (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.
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. • Complication/patient safety for selected indicators (composite). • Mortality for selected medical conditions (composite).
AHRQ PSI and Nursing Sensitive Care.	• PSI 04 Death among surgical in patients with serious treatable complications.
Structural measures	• 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	• Central Line Associated Bloodstream Infection. • Surgical Site Infection.* • Catheter-Associated Urinary Tract Infection.**

Topic	Hospital IQR program measures for FY 2014 payment determination reflecting retirement of 4 measures, suspension of data collection for 4 measures and adoption of 3 new measures
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.
Emergency Department Throughput	• 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 Measures.	• Immunization for Influenza.*
	• Immunization for Pneumonia.*
Cost Efficiency	• Medicare Spending per Beneficiary.**

* Measures finalized in the FY 2011 IPPS/LTCH PPS final rule for the FY 2014 payment determination.
** Additional measures adopted in this final rule for FY 2014 payment determination.

c. Hospital IQR Program Quality Measures for the FY 2015 Payment Determination

(1) Retention of FY 2014 Payment Determination Measures for the FY 2015 Payment Determination

We generally retain the Hospital IQR Program measures from one year to the next. Consistent with this approach, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25901), we proposed to retain all of the proposed measures for the FY 2014 payment determination, if finalized, for the FY 2015 payment determination.

We did not receive any comments related to this proposal and are, therefore, finalizing it.

(2) New Hospital IQR Program Measures for the FY 2015 Payment Determination

(A) New CDC/NHSN–Based Healthcare-Associated Infection (HAI) Measures for the 2015 Payment Determination

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25901 through 25903), for the FY 2015 payment determination, we proposed to adopt three additional HAI measures that are currently collected by CDC via the NHSN. These measures are: (1) Methicillin-resistant Staphylococcus Aureus (MRSA) Bacteremia measure; (2) Clostridium *difficile* (C. *difficile*) standardized infection ratio (SIR); and (3) Healthcare Personnel (HCP) Influenza Vaccination and the specifications for these measures are available at *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.* Like the CLIP and the CAUTI measures that we proposed for the FY 2014 payment determination, all three proposed HAI measures are high priority HAI measures listed in the HHS Action Plan to Prevent HAIs and were listed in previous rulemaking as possible quality measures for future payment determinations.

Our review indicated that there are no measures for MRSA or C. *difficile* SIR that have been endorsed by the NQF or another consensus entity for the hospital inpatient setting. Therefore, we proposed to adopt these non-NQF-endorsed measures under the Secretary's authority to select non-NQF endorsed measures where such measures do not exist for a specified topic or medical topic. We proposed to adopt these two CDC-developed measures (MRSA and C. *difficile* SIR) under the exception authority provided in section 1886 (b)(3)(B)(IX)(bb) of the Act.

The HCP Influenza Vaccination measure is NQF-endorsed (NQF #0431) for the hospital setting. Therefore, this measure meets the requirement for measure selection under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act.

The proposed reporting mechanism for these proposed HAI measures is discussed in greater detail in section IV.A.5.i. of the FY 2012 IPPS/LTCH PPS proposed rule. We invited public comment on these proposed HAI measures.

Comment: One commenter applauded CMS's proposed use of the measure exception authority under section 1886(b)(3)(B)(IX)(bb) of the Act to adopt the CDC-developed, non-NQF-endorsed MRSA and C. *difficile* SIR measures in the interest of public safety. The commenter believed that CMS's proposal has met Congressional intent and takes into account the statutory requirements that govern the Hospital VBP Program, which mandate that measures be selected for that program on HAIs, as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent HAIs.

Response: We appreciate the commenter's recognition of our efforts to adopt measures for the Hospital IQR Program to protect patient safety while fulfilling statutory mandates and promoting HHS initiatives.

Comment: A commenter believed that the three proposed HAI measures for the FY 2015 payment determination need further refinement before they can be included in the Hospital IQR Program.

Response: We thank the commenter for the comment. We will continue to collaborate with CDC to assure the specifications for the three proposed HAI measures are complete before the data collection period begins.

Comment: Some commenters did not support the proposed MRSA and C. *difficile* SIR HAI measures because they are not NQF-endorsed.

Response: Given the high priority of the MRSA and C. *difficile* SIR measures in the HHS Action Plan to Prevent HAIs, we proposed to implement these two measures to advance the goals of this initiative, despite of the lack of endorsement for the measures. As stated previously, we were unable to identify any other measures specifically for MRSA and C. *Difficile* SIR that have been NQF-endorsed for the hospital inpatient setting. We found no other measures that have been endorsed or adopted by a consensus entity. Therefore, we proposed to adopt these two non NQF-endorsed measures under the Secretary's exception authority set out in section 1886(b)(3)(B)(IX)(bb) of the Act to select non-NQF endorsed

measures where such measures do not exist for a specified area or medical topic. We have chosen to leverage the existing NHSN reporting system to collect HAI measures because we have already established a mechanism for reporting to the NHSN and it reduces potential hospital burden since many hospitals currently use the system.

(1) Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia Measure

There are different types of staphylococcus aureus bacteria, commonly called ''staph.'' Staph bacteria are normally found on the skin or in the nose. The bacteria are generally harmless unless they enter the body through a cut or other wound, and even then they usually cause only minor skin problems in healthy people. MRSA infection is caused by a strain of staph bacteria that has become resistant to the antibiotics commonly used to treat ordinary staph infections. Older adults with weakened immune systems and patients in hospital or nursing home settings are most vulnerable to MRSA infections. Health care-associated MRSA infections typically are associated with invasive procedures or devices, such as surgeries, intravenous tubing, urinary catheters, or artificial joints. MRSA infections account for about 60 percent of skin infections seen in United States emergency departments and invasive MRSA infections may cause about 18,000 deaths during a hospital stay a year.[13] Currently, there are 6 States that require facilities to report MRSA information to NHSN. As stated above, we were unable to identify any other measures specifically for MRSA that have been endorsed by the NQF for the hospital inpatient setting. We found no other measures that have been endorsed or adopted by a consensus entity. Therefore, we proposed to adopt this non-NQF-endorsed and CDC-developed measure under the Secretary's authority to select non-NQF-endorsed measures where such measures do not exist for a specified area or medical topic, under the exception authority provided in section 1886(b)(3)(B)(IX)(bb) of the Act. The proposed reporting mechanism for the MRSA measure is discussed in greater detail in section IV.A.5.i. of the FY 2012 IPPS/LTCH PPS proposed rule. We invited public comment on this proposed HAI measure.

Comment: A commenter pointed out that the MRSA measure poses particular issues because it requires linkages between laboratory data with admission-discharge-transfer systems. The commenter indicated that hospitals using this measure must manually enter the data. Therefore, the commenter recommended delaying the adoption of this measure until there is adequate vendor support for hospitals to manage the demands of reporting NHSN measures.

Response: Like C. *difficile* laboratory identified events, MRSA bacteremia event data are a combination of laboratory results and admission/discharge/transfer data. As with C. *difficile* laboratory event reporting, these two data types are often available electronically, and CDC expects that hospitals will increasingly use electronic data sources to report MRSA event data.

According to CDC, users can enter the required LabID Event data either manually or electronically. Capacity to electronically link admission/discharge/transfer and laboratory results data is not a prerequisite for reporting LabID event data to NHSN, but that capacity is a way to significantly improve efficiency and economy of reporting. CDC is already working with a number of vendors who are submitting LabID data via the CDC Clinical Document Architecture (CDA) import function and that number continues to grow. In addition, the monthly patient day and admission counts for an entire facility are often regularly tabulated for the facility for other administrative uses and so is more likely to be readily available compared to location specific monthly counts, which often require separate efforts to be tabulated within the facility's data system.

The denominator and laboratory data demands that are required for C. *Difficile* and MRSA Bacteremia have proven to be manageable among facilities who are already reporting at the facility-wide inpatient level in the States who have mandated such reporting. Facilities that do not use vendor CDA reporting, may still receive helpful lab printouts and reports to assist with identification of results that meet criteria for LabID Event reporting. The LabID form is short and requires only a limited number of variables, and the number of C. *difficile* and MRSA blood tests identified using the 14-day rule has shown to be within reasonable and manageable limits for currently participating facilities. If such numbers are very high for an entire facility, this may indicate the need for this important monitoring and surveillance to help guide appropriate facility infection control response.

Comment: A commenter recommended that CMS allow hospitals to select two most applicable patient care units for purposes of reporting data on this proposed measure. The selected units should initially report a year of baseline data, followed by reporting data to CDC for no more than 6 months each year.

Response: The MRSA bacteremia measure that we proposed and are finalizing in this final rule applies to patients hospital-wide, which is consistent with how the measure is presented in the HHS Action Plan to Prevent HAIs. We thank the commenter for the recommendation to allow hospitals to select two most applicable patient care units to report data on. However, allowing hospitals to choose two units could possibly skew the data and make it impossible to compare performance among hospitals. We found that monitoring at the location level and allowing facilities to choose their specific locations has not provided enough substantial data for meaningful nationwide comparative rates. This type of reporting was attempted in the CMS 9th SOW and showed that facilities tended to not choose locations with the highest rates and in need of further prevention efforts and also did not provide enough numbers by location type for reliable benchmarked, risk-adjusted rates.

After consideration of the public comments we received, we are finalizing the MRSA measure for the FY 2015 payment determination.

(2) C. *difficile* SIR Measure

Clostridium *difficile* (C. *difficile*) is a bacterium that can cause symptoms ranging from diarrhea, pseudo-membranous colitis, and toxic megacolon to life-threatening sepsis and even death. Illness from C. *difficile* most commonly affects older adults in hospitals or in long term care facilities where germs spread easily, antibiotic use is common and people are especially vulnerable to infection. Illness from C. *difficile* typically occurs after use of antibiotic medications. C. *difficile* spreads mainly on hands from person to person, but also on commonly touched services such as cart handles, bedrails, bedside tables, toilets, sinks, stethoscopes, thermometers, and telephones.

In recent years, C. *difficile* infections have become more frequent, more severe and more difficult to treat. Each year, tens of thousands of people in the United States get sick from C. *difficile,* including some otherwise healthy people who are not hospitalized or taking antibiotics. Healthcare providers

[13] Catherine Liu, Arnold Bayer, et al., Clinical practice Guidelines by the for the treatment of Methicillin-Resistant Staphylococcus Aureus Infections in Adult and Children. Infectious Disease Society of America 2011; 52:e18

have become more aware of the C. *difficile* infection and therefore, more testing is being done for symptomatic patients. The C. *difficile* pathogens may require specialized monitoring to evaluate if intensified infection control efforts are required to reduce the occurrence of these organisms and related infections. Currently, there are 3 States that require facilities to report C. *difficile* data to NHSN. Our goal for this proposed C. *difficile* SIR measure is to provide a common mechanism (CDC/NHSN) for all hospitals including hospitals participating in the Hospital IQR Program to report and analyze these data in order to inform infection control staff of the impact of targeted prevention efforts. The NHSN is listed in the HHS Action Plan to Prevent HAIs as the data source for HAI measures.

Comment: Some commenters believed that the calculation of C. *difficile* SIRs will be challenging because hospitals use testing mechanisms with differing sensitivity to identify the presence of C. *difficile.* These commenters were concerned that the resulted difference in C. *difficile* SIR measurement may unfairly portray hospitals that use the more sensitive testing technology as having more C. *difficile* cases. A commenter pointed out that the C. *difficile* SIR measure poses particular issues because it requires linkages between laboratory data with admission-discharge-transfer systems. The commenter noted that currently, hospitals using this measure must manually enter the data. Therefore, the commenter recommended delaying the proposed adoption of this measure until there is adequate vendor support for hospitals to electronically interface with the NHSN for reporting.

Response: CDC acknowledged that differences in the sensitivity of C. difficile laboratory testing methods could make a difference in the C. difficile event data that hospitals report. CDC is currently evaluating the impact and possible implications for C. difficile reporting through NHSN. C. difficile laboratory event data is a combination of laboratory results and admission/discharge/transfer data. These two data types are often available electronically, and CDC expects that hospitals will increasingly use electronic data sources to report C. difficile event data. However, EHRs are not the only means of capturing such information. The same data can be abstracted from hospital reports and entered manually into NHSN. Therefore, there is not a dependence on electronic data capture, but there is an important opportunity to use electronic means to report, and waiting until widespread EHR adoption would delay progress that could be made on these HAIs. Like MRSA Bacteremia, C. difficile facility-wide Lab-ID event reporting will be risk-adjusted by hospital type, teaching and med affiliation, and bed size. In addition, NHSN has added a question on the required annual facility survey beginning with 2010 data that asks about the type of testing the lab conducts for C. difficile and this information will be used for additional risk-adjustment along with review of usability of admission on prevalence.

Comment: One commenter requested clarification that the measure is only applicable to high-risk units and not hospital-wide.

Response: The CDC measure of C. difficile listed in the HHS Action Plan to Prevent HAIs calls for hospital-wide measurement of C. difficile events. Because the risk of C. difficile extends throughout the hospital, the measure applies to all hospital C. difficile events, and this is part of the specifications for this measure.

After consideration of the public comments we received, we are finalizing this measure for the FY 2015 payment determination. Data collection will begin with January 1, 2013 infection events.

(3) Healthcare Personnel (HCP) Influenza Vaccination (NQF # 0431)

For the FY 2015 payment determination, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25902 through 25903), we proposed to adopt one additional HAI measure that is currently collected by CDC via the NHSN: Healthcare Personnel (HCP) Influenza Vaccination (NQF # 0431). This measure assesses the percentage of HCP employed at the facility that received a prophylactic vaccination for influenza. This measure is NQF-endorsed, and therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act.

Rates of serious illness and death resulting from influenza and its complications are increased in high-risk populations such as persons over 50 years or under four years of age, and persons of any age who have underlying conditions that put them at an increased risk. HCP can acquire influenza from patients and can transmit influenza to patients and other HCP. Many HCP provide care for, or are in frequent contact with, patients with influenza or patients at high risk for complications of influenza. The involvement of HCP in influenza transmission has been a long-standing concern.[14 15 16]

Vaccination is an effective preventive measure against influenza, and can prevent many illnesses, deaths, and losses in productivity.[17] HCP are considered a high priority for expanding influenza vaccine use. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients and reduce disease burden and healthcare costs. Results of several studies indicate that higher vaccination coverage among HCP is associated with lower incidence of nosocomial influenza.[18 19 20] Such findings have led some to call for mandatory influenza vaccination of HCP.[21 22 23 24 25]

Until recently, vaccination coverage among HCP has been well below the national Healthy People 2010 target of

[14] Maltezou HC, Drancourt M., Nosocomial influenza in children. Journal of Hospital Infection 2003; 55:83–91.

[15] Hurley JC, Flockhart S., An influenza outbreak in a regional residential facility. Journal of Infection Prevention 2010; 11:58–61.

[16] Salgado CD, Farr BM, Hall KK, Hayden FG., Influenza in the acute hospital setting. The Lancet Infectious Diseases 2002; 2:145–155.

[17] Wilde JA, McMillan JA, Serwint J, Butta J, O'Riordan MA, Steinhoff MC., Effectiveness of influenza vaccine in health care professionals: a randomized trial. The Journal of the American Medical Association 1999; 281:908–913.

[18] Salgado CD, Giannetta ET, Hayden FG, Farr BM., Preventing influenza by improving the vaccine acceptance rate of clinicians. Infection Control and Hospital Epidemiology 2004; 25: 923–928.

[19] Potter J, Stott DJ, Roberts MA, et al., Influenza vaccination of health-care workers in long-term-care hospitals reduces the mortality of elderly patients. Journal of Infectious Diseases 1997; 175:1–6.

[20] Hayward AC, Harling R, Wetten S, et al., Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. British Medical Journal 2006; 333:1241–1246.

[21] Talbot TR, Bradley SF, Cosgrove SE, et al., SHEA position paper: Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. Infection Control and Hospital Epidemiology 2005; 26:882–890

[22] American College of Physicians (ACP), ACP policy on influenza vaccination of health care workers. *http://www.acponline.org/running_practice/quality_improvement/projects/adult_immunization/flu_hcw.pdf*

[23] Greene LR, Cain TA, Dolan SA et al., APIC position paper: influenza immunization of healthcare personnel. Association of Professionals in Infection Control (APIC). November 2008. *http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Influenza/APIC_Position_Paper_Influenza_11_7_08final_revised.pdf*

[24] National Patient Safety Foundation (NPSF), Mandatory flu vaccinations for healthcare workers. Press Release, November 18, 2009. *http://www.npsf.org/pr/pressrel/2009–11-18.php*

[25] Infectious Diseases Society of America (IDSA), IDSA policy on mandatory immunization of health care workers against seasonal and 2009 H1N1 influenza. Infectious Diseases Society of America (IDSA). September 30, 2009. *http://www.idsociety.org/HCWimmunization/*

60 percent,[26] but preliminary data suggest 62 percent of HCP reported receiving seasonal influenza vaccine in 2009–2010.[27] Only 37 percent reported receiving the 2009 pandemic A/H1N1 vaccine.[28]

HCP refers to all personnel working in healthcare settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air.[29] HCP may include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (for example, clerical, dietary, house-keeping, laundry, security, maintenance, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients. Settings in which HCP may work include, but are not limited to, acute care hospitals, long-term care facilities, skilled nursing facilities, rehabilitation centers, physicians' offices, urgent care centers, outpatient clinics, home health agencies, and emergency medical services.

Currently, four States have ''offer'' laws for influenza vaccination of HCP, meaning that vaccine must be offered to HCP by healthcare facilities; and three States (Alabama, California, and New Hampshire) have ''ensure'' laws for influenza vaccination of HCP, meaning that vaccination of non-immune HCP is mandatory in the absence of a specified exemption or refusal; and, additionally, numerous hospitals and other healthcare facilities have established policies requiring mandatory influenza vaccination of their HCP.[30]

Currently, no State requires that hospitals report this measure to NHSN. However, approximately 13 hospitals (including long term acute care and rehabilitation), outpatient hemodialysis centers, long term care facilities, and ambulatory surgical centers are currently reporting HCP immunization data to NHSN. In September 2009, CDC released the Healthcare Personnel Safety (HPS) Component of NHSN, which complements Patient Safety and Biovigilance components available in NHSN. The HPS Component replaced CDC's National Surveillance System for Health Care Workers (NaSH) and is comprised of two modules: the Blood/Body Fluid Exposure Module and the Influenza Vaccination and Management and Exposure Module.[31] Currently, participation in either module is voluntary. The current Influenza Vaccination and Management and Exposure Module may soon offer options for healthcare facilities to submit vaccination summary data. NHSN plans to partner with vendor-based surveillance systems to permit periodic data extractions into NHSN.

The modules feature basic, custom, and advanced analysis capabilities available in real-time, which allow individual healthcare facilities to compile and analyze their own data, as well as benchmark these results to aggregate NHSN estimates. The HPS Component can assist participating facilities in developing surveillance and analysis capabilities to permit the timely recognition of HCP safety problems and prompt interventions with appropriate measures. Influenza vaccination data submitted to CDC will ultimately capture regional trends on the yearly uptake of the vaccine, prophylaxis and treatment for healthcare personnel, as well as the elements within yearly influenza campaigns that succeed or require improvement. At the State and national levels, the HPS Component will aid in monitoring rates and trends.

We proposed to adopt the Healthcare Provider Influenza Vaccination measure that is currently collected by the CDC via the NHSN because of its importance in preventing influenza not only among healthcare workers but also among the patients that they attend. As stated earlier, this measure assesses the percent of Healthcare Personnel employed at the facility that received a prophylactic vaccination for influenza. Detailed specifications for the proposed measure are available at: *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.* As we also stated above, this measure is NQF-endorsed for the hospital setting. The proposed reporting mechanism for this proposed HAI measure is discussed in greater detail in section IV.A.5.i. of the FY 2012 IPPS/LTCH PPS proposed rule. We invited public comment on this proposed HAI measure.

Comment: Many commenters fully supported the proposed measure and stated that the measure will promote efforts in improving hospitals influenza vaccination rates and patient safety. Some commenters urged CMS to adopt this measure for the FY 2014 payment determination. Commenters recommended additional measures for other vaccines that prevent highly communicable diseases, such as pertussis, and diseases such as hepatitis B. A commenter strongly supported the adoption of this measure for the Hospital VBP Program. Finally, a commenter recommended that CMS adopt an adult immunization composite measure that is endorsed by NQF.

Response: We thank the commenters for their recognition of the significance of this measure and for their strong support of the measure. Because the measure is scheduled to undergo NQF maintenance, we proposed to begin collection of the measure for the Hospital IQR Program in 2013 (FY 2015 payment determination) rather than 2012 (FY 2014 payment determination) as suggested by the commenter in order to ensure that necessary revisions to the specifications are in place before the start of collection. We will consider the commenters' suggestions for additional measure topics as we select future measures.

Comment: Many commenters supported the public reporting of this proposed measure. However, a commenter was concerned that the collection of data via NHSN is redundant and labor intensive because the current specifications of the NHSN system require hospitals to submit detailed data on every employee, rather than aggregated data on vaccination rates. Some commenters believed that most hospitals already have a database to track employee vaccination status. The commenters recommended that CMS either identify an alternative NQF-endorsed measure or postpone the

[26] Walker FJ, Singleton JA, Lu P, Wooten KG, Strikas RA., Influenza vaccination of healthcare workers in the United States, 1989–2002. Infection Control and Hospital Epidemiology 2006; 27:257–265.

[27] *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e209a1.htm* Influenza Vaccination of Health-Care Personnel.

Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices.

[28] Centers for Disease Control and Prevention., Interim results: Influenza A (H1N1) 2009 and Monovalent Seasonal Influenza Vaccination Coverage Among Health-Care Personnel—United States August 2009- January 2010. Morbidity and Mortality Weekly Report (MMWR); 59:357–362. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5912a1.htm.*

[29] Adapted from: Pearson ML., Bridges CB., Harper SA.,: Influenza vaccination of health-care personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). Morbidity and Mortality Weekly Report (MMWR) 2006; 55:1–16. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm.*

[30] For additional information regarding healthcare facilities' influenza vaccine policies, please see: *http://www.immunize.org/honor%2Droll/.*

[31] Available at: *http://www.cdc.gov/nhsn/hps.html.*

adoption of the measure in the Hospital IQR Program until the CDC has completed and fully tested the summary data collection tool. A few commenters suggested delaying the proposed measure until data can be collected via EHRs. A few commenters believed that current NQF-endorsed measures specifying the reporting of the vaccination status of all healthcare personnel are too labor-intensive. Commenters recommended that CMS either adopt a simplified definition of the measure that focuses solely on hospital employees and excludes contracted staff, or allow hospitals to submit summary data on HCP rates, ideally from existing databases, to reduce burden. Commenters also suggested that CMS allow for external factors outside of the facilities control (for example, vaccination shortage).

Response: The measure is currently being respecified by the CDC to eliminate unnecessary burden on hospitals. CDC will be adding aggregate reporting of healthcare personnel influenza vaccination coverage to NHSN and has submitted a proposed measure to NQF that uses aggregate reporting in the measure proposal. The scope of the proposed respecified measure is hospital employees and credentialed non-employees. These steps will enable hospitals—and other healthcare facilities—to take advantage of aggregate reporting capacity that is built into occupational health information systems. We are confident that such revisions to the measure specifications will be fully implementable by the proposed FY 2015 payment determination. This is a change to how the measure is reported to NHSN (reporting on the influenza vaccination coverage of at the facility level, rather than for individual personnel at the facility, and is not a change in the substance of the measure itself).

After consideration of the public comments received, we are finalizing the HCP Influenza Vaccination measure for the FY 2015 payment determination. Required data collection for the FY 2015 payment determination will cover the period from January 1, 2013 through March 31, 2013. For future payment determinations, data collection will cover the period from October 1 through March 31st to coincide with the flu season.

(B) New Chart-Abstracted Measures for the FY 2015 Payment Determination

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25903 through 25907), we proposed to adopt two sets of chart-abstracted measures for the FY 2015 payment determination: the Stroke and Venous Thromboembolism (VTE) measure sets. All of these proposed measures have either previously been proposed for the Hospital IQR Program, or have been listed as being under consideration for future adoption into the program. In addition, with one exception (STK–1: VTE Prophylaxis), all of the measures in these two measure sets have been electronically specified and are among the measures adopted for the EHR Incentive Program for eligible hospitals. While we proposed to adopt these for chart-abstracted submission in 2013 for the FY 2015 payment determination, we believe that by a future date, such as 2015, hospitals will be able to switch to EHR-based submission of these and all other chart-abstracted measures submitted for the Hospital IQR Program, and, as we discuss in greater detail below, we intend to work toward this goal over the next few years.

The Stroke measure set we proposed to adopt consists of 8 measures; and the VTE measure set consists of 6 measures. Both measure sets are NQF-endorsed and their specifications are currently available in the Specifications Manual, which can be found on QualityNet. We believe that both of the proposed measure sets compliment the data elements in our current SCIP VTE and AMI measure sets.

Comment: Many commenters supported the adoption of the Stroke measure set and the VTE measure set into the Hospital IQR Program because the measures in the sets are NQF-endorsed and HQA-adopted, and they are used by The Joint Commission as core measure sets. Commenters believed that the measures will provide meaningful information regarding how well Stroke care and VTE care are being managed in a hospital setting. The commenters further noted that the measure sets are already e-specified for the meaningful use criteria under the EHR Incentive Program. The commenters recommended delaying the adoption of the measure sets until there is harmonization of the measure sets for both the EHR Incentive Program and the Hospital IQR Program, so that the reporting burden would be significantly reduced for hospitals. Some commenters disagreed with CMS' assertion that the addition of measures will align the Hospital IQR Program with the EHR Incentive Program because the Stroke measure set and the VTE measure set calculations derived from chart-based measure specifications are not the same as those derived from e-measure specifications. The commenters believed that any discrepancy in calculation of performance rates may lead to confusion when they are publicly reported. Commenters recommended comparison of data collected through manual abstraction and EHR-based reporting to resolve discrepancies in calculations prior to display on *Hospital Compare.*

Response: We thank the commenters for their support of the Stroke measure set and the VTE measure set. Providing hospitals with one set of harmonized specifications is a key goal for CMS for the future. We are aware of the differences in the chart-abstracted and EHR e-measure specifications, and have been working with relevant stakeholders to remedy the situation. We also recognize that many hospitals participating in the Hospital IQR Program have not adopted EHR technology at this time. Therefore, we are finalizing our proposal to include the chart-abstracted Stroke and VTE measure sets for data collection beginning with January 1, 2013 discharges.

We also thank the commenters for their recommendations. We plan to update the Specifications Manual's chart-abstracted specifications for the stroke clinical quality measure set in order to align with the electronic specifications for these measures. As we move towards alignment and harmonization of clinical quality measures reporting among federal reporting initiatives, we plan to compare, test, and align these reporting specifications using different data sources.

(i) Stroke Measure Set

Stroke is a topic of great relevance to the Medicare population due to its impact on morbidity and mortality, and it is an area with great potential for quality improvement for hospitals caring for stroke patients. Stroke is the third most common cause of death in the United States and is one of the top 20 conditions contributing to Medicare costs. Approximately 8 to 12 percent of ischemic strokes are fatal,[32] and mortality following stroke is influenced by the quality of care provided to patients during their initial hospitalization.[33] In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43873), we listed 8 Stroke measures as being under consideration for adoption for the FY 2012 Hospital IQR payment determination. Numerous commenters encouraged us to adopt the listed stroke

[32] American Heart Association, Heart Disease and Stroke Statistics—2009 Update. American Heart Association, 2009: p. 1–36.

[33] Weir, N.U., *et al.,* Variations between countries in outcome after stroke in the International Stroke Trial (IST). Stroke, 2001. 32(6): p. 1370–7.

measures which they see as evidence-based measures that accurately measure the care of the stroke patient (74 FR 43875 through 43876). Commenters believed that the measures are widely recognized for their roles in minimizing secondary strokes and other complications.

We proposed to adopt a stroke measure set with 8 NQF-endorsed process of care measures for the FY 2015 payment determination. The table below lists and describes each of these eight proposed measures.

8 PROPOSED STROKE MEASURES

STK–1: Venous Thromboembolism (VTE) Prophylaxis for patients with ischemic or hemorrhagic stroke. (NQF #0434).	Percent of patients with an ischemic stroke or a hemorrhagic stroke and who are non-ambulatory should start receiving DVT prophylaxis by end of hospital day two.
STK–2: Ischemic stroke patients discharged on antithrombotic therapy. (NQF #0435).	Percent of patients with an ischemic stroke prescribed antithrombotic therapy at discharge.
STK–3: Anticoagulation therapy for atrial fibrillation/flutter. (NQF #0436).	Percent of patients with an ischemic stroke with atrial fibrillation discharged on anticoagulation therapy.
STK–4: Thrombolytic Therapy for Acute ischemic stroke patients. (NQF #0437).	Percent of acute ischemic stroke patients who arrive at the hospital within 120 minutes (2 hours) of time last known well and for whom IV t-PA was initiated at this hospital within 180 minutes (3 hours) of time last known well.
STK–5: Antithrombotic therapy by the end of hospital day two. (NQF #0438).	Percent of patients with ischemic stroke who receive antithrombotic therapy by the end of hospital day two.
STK–6: Discharged on statin medication. (NQF #0439)	Percent of ischemic stroke patients with LDL >/= 100 mg/dL, or LDL not measured, or, who were on cholesterol reducing therapy prior to hospitalization are discharged on a statin medication.
STK–8: Stroke education. (NQF #0440)	Percent of patients with ischemic or hemorrhagic stroke or their caregivers who were given education or educational materials during the hospital stay addressing all of the following: personal risk factors for stroke, warning signs for stroke, activation of emergency.
STK–10: Assessed for rehabilitation services. (NQF #0441)	Percent of patients with an ischemic stroke or hemorrhagic stroke who were assessed for rehabilitation services.

Because the NQF is the entity that holds a contract with the Secretary under section 1890(a) of the Act, measures that are endorsed by the NQF meet the requirement for measure selection under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. Aside from the consideration of NQF endorsement, we believe that the inclusion of the proposed stroke measure set in the Hospital IQR Program would provide a comprehensive view of how well stroke care is being managed in a hospital setting. As stated earlier, detailed measure specifications for these 8 proposed measures are available in the Specifications Manual located in QualityNet. We invited public comment on the proposed stroke measure set.

Comment: A commenter stated that there are errors in the e-specifications of the Stroke measure set and requested corrections of the errors to avoid variability of rates caused by discrepancy in measure specifications.

Response: We have received public comments identifying a number of issues and questions about the electronic specifications for the Stroke related HITSP measure specifications listed in TN906/v1.0. We are working with the measure steward to make updates to these electronic specifications and will notify the public when the updates are published. In the future, we anticipate that electronic specification review will be part of the NQF measure endorsement process.

After consideration of the public comments we received, we are finalizing the Stroke measure set for the FY 2015 payment determination.

(ii) VTE Measure Set

It is widely agreed that VTE is the number one preventable cause of hospital death in the United States and the cost of VTE when it occurs is very high. A recent study from AHRQ in Health Affairs highlighted that when an acute VTE event occurs, it increases the costs of care by 25 percent. In 2008, the Surgeon General issued a Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism. (This document can be found at: *http://www.surgeongeneral.gov/topics/deepvein/calltoaction/call-to-action-on-dvt-2008.pdf.*) VTE prevention with pharmacologic agents can impact the cost effectiveness of care. Specifically, patients who received anti-coagulant medication during hospitalization have less likelihood of recurrence of VTEs upon discharge to home. Parenteral anticoagulation is the first line of therapy because of its rapid onset of action. Because the oral anticoagulant medication has a very slow onset of action, it cannot be used as mono-therapy for acute VTE. A minimum of 5 days of parenteral anticoagulation is recommended as ''overlap therapy'' while oral anticoagulant medication is being initiated. More thrombotic complications and higher costs are associated with treatment in patients demonstrating a subtherapeutic aPTT. Unfractionated Heparin (UFH) Dosages/Platelet Count Monitoring by Protocol (or Nomogram) has significantly advanced the use of UFH with the demonstrated ability to achieve therapeutic aPTTs more rapidly than with standard UFH dosing. When this occurs, patients can be discharged sooner. However, anticoagulation therapy poses risks to patients and often leads to adverse drug events due to complex dosing, requisite follow-up monitoring and inconsistent patient compliance. The use of standardized practices for anticoagulation therapy that includes patient/caregiver involvement may reduce the risk of adverse drug events.

The Hospital IQR Program currently has 2 measures of VTE prophylaxis for surgical patients (SCIP–VTE–1: Venous thromboembolism (VTE) prophylaxis ordered for surgery patients; and SCIP–VTE–2: VTE prophylaxis within 24 hours pre/post surgery) in the SCIP measure set. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43873), we listed 5 VTE measures (VTE–1: Venous thromboembolism prophylaxis; VTE–3: Venous thromboembolism patients with anticoagulation overlap therapy; VTE–4: Venous thromboembolism patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol; VTE–5: Venous thromboembolism discharge instructions; and VTE–6: Incidence of

potentially-preventable venous Thromboembolism) as possible new measures for the FY 2012 payment determination. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50213 through 50218), we listed 6 VTE measures (VTE–1: Venous thromboembolism prophylaxis; VTE–2: Intensive care unit venous thromboembolism prophylaxis; VTE–3: Venous thromboembolism patients with anticoagulation overlap therapy; VTE–4: Venous thromboembolism patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol; VTE–5: Venous thromboembolism discharge instructions; and VTE–6: Incidence of potentially-preventable venous thromboembolism) as measures we were considering for possible future adoption into the program.

We proposed to adopt for the FY 2015 Hospital IQR measure set 6 VTE measures which are aimed at preventing the incidence of potentially preventable VTE. These 6 measures are listed and described below.

6 PROPOSED VENOUS THROMBOEMBOLISM (VTE) MEASURES

VTE–1: Venous thromboembolism prophylaxis (NQF #0371).	Percent of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.
VTE–2: Intensive care unit venous thromboembolism prophylaxis (NQF #0372).	Percent of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).
VTE–3: Venous thromboembolism patients with anticoagulation overlap therapy (NQF #0373).	Percent of patients diagnosed with confirmed VTE who received an overlap of parenteral (intravenous [IV] or subcutaneous [subcu]) anticoagulation and warfarin therapy. For patients who received less than 5 days of overlap therapy, they must be discharged on both medications. Overlap therapy must be administered for at least 5 days with an international normalized ratio (INR) = 2 prior to discontinuation of the parenteral anticoagulation therapy or the patient must be discharged on both medications.
VTE–4: Venous thromboembolism patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol (NQF #0374).	Percent of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol.
VTE–5: Venous thromboembolism discharge instructions (NQF #0375).	Percent of patients diagnosed with confirmed VTE that are discharged to home, to home with home health or home hospice on warfarin with written discharge instructions that address all four criteria: Compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/interactions.
VTE–6: Incidence of potentially-preventable venous Thromboembolism (NQF #0376).	Percent of patients diagnosed with confirmed VTE during hospitalization (not present on arrival) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date.

These 6 measures were endorsed in a 2008 NQF project titled: National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism: Additional Performance Measures. Because the NQF is the entity that holds a contract with the Secretary under section 1890(a) of the Act, measures that are endorsed by the NQF meet the requirement for measure selection under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. Aside from the consideration of NQF-endorsement, we believe that the inclusion of the VTE measure set in the Hospital IQR Program would provide a comprehensive view of how well VTE care is being managed in a hospital setting. Detailed measure specifications for these 6 proposed measures are available in the Specifications Manual located on QualityNet. We invited public comment on the proposed VTE measure set.

Comment: One commenter supported the adoption of VTE 1, VTE 2, and VTE 3 but noted that the excluded populations in the denominator of the measures need to be expanded so that the compliance rates can be better portrayed. One commenter opposed the adoption of VTE 4 and VTE 5 because the commenter believed that the level of detail being reported does not meet the objectives of the Hospital IQR Program. Further, the commenter recommended that VTE 6 not be adopted because the commenter believed that the definition is not consistent with epidemiological principles.

Response: VTE is a condition that can be reasonably prevented by following evidence based guidelines, which are the basis for the VTE measure set. We believe including this VTE measure set will encourage broad use of VTE prophylaxis in both medical and surgical patients. VTE 1, VTE 2, and VTE 3 address appropriate preventive treatment for surgical patients, patients in the ICU, and patients on anticoagulants. VTE 4 and VTE 5 assess important factors in VTE prophylaxis. VTE 4 seeks to encourage hospitals to use a standardized tool for the titration of VTE prophylactic agents to achieve appropriate levels of effectiveness. The use of a nomogram or standardized protocol may reduce the incidence of adverse events related to non-therapeutic blood levels. VTE 5 is a measure of patient education related to VTE and prophylaxis including follow up care, dietary restrictions, and adverse interactions. VTE 6 is an important measure of the incidence of VTE in the hospitalized patient. Therefore, we are finalizing the adoption of the VTE measure set for discharges beginning on or after January 1, 2013.

Comment: One commenter urged CMS to separately report on *Hospital Compare* measure rates calculated using e-specifications and measure rates calculated using chart-abstracted data.

Response: We thank the commenter for the suggestion. Currently the e-specifications are not used for Hospital IQR, but are used for Medicare EHR Incentive Programs. We currently do not post measure rates for Medicare EHR Incentive Programs on the Hospital Compare Web site. We will continue to post measure data collected as part of the Hospital IQR and Hospital VBP Programs on the *Hospital Compare* Web site.

Comment: One commenter stated that the reporting of 76 measures by FY 2015 is a resource and data burden for hospitals.

Response: We anticipate that once hospitals have acquired the capability to submit data on measures electronically in a future date such as 2015, the burden will be reduced significantly.

After consideration of the public comments we received, we are finalizing the proposed VTE measure set for the FY 2015 payment determination. Data collection will begin with discharges on or after January 1, 2013.

In summary, after consideration of the public comments received, we are finalizing the retention of 59 measures for the FY 2014 measure set, and adding 17 new measures to the measure set for the FY 2014 payment determination: 3 HAI measures collected through the NHSN, (MRSA Bacteremia, C. difficile SIR, and the Healthcare Personnel Influenza Vaccination), the Stroke measure set (8 measures) and the VTE measure set (6 measures). As a result, there will be a total of 76 measures in the FY 2015 Hospital IQR measure set, but we will only be collecting data on 72 of those measures for purposes of the FY 2015 payment determination. The 76 measures are listed below, and the 4 measures for which we will not be collecting data are designated with the word ''SUSPENDED.''

Topic	Hospital IQR program measures for FY 2015 payment determination
Acute Myocardial Infarction (AMI) Measures.	• AMI–1 Aspirin at arrival [SUSPENDED]. • AMI–2 Aspirin prescribed at discharge. • AMI–3 ACEI/ARB for left ventricular systolic dysfunction [SUSPENDED]. • AMI–5 Beta-blocker prescribed at discharge [SUSPENDED]. • AMI–7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival. • 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 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.** • 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–6: Appropriate Hair Removal [SUSPENDED]. • 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 INF–VTE-1: Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered. • 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 Measure.	• HCAHPS survey.
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.
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. • Complication/patient safety for selected indicators (composite). • Mortality for selected medical conditions (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 Stroke Care.

Topic	Hospital IQR program measures for FY 2015 payment determination
Healthcare-Associated Infections Measures.	• Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care. • Participation in a Systematic Clinical Database Registry for General Surgery.* • Central Line Associated Bloodstream Infection. • Surgical Site Infection. • Catheter-Associated Urinary Tract Infection.* • MRSA Bacteremia.** • Clostridium d*ifficile* (C. d*ifficile*).** • Healthcare Provider Influenza Vaccination.**
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.
Emergency Department 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 Measures.	• Immunization for Influenza. • Immunization for Pneumonia.
Cost Efficiency	• Medicare Spending per Beneficiary.*

* New quality measures for the FY 2014 payment determination.
** New quality measures for FY 2015 payment determination.

4. Possible New Quality Measures and Measure Topics for Future Years

We anticipate that as EHR technology evolves, and more infrastructure is put in place, we will have the capacity to accept electronic reporting of all of the clinical chart-abstracted measures that are currently part of the Hospital IQR Program or have been proposed for adoption into the program. We intend for this future progress to significantly reduce the administrative burden on hospitals under the Hospital IQR Program. We recognize that considerable work needs to be done by measure owners and developers to make this possible with respect to the clinical quality measures that we proposed. This includes completing electronic specifications for measures, pilot testing, reliability, and validity testing, and implementing such specifications into EHR technology to capture and calculate the results, and implementing the systems. We believe that at a future date, such as 2015, CMS and hospitals will be able to switch to complete EHR-based reporting of all chart-abstracted measures to CMS for the Hospital IQR Program, and we intend to work diligently toward this goal. We believe this will simplify measure collection and submission for the Hospital IQR Program, and will reduce the burden on hospitals. We invited public comment and suggestions on this topic.

In future rules, it is our intention to propose to adopt outcome measures for stroke and joint replacement surgery which we have developed and anticipate submitting for NQF review. In addition, we intend to propose additional HAI measures as they gain NQF endorsement. We also invited public comment on the following quality measures and topics set out below that we are considering for the future. We seek to limit the number of chart-abstracted measures and topics in the near future, in order to facilitate the transition to EHR-based reporting.

POSSIBLE HOSPITAL IQR PROGRAM FUTURE MEASURES AND TOPICS

Measurement topic	Measure title/description/concept
Mortality/Complications	• Acute stroke 30-day mortality rate. • Total Hip and Total Knee arthroplasty 30-day complications.
Readmissions	• Stroke 30-Day Risk Standardized Readmission Measure. • Total Hip and Total Knee Arthroplasty 30-Day Risk Standardized Readmission Measure.
Patient Safety	• Surgical checklist use for surgical procedures. • NQF approved Serious Reportable Events.
Medication Safety	• Universal Documentation and Verification of Current Medications in the Medical Record. • Drug-Drug interaction. • Medication Reconciliation.
Surgical Outcome Measures	• Lower Extremity Bypass Complications. • ICD Complications. • Risk Adjusted Case Mix Adjusted Elderly surgery outcomes. • Risk Adjusted Case Mix Adjusted Colorectal surgery outcomes.
Healthcare-Associated Infections	• Ventilator Associated Pneumonia. • Post Procedure Pneumonias. • Multi Drug Resistant Organisms—VRE, Klebsiella, Acinetobacter.
Readmissions	• COPD 30-day Risk Standardized Readmission Rate. • CABG 30-day Risk Standardized Readmission Rate. • Other Vascular Condition 30-day Risk Standardized Readmission. • Percutaneous Coronary Intervention (PCI) 30-day Risk Standardized Readmission Rate.

POSSIBLE HOSPITAL IQR PROGRAM FUTURE MEASURES AND TOPICS—Continued

Measurement topic	Measure title/description/concept
	• All-Patient Condition-Specific Readmission Rates for AMI, Heart Failure, Pneumonia, CABG, COPD, PCI, other vascular conditions.
	• All-condition 30-day readmission rate.
Average Length of Stay	• Overall inpatient hospital average length of stay (ALOS) and ALOS by medical service category.
Mortality	• 30-day Risk Standardized Mortality Rate following PCI for STEMI/shock patients.
	• 30-day risk-standardized mortality rate following PCI for non-STEMI/non-shock patients.
SCIP	• Short Half-Life prophylactic administered preoperatively redosed within 4 hours after preoperative dose.
Care Coordination	• Cardiac Rehabilitation Referral for AMI, HF, Cardiac Surgery.
Heart Failure	• Symptom and Activity Assessment.
	• Symptom Management.
	• Patient Education.
	• Combination Medical Therapy for LVSD.
	• Beta Blocker Therapy for LVSD.
	• Counseling Regarding ICD for Patients with LVSD.
Tobacco & Alcohol Cessation	• TAM–1: Tobacco Use Screening.
	• TAM–2: Tobacco Use Treatment.
	• TAM–3: Tobacco Use Treatment Management at Discharge.
	• TAM–4: Assessing Status after Discharge.
	• TAM–5: Alcohol Use Screening.
	• TAM–6: Alcohol Use Brief Intervention.
	• TAM–7: Alcohol and other Drug dependence—Treatment Management at Discharge.
	• TAM–8: Substance Use—Assessing Status after Discharge.
Nursing Sensitive (remainder of measures)	• NSC–2: Patients surveyed on an eligible reporting unit that have at least one stage II or greater [National Ulcer Advisory Panel (NPUAP)] nosocomial pressure ulcer on the day of the prevalence study.
	• NSC–3: Number of patient falls, with or without injury to the patient, by type of Unit during the calendar month × 1000.
	• NSC–4: Number of patient falls with an injury level of minor or greater by Type of Unit during the calendar month × 1,000.
	• NSC–5: Patients surveyed on the eligible reporting unit that have a vest restraint and/or limb restraint (upper or lower or both) on the day of the prevalence study.
	• NSC–12: Number of productive hours worked as specified in the Set Measure Identifier.
	• NSC–13: Total number of productive hours worked by nursing staff (stratified by type of certification RN, LPN/LVN, UAP) with direct patient care responsibilities by Type of Unit during the calendar month.
	• NSC–14: Nursing satisfaction survey.
	• NSC 15: The total number of voluntary separations (as specified under the Performance Measure Identifier and Description above) during the calendar month.
Cardiac Surgery measures	• Post-operative Renal Failure.
	• Surgical Re-exploration.
	• Anti-Platelet Medication at Discharge.
	• Beta Blockade at Discharge.
	• Anti-Lipid Treatment Discharge (Statin at Discharge).
	• Risk-Adjusted Operative Mortality for CABG.
	• Risk-Adjusted Operative Mortality for Aortic Valve Replacement (AVR).
	• Risk-Adjusted Operative Mortality for Mitral Valve Replacement/Repair (MVR).
	• Risk-Adjusted Operative Mortality MVR+CABG Surgery.
	• Risk-Adjusted Operative Mortality for AVR+CABG.
	• Surgical Volume—a. Isolated Coronary Artery Bypass Graft (CABG) Surgery, b. Valve Surgery, c. CABG+Valve Surgery.
	• Timing of Antibiotic Prophylaxis for Cardiac Surgery Patients.
	• Selection of Antibiotic Prophylaxis for Cardiac Surgery Patients.
	• Pre-Operative Beta Blockade.
	• Duration of Prophylaxis for Cardiac Surgery Patients.
	• Prolonged Intubation (ventilation).
	• Deep Sternal Wound Infection Rate.
	• Stroke/Cerebrovascular Accident.
	• CABG Composite Score.

Comment: Commenters generally supported CMS adopting more outcome measures in the future. The commenters further stated that CMS should not dismiss process of care measures that have a direct link to outcome measures.

Response: We thank the commenters for their suggestions which we will take into consideration for future measures.

Comment: Many commenters were supportive of our proposed list of future measures and measure topics.

Response: We thank the commenters for their support of our future measure topics and will take their comments into consideration in our selection of future measures.

Comment: Many commenters supported the inclusion of The Joint Commission Smoking Cessation and Tobacco measure sets for the Hospital IQR Program and recommended EHR-

based reporting for these measures. For future cardiac readmission measures, one commenter recommended that CMS take into account the FDA-approved new classes of medications for prevention of cardiac readmissions and improvement of patient outcomes. One commenter suggested that any 30-day ischemic stroke mortality or readmission measure must include stroke severity as a risk-adjustment factor.

Response: We thank the commenters for their specific suggestions and will consider them as we decide which measures to propose to adopt in the future for the Hospital IQR Program.

Comment: Some commenters were opposed to some measures and measure topics on our list of future measure and measure topics: One commenter opposed the Nursing Sensitive Care measures and Readmission measures for AMI, HF, PN, and PCI. One commenter opposed the adoption of the ventilator associated pneumonia (VAP) measure because the commenter believed that the definitions and diagnosis are problematic, and opposed the adoption of the SCIP, and MDRO measures because they are not NQF-endorsed. Two commenters were opposed to the care coordination measure. A commenter opposed the adoption of the SCIP (process) measure (short Half-Life prophylactic administered preoperatively redosed within 4 hours after preoperative dose) because the related Surgical Site Infection (SSI) outcome measure is already part of the Hospital IQR Program.

Response: We thank the commenters for their recommendations and will take them into consideration as we decide which measures to propose to adopt in the future for the Hospital IQR Program.

Comment: Some commenters recommended measures that are not on our list of future measures and measure topics. One commenter proposed a new measure for hyponatremia. One commenter proposed a measure for AMI and HF such as the NQF-endorsed Heart Failure (HF): Beta-blocker therapy (NQF #0083). One commenter supported a surgical checklist measure for Hospital IQR Program. One commenter recommended NQF-endorsed wound care measures and malnutrition evaluation measures if they are available. One commenter recommended adopting measures that would indicate share-decision making in hospitals. One commenter suggested a measure for Surgical Site Infection following implementation of a CIED. One commenter recommended PTCA Readmission measures. One commenter strongly urged CMS to adopt measures based on registry data (for example, CABG), CTM–3, PAC measures, efficiency measures, CAD and CHD measures, patient-reported outcomes, and cross-cutting measures of care for patients with multiple chronic conditions.

Response: We appreciate all the suggestions for additional measures and measure topics and will take them into consideration as we decide which measures to propose to adopt in the future for the Hospital IQR Program.

Comment: One commenter recommended that, in addition to current reporting efforts, future reporting should strike a balance between driving quality and system improvement as well as attempt to capture the entire episode of care so that the quality of care and care continuum can be better portrayed.

Response: We thank the commenter for the recommendation and will take it into consideration as we decide which measures to propose to adopt in the future for the Hospital IQR Program.

We thank the commenters for their comments and suggestions regarding future Hospital IQR measure adoption.

5. 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 quality data in a form and manner, and at a time, specified by the Secretary. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/.* CMS requires that hospitals submit data in accordance with the specifications for the appropriate discharge periods. Hospitals submit quality data through the secure portion of the QualityNet Web site (formerly known as QualityNet Exchange) (*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 FY 2012 Payment Determinations and Subsequent Years

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25914 through 25920), we proposed Hospital IQR Program procedural requirements that are, for the most part, the same as the procedures adopted in the FY 2011 IPPS/LTCH PPS final rule for the Hospital IQR Program. Hospitals must comply with the following procedural requirements to participate—

- Register with QualityNet, before participating hospitals initially begin reporting data, regardless of the method used for submitting 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. New subsection (d) hospitals and existing hospitals that wish to participate in the Hospital IQR Program for the first time must complete an online Notice of Participation (formerly known as ''Reporting Hospital Quality Data for Annual Payment Update Notice of Participation,'' also referred to as IPledge) that includes the name and address of each hospital campus that shares the same CMS Certification Number (CCN). We revise the Notice of Participation periodically as needed and provide appropriate notification of any revisions to hospitals and QIOs through the routine Hospital IQR Program communication channels, which include memo and e-mail notification and QualityNet Web site articles and postings.
- Any hospital that receives a new CCN on or after October 15, 2009 (including new subsection (d) hospitals and hospitals that have merged) that wishes to participate in the Hospital IQR Program and has not otherwise submitted a Notice of Participation using the new CCN must submit a completed Notice of Participation 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 (QIES) (which we referred to in the proposed rule as the CMS Online System Certification and Reporting (OSCAR) system) to participate in the Hospital IQR Program. We proposed regulation text to codify this requirement.
- We will accept Hospital IQR Program withdrawal forms for the FY 2013 payment determination from hospitals any time from October 1, 2011 until August 15, 2012. The August 15, 2012 deadline will give us sufficient

time to update the FY 2013 payment to hospitals starting on October 1, 2012. If a hospital withdraws from the program for the FY 2013 payment determination, it will receive a reduction of 2.0 percentage points to the FY 2013 applicable percentage increase. Once a hospital has submitted a Notice of Participation, it is considered to be an active Hospital IQR Program participant until such time as the hospital submits a withdrawal form to CMS.

- We will determine if a hospital has complied with our data submission requirements by looking at whether the hospital has properly submitted data to the appropriate data warehouses for HCAHPS, CDC/NHSN, chart-abstracted measures, and structural measure quality measure data during the four calendar year quarters of FY 2012.

The Hospital IQR Program procedural requirements have remained relatively unchanged for the past several years and we proposed to codify them at 42 CFR 412.140. We invited public comment on this proposal.

We received no comments on our proposal to codify the Hospital IQR Program procedural requirements. Therefore, for the reasons described above, we are codifying the Hospital IQR Program procedural requirements at 42 CFR 412.140.

c. Procedural Requirements for FY 2013 and Subsequent Years

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25915), we proposed that hospitals that have an open date (as noted on the approved CMS OSCAR system/QIES) before March 31, 2009 that did not participate in the Hospital IQR Program in FY 2011 or FY 2012 but that wish to participate in the Hospital IQR Program for the FY 2013 payment determination must submit a completed Notice of Participation to CMS on or before December 31, 2011. These hospitals, unlike hospitals that receive a new CCN, do not need to get their operations up and running. Therefore, we believe this is a reasonable deadline that will enable these hospitals to decide whether they want to participate in the Hospital IQR Program while also enabling us to collect enough data from them to make an accurate FY 2013 payment determination. We proposed regulation text that provides that hospitals that would like to participate in the Hospital IQR Program for the first time, or that previously withdrew from the program and would like to participate again, must submit to CMS a completed Notice of Participation Form by December 31 of the fiscal year preceding the fiscal year in which they would like to participate.

We received no comments regarding the proposal to require hospitals to submit a completed Notice of Participation Form by December 31 of the fiscal year preceding the fiscal year in which they would like to participate. Therefore, for the reasons described above, we will require a completed Notice of Participation Form by December 31 of the fiscal year preceding the fiscal year in which they would like to participate.

d. Data Submission Requirements for Chart-Abstracted Measures

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 2525915), we proposed to reduce the quarterly submission deadline for chart-abstracted quality measures from 4½ months to 104 days. In other words, for FY 2014 payment determinations, the quarterly deadline for the quality measures under the topic that require chart abstraction (AMI, HF, PN, SCIP, Emergency Department Throughput (EDT), and Global Immunization (GIM)) will be 104 days following the last discharge date in the calendar quarter. We proposed to reduce the data submission deadline in order to allow for a correction period, which we will propose in future rulemaking. We also believe that this proposed change will encourage hospitals to utilize quality measure information in a more rapid manner to facilitate quality improvement. We also want to provide hospitals sufficient notice of any proposed changes to our submission deadline, since we recognize the advance time needed by hospitals to modify their recordkeeping and abstraction practices to comply with this proposed requirement. We also proposed to change the aggregate population and sampling deadline from 4 months to 3 months to align with the corresponding proposal to change the data submission deadline from 135 to 104 days.

We will continue to require hospitals 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 (currently AMI, HF, PN, and SCIP) (75 FR 50221). Starting with the FY 2014 payment determination, we proposed to change the submission deadline for hospitals to submit aggregate population and sample size count data for the measures requiring chart abstraction from 4 months to 3 months following the last discharge date in the calendar quarter. We proposed this 3-month deadline for submission of the aggregate population and sample size counts data to provide CMS with information necessary to notify hospitals about their data completeness status. Specifically, we currently provide a Provider Participation Report the day after the submitted file is processed, which includes a calculation of the number of hospital submitted cases by topic, hospital self-reported aggregate population and sample size count, and Medicare FFS claims by clinical topic and SCIP surgical category. We expect that hospitals will use this report after submission to assess their patient-level data completeness and will submit additional patient-level cases before the proposed quarterly patient-level deadline. We proposed to provide hospitals with the same 14-day period after the proposed aggregate population and sample size count deadline to submit the required patient-level records.

Comment: Several commenters opposed the shorter timeframes due to the increased administrative burden that this would create for hospitals.

Response: We appreciate the comment and are sensitive to the burden faced by hospitals to meet the requirements under the Hospital IQR Program. In the CY 2012 OPPS/ASC proposed rule (76 FR 42363 through 42365), we proposed to implement a review and corrections process for the Hospital VBP Program that would give hospitals an opportunity to review and correct data submitted on all Hospital IQR Program chart-abstracted measures, whether or not those measures are adopted as Hospital VBP Program measures. We noted that under the Hospital IQR Program, hospitals currently have an opportunity to submit, review, and correct any of the chart-abstracted information submitted to the QIO Clinical Warehouse for the full 4½ months following the last discharge date in a calendar quarter, although we also noted that we had proposed to shorten this period. In response to the comments stating that the shortened timeframe would increase the burden to hospitals under the Hospital IQR Program, we re-examined the timing issues that had prompted us to propose to shorten the period and concluded that the existing 4½ month submission period would give hospitals a sufficient amount of time to review and correct their chart-abstracted data, and would also give us a sufficient amount of time to perform our administrative functions. For this reason, we will not finalize our proposal to shorten the chart-abstracted data submission period to 104 days, and hospitals will continue to have 4½ months following the last discharge date in a calendar quarter to submit their

chart-abstracted data for that quarter. To be consistent with our decision to retain the 4½ month data submission period, we will also not finalize our proposal to shorten the aggregate population and sampling deadline from 4 months to 3 months, and hospitals will continue to have 4 months to submit this data.

Comment: One commenter expressed concern that the reduced submission deadline would reduce the amount of time vendors have to analyze, report and resubmit the various data files.

Response: We thank the commenter for their input and appreciate the commenter's concern regarding the proposed reduced timeframes. For the reasons stated above, we will not finalize our proposals to shorten the chart-abstracted data submission deadline or the aggregate population and sampling deadline.

Comment: A few commenters suggested that efforts be made to synchronize reporting timeframes with other standard reporting requirements, such as The Joint Commission's requirements and timeframes.

Response: We believe that the reporting deadlines we have developed for the Hospital IQR Program take into consideration both the burden to hospitals and our administrative and operational needs. However, we appreciate the commenters' suggestion to align our reporting deadlines with the reporting deadlines imposed by other organizations and will take it into consideration in developing future rulemaking.

Comment: Many commenters suggested that CMS shorten the data submission timeline from 135 days to 122 days, not the proposed 104 days. These commenters asserted that this would build in time for a data correction period while ensuring that hospitals are not overwhelmed by a drastically shortened data collection period.

Response: We thank the commenters for their input. As noted above, we are not finalizing our proposals to shorten the chart-abstracted data submission deadline or the aggregate population and sampling deadline. However, we will take the commenters' suggestions into consideration in developing future rulemaking.

Comment: One commenter supported the reduction in submission days because it would increase efficiency in the program. A few commenters supported the opportunity to review and correct data and suggested the reduced submission deadline was not a burden in exchange for the review opportunity.

Response: We thank the commenters for supporting our proposals to shorten the chart-abstracted data submission deadline and the aggregate population and sampling deadline, however for the reasons noted above, we will not be finalizing these proposals.

After consideration of the public comments we received, we will not finalize our proposal to shorten the chart-abstracted data submission period to 104 days, and hospitals will continue to have 4½ months following the last discharge date in a calendar quarter to submit their chart-abstracted data for that quarter. To be consistent with our decision to retain the 4½ month data submission period, we will also not finalize our proposal to shorten the aggregate population and sampling deadline from 4 months to 3 months, and hospitals will continue to have 4 months to submit this data.

We did not receive any comments on our proposal to continue providing hospitals with 14 days after the aggregate population and sample size count deadline to submit the required patient-level records, and we are finalizing that proposal.

e. Sampling and Case Thresholds Beginning with the FY 2015 Payment Determination

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25915 through 25916), we proposed to continue the requirement for hospital submission of population and sampling data for the FY 2015 payment determination and future years. Hospitals must submit to CMS quarterly aggregate population and sample size counts for Medicare and non-Medicare discharges for the topic areas for which chart-abstracted data must be submitted (AMI, HF, PN, SCIP, EDT and GIM). Hospitals are required to submit their aggregate population and sample size count for each topic area.

In accordance with the policy we adopted in the FY 2011 IPPS/LTCH PPS final rule, hospitals that have not treated patients in a specific topic area must still submit quarterly population and sample size counts for all Hospital IQR chart-abstracted data topics. For example, if a hospital has not treated AMI patients, the hospital is still required to submit a zero for its quarterly aggregate population and sample count for that topic in order to meet the requirement. We view it as vital for hospitals to determine accurately their aggregate population and appropriate sampling size data in order for CMS to assess hospitals' data reporting completeness for their total population of cases, Medicare and non-Medicare.

In order to reduce the burden on hospitals that treat a low number of patients in a Hospital IQR Program topic area, a hospital that has five or fewer discharges (Medicare and non-Medicare combined) in a topic area during a quarter in which data must be submitted would not be required to submit patient-level data for that topic area for the quarter. The hospital must still submit its aggregate population and sample size counts for Medicare and non-Medicare discharges for the topic areas each quarter. Hospitals meeting the five or fewer patient discharge exception may voluntarily submit these data.

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.

We did not receive any public comments related to this proposal. Therefore, we are finalizing our proposal regarding hospital submission of population and sampling data for the FY 2015 payment determination and future years as proposed.

f. HCAHPS Requirements for the FY 2013, FY 2014, and FY 2015 Payment Determinations

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25916 through 25917), beginning with discharges occurring in third quarter CY 2011, we proposed to move the HCAHPS data submission deadline forward by one week in order to allow for a review and correction period, which we will propose in future rulemaking. Currently, hospitals have about 14 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse. If this proposal is adopted, 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.

Other than this proposed change, we did not propose any other changes to the HCAHPS requirements for the FY 2013 and FY 2014 Hospital IQR Program payment determinations, which were adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220). For FY 2015 Hospital IQR payment determinations, we proposed to continue the HCAHPS requirements as follows. 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 2015 Hospital IQR Program, we proposed that the HCAHPS data will be based on discharges from January 1, 2013 through December 31, 2013.

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 wish to 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, 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 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 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 a 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) that are available. These reports enable a hospital to ensure that its survey vendor has submitted the data on time and the data has been accepted into the QIO Clinical Warehouse.

In order to ensure compliance with HCAHPS survey and administration protocols, hospitals and survey vendors must 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 wish to 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 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 again are encouraging hospitals to regularly check the HCAHPS Web site at *http://www.hcahpsonline.org* for program updates and information.

Comment: One commenter asked about the purpose of the proposed HCAHPS review and correction period. Another commenter recommended that CMS change its HCHAPS data submission timeline to match the current Joint Commission data submission schedule, which is two weeks earlier than the CMS deadline.

Response: The proposed one-week HCAHPS review and correction period would allow a formal opportunity for hospitals (or their HCAHPS survey vendors) to resubmit data for patients in order to correct errors in the data submitted for those patients prior to the review and correction period.

Given the amount of time necessary for participating hospitals or their survey vendors to fully administer the HCAHPS survey, receive survey responses, and create the necessary data files, we do not believe it is appropriate to further shorten the data submission period either by beginning the period sooner, or ending it sooner.

After consideration of the public comments we received, we are finalizing the HCAHPS requirements discussed above, as proposed.

In the Hospital Inpatient VBP Program proposed rule, we proposed that HCAHPS scores become part of the FY 2013 Hospital VBP Program (76 FR 2462). We adopted that proposal in the Hospital Inpatient VBP Program final rule (76 FR 26510). As HCAHPS scores become incorporated in hospital payment, we believe that a neutral third-party should administer the

survey for hospitals whose annual payment updates will be affected by their HCAHPS scores. It is our belief that an experienced survey vendor will be best able to ensure reliable results. Therefore, we are considering whether to require that-subsection (d) hospitals engage an HCAHPS-approved survey vendor to administer the HCAHPS survey. We invited public comment that will inform our future policy on this issue

Comment: One commenter expressed support for requiring the use of an approved survey vendor to administer the HCAHPS survey when the survey will be used for hospital payment purposes.

Response: We thank the commenter for this suggestion. We are considering this policy change for the future and we will take this suggestion into consideration as we develop future proposals.

g. Procedures for Claims-Based Measures

In the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to adopt a new claims-based measure for FY 2014, the Medicare Spending per Beneficiary Measure, which is included in the chart below.

Topic	FY 2014 Payment determination: adopted and proposed claims-based quality measures (no additional hospital data submission required)
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.
Readmission Measure (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.
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. • Complication/patient safety for selected indicators (composite). • Mortality for selected medical conditions (composite).
AHRQ PSI and Nursing Sensitive Care	• PSI 04 Death among surgical inpatients with serious treatable complications.
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.
Cost Efficiency	• Medicare Spending per Beneficiary.*

* New proposed measure for FY 2014.

We did not propose to change the procedures and time periods we adopted in the FY 2011 IPPS/LTCH PPS final rule for the FY 2012, FY 2013 and FY 2014 payment determinations. For the FY 2014 payment determination, we proposed to use up to 3 years of Medicare FFS claims data to calculate the measures, as appropriate for the measures.

Hospitals are encouraged to regularly check the QualityNet Web site, *http://www.QualityNet.org*, for program updates and information.

We received no comments on these procedures and are finalizing them with the clarification that we will use 3 years of Medicare FFS claims data to calculate the measures.

h. Data Submission Requirements for Structural Measures

Structural measures assess the characteristics and capacity of the provider to deliver quality healthcare. In the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to add one additional structural measure for the FY 2014 payment determination, Participation in a Systematic Clinical Database Registry for General Surgery. Beginning with FY 2013, we proposed to align the submission deadline for all structural measures with the submission deadline for the fourth calendar quarter of the chart-abstracted measures.[34] We proposed to update the period of data collection that hospitals will submit the required registry participation information once annually for the structural measures via a Web-based collection tool between April 1, 2012 and May 15, 2012 with respect to the time period of January 1, 2011 through December 31, 2011. This proposal will give CMS a more complete picture of registry participation as well as synchronize data submissions for structural and chart-abstracted measures. These measures do not require the hospital to participate in a registry.

Below is the list of structural measures we have adopted for the FY 2014 payment determination:

Topic	FY 2014 Payment determination: Structural measures
Cardiac Surgery	• Participation in a Systematic Database for Cardiac Surgery.
Stroke Care	• Participation in a Systematic Clinical Database Registry for Stroke Care.

[34] We corrected this language in the proposed rule in a correction notice published at 76 FR 34633 to remove an incorrect reference to these measures aligning in FY 2014, when in fact they will be aligned starting in FY 2013.

Topic	FY 2014 Payment determination: Structural measures
Nursing Sensitive Care	• Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care.
General Surgery	• Participation in a Systematic Clinical Database Registry for General Surgery.*

* New measure for FY 2014 proposed in the FY 2012 IPPS/LTCH PPS proposed rule and adopted in this final rule.

Comment: Several commenters noted an error in the proposed rule regarding the date of collection and the period of collection for the proposed structural measure as well as the existing structural measures.

Response: We issued a correction notice on this issue on June 14, 2011 (76 FR 34633 through 34634). The correction notice corrected both the period of time for which the data will be corrected as well as the timeframe during which we will actually collect the data. We erroneously stated in the proposed rule at (76 FR 25898) that collection would begin in July 2012 with respect to the time period January 1, 2012 to June 30, 2012, instead of collection to begin in April 2013 with respect to the time period January 1, 2012 through December 31, 2012.

Comment: A few commenters supported the alignment of the data collection for structural measures with the data submission deadline for the fourth quarter of the chart-abstracted measures.

Response: We appreciate the commenters' support for this proposed alignment.

After consideration of the public comments we received, we are finalizing our proposal that, beginning with FY 2013, we are aligning the submission deadlines for all structural measures with the submission deadline for the fourth calendar quarter of the chart-abstracted measures. For FY 2013, hospitals will be required to submit the required registry participation information once annually for the structural measures via a Web-based collection tool between April 1, 2012 and May 15, 2012 with respect to the time period of January 1, 2011 through December 31, 2011. For FY 2014, hospitals will be required to submit the required registry participation information once annually for the structural measures via a Web-based collection tool will be between April 1, 2013 and May 15, 2013 with respect to the time period of January 1, 2012 through December 31, 2012.

i. Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

As discussed above, in the FY 2012 IPPS/LTCH PPS proposed rule we proposed to adopt 2 new HAI measures for the FY 2014 payment determination and 3 HAI measures for FY 2015 payment determination. For FY 2014, only the Catheter Associated Urinary Tract Infection will be adopted. For FY 2015, we are adopting all of the three HAI measures that we proposed: Healthcare Provider Influenza Vaccination, MRSA Bacterimia and C. *Difficile.* Below is the list of HAI measures we are finalizing for the FY 2014 and FY 2015 payment determinations:

Topic	FY 2014 and 2015 Payment determination: Adopted healthcare-associated infection measures (CDC/NHSN)
	• Surgical Site Infection.* • Catheter Associated Urinary Tract Infection.** • Clostridium *Difficile*.*** • Healthcare Provider Influenza Vaccination.*** • MRSA Bacteremia.***

* Measures adopted for FY 2014 payment determination in the FY 2011 IPPS/LTCH PPS final rule.
** Measure adopted for FY 2014 payment determination in this final rule.
*** Measures adopted for FY 2015 payment determination in this final rule.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 259219 through 25920), we proposed to update the current data submission and reporting requirements for these proposed measures. Specifically, we proposed to utilize the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of these measures to NHSN. We refer readers to the CDC's NHSN Web site (*http://www.cdc.gov/nhsn*) for detailed data submission and reporting procedures. We believe that these procedures are feasible because they are already widely used by over 4,000 hospitals reporting HAI data using the NHSN. Our proposal seeks to reduce hospital burden by aligning CMS data submission and reporting procedures with NHSN procedures currently used by hospitals, including hospitals complying with 28 State HAI reporting requirements. The existing data collection and submission timeframes for the HAI measures for the FY 2014 payment determination, which we proposed to use for the HAI measures we have proposed above, are shown below. Hospitals must submit their quarterly data to NHSN for Hospital IQR Program purposes on or around the dates shown in the table below (updates to this will be posted on the QualityNet Web site).

SUBMISSION TIMEFRAMES FOR HAI MEASURES FOR THE FY 2014 PAYMENT DETERMINATION

CY 2012 Infection Events	CDC–NHSN Collection and quarterly report generation timeframe	Final submission deadline for hospital IQR program FY 2014 payment determination
Q1 (Jan–Mar 2012)	January 31st—August 15th	August 15, 2012.
Q2 (Apr–Jun 2012)	April 30th—November 15th	November 15, 2012.
Q3 (Jul–Sep 2012)	July 31st—Feb-15th	February 15, 2013.
Q4 (Oct–Dec 2012)	October 31st—May 15th	May 15, 2013.

Hospitals would have until the Hospital IQR Program final submission deadline to submit their quarterly data to NHSN. After the final Hospital IQR Program submission deadline has occurred for each CY 2012 quarter, CMS will obtain the hospital-specific calculations that have been generated by the NHSN for the Hospital IQR Program.

We invited public comment on this proposal.

Comment: A few commenters requested clarification of the data collection dates for the MRSA and C. *Difficile* SIR measures for FY 2015 payment determination.

Response: For the FY 2015 payment determination, data collection will begin with January 1, 2013 events.

After consideration of the public comments we received, we will adopt the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of these measures to NHSN as listed above.

6. Chart Validation Requirements for Chart-Abstracted Measures

a. Changes to the Chart Validation Requirements and Methods for the FY 2012 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25920 through 25922), we proposed several changes to the chart validation requirements and methods we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225 through 50229) for the FY 2012 payment determination and subsequent years. In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45 days from the date of the request to submit the requested records. If any record(s) were not received by the 45-day requirement, the CMS CDAC contractor assigned a ''zero'' validation score to each measure in a missing record. We proposed to change the time period given to hospitals to submit medical records to the CDAC contractor to 30 calendar days, and we proposed to codify this proposal at 42 CFR 412.140(d)(1). This proposed change in submission timeframe will align the current process with the requirements in 42 CFR 476.78(b)(2), which currently allow only 30 days for chart submission in the context of reviews by QIOs. We proposed this deadline modification to reduce the time we need to complete validation, and provide hospitals with feedback on their abstraction accuracy. We believe that this linkage between Hospital IQR Program validation discharge quarters and the same fiscal year's Hospital VBP Program proposed performance period would improve the reliability and accuracy of the Hospital VBP Program's chart-abstracted measures. Hospitals that are subject to Hospital IQR payment reduction due to not passing our validation requirement would be excluded from receiving a Hospital VBP performance score and corresponding incentive payment under section 1886(o)(1)(C)(ii)(I) of the Act. Thus, CMS would ensure that the data submitted on chart-abstracted measures we adopt for the Hospital VBP Program is accurate by virtue of validating it under the validation procedures we have adopted for the Hospital IQR Program.

Comment: A few commenters recommended that CMS consider options to receive electronic copies of records rather than paper records.

Response: We appreciate the feedback and will consider the suggestion in developing future rulemaking to reduce the validation burden to hospitals using electronic health records. We recognize that many more hospitals will transition their recordkeeping to EHRs in the coming years, and we will strive to provide the public with accurate quality data while maintaining alignment with hospital recordkeeping practices.

Comment: Most commenters supported the reduction in the time frame for hospitals to submit the requested records to the CDAC contractor from 45 calendar days to 30 calendar days if the reduction will improve the timeliness of feedback to the hospitals.

Response: We appreciate the input and believe that the reduction will improve the timeliness of feedback to the hospitals.

Comment: Some commenters oppose the reduction in the time frame as this decrease in the timeframe would negatively impact hospitals' capability to respond in a timely manner and could negatively affect hospitals' ability to perform quality checks.

Response: We appreciate the comment, but believe that decreasing the time frame for chart submission will allow CMS to provide more timely feedback to hospitals on the validation results.

Comment: One commenter believed that validating Hospital VBP data under the Hospital IQR Program data would efficiently use both CMS and hospital resources.

Response: We appreciate the commenter's support for this proposal.

After consideration of the public comments we received, we are adopting as final our proposal to change the time period given to hospitals to submit medical records to the CDAC contractor from 45 to 30 calendar days, and are codifying this policy at 42 CFR 412.140(d)(1).

b. Supplements to the Chart Validation Process for the FY 2014 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25920 through 25922), we proposed to continue to use the supplements to the chart validation requirements and methods we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227 through 50229) for FY 2014 payment determinations and future years with several proposed modifications.

We proposed to add hospitals to our validation sample if they were open under their current CCNs in FY 2012 but not selected for validation in the three previous annual Hospital IQR Program validation samples. We proposed this addition to supplement our validation approach to ensure that all eligible Hospital IQR Program hospitals are selected for validation at least once every 4 years. We proposed this addition starting in FY 2015 because FY 2015 would be the fourth year that CMS would have used the random validation approach (which begins in FY 2012 as adopted in the FY 2011 IPPS/LTCH PPS final rule). We invited public comment on this proposal.

Comment: One commenter disagreed with the policy we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50229) to conduct random sampling of hospitals, and believes that CMS should utilize the charts provided to the QIOs to identify hospitals potentially submitting poor quality data.

Response: Section 1886(b)(3)(B)(viii)(XI) of the Act states that ''the Secretary shall establish a process to validate measures specified under this clause as appropriate. Such process shall include the auditing of a number of randomly selected hospitals sufficient to ensure validity of the reporting program under this clause as a whole and shall provide a hospital with an opportunity to appeal the validation of measures reported by such hospital.'' We believe that our FY 2012 Hospital IQR Program validation process meets the requirement regarding randomly selected hospitals in section 1886(b)(3)(B)(viii)(XI) of the Act. While we appreciate the commenter's concern, we believe that by ensuring all hospitals are validated at least once every four years, we will ensure that hospitals with poor data are identified. In addition, we note that, under the policy that we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227 through 50229),

hospitals that fail validation for the FY 2012 payment determination and subsequent years will be selected for validation the following year to ensure deficiencies are corrected.

Comment: Most commenters supported a requirement that eligible hospitals be selected at least once every four years for validation. Most commenters also stated that because CMS intends to use the results of Hospital IQR chart validation for the Hospital VBP Program, all eligible hospitals should be regularly included in the chart validation process.

Response: We appreciate the commenters' support for this proposal to ensure that all hospitals are validated at least once every 4 years.

After considering the public comments we received, we are adopting as final the proposal to supplement our validation approach to ensure that all eligible Hospital IQR Program hospitals are selected for validation at least once every 4 years.

Starting with the FY 2012 payment determination and continuing in subsequent fiscal years, the chart validation process audits 800 randomly selected hospitals for the discharge quarters. This sample size is sufficient to validate more than 22 percent of subsection (d) hospitals in an applicable fiscal year and ensure accuracy of the Hospital IQR Program quality data.

For the FY 2014 payment determination, we proposed to validate 24 chart-abstracted measures including 19 currently validated measures, and 5 proposed additional measures. The FY 2014 proposed validation reflects the 5 measures we proposed to add (2 EDT measures, Central Line Associated Blood Stream Infection, Global Influenza Immunization, and Global Pneumonia Immunization measures) and the 8 measures we proposed to retire (AMI–1, AMI–3, AMI–4, AMI–5, HF–4, PN–4, PN–5c, and SCIP Infection 6).

Validation of the HCAHPS measure is conducted through our oversight activities. We provide oversight of all HCAHPS survey vendors and hospitals self-administering the survey in order to ensure that the data collection protocols are followed. We also provide oversight and validation through our review of Quality Assurance Plans, site visits, conference calls and detailed data analyses each quarter to ensure there are no anomalies found in the data. In particular, we use site visits to review all data collection activities, including data reviews to track a discharged patient from sampling to survey administration to data submission.

We proposed, starting with FY 2014 payment determinations, a modest increase to the current Hospital IQR Program validation sample of SCIP, AMI, HF, and PN cases. Specifically, we proposed to add three charts per selected hospital per quarter to the validation sample. This additional quarterly sample would enable us to validate the CLABSI measure that we added to the Hospital IQR Program measure set beginning with the FY 2014 payment determination. CLABSI is a relatively rare event compared to SCIP, AMI, HF, and PN cases. In 2009, about 18,000 CLABSIs occurred in ICU patients in the United States, and these infections were a major contributor to prolonged hospital stays and inpatient mortality. We proposed a process to validate the CLABSI measure that takes into account the relative infrequency of this event and the case-finding methodology for it, specifically the requirements for a positive blood culture result and the presence of a central venous catheter in the patient at the time of, or within 48 hours before, onset of the infection.

We recognize that the current validation process and sample size for AMI, HF, PN, and SCIP measures is not likely to be sufficiently reliable to detect systematic underreporting of CLABSI. Unlike the current AMI, HF, PN, and SCIP chart-abstracted process of care measures, CLABSI is a rarely occurring infection among acute care inpatient discharges. We estimate that about 0.1 percent to 0.2 percent of all acute care inpatient patient discharges nationwide involve patients who are infected with a CLABSI. We believe that our current Hospital IQR Program AMI, HF, PN, and SCIP sample sizes and sample methods would not reliably validate CLABSI measure rates at the hospital level because of the relatively rare occurrence of these events. We also seek to target validation of the CLABSI measure to minimize hospital burden in complying with our sample size proposals, for which hospitals must find, photocopy, and return requested medical records to CMS. If CMS did not utilize this targeted validation approach for the CLABSI measure, hospitals would have to submit 200 to 300 additional randomly selected cases in order to effectively validate this measure, given its rare occurrence. We believe that our proposed CLABSI validation process addresses these limitations through the use of a targeted incremental validation sample comprised of three charts of possible CLABSI events, and will reliably validate the Hospital IQR Program CLABSI measure while not overly burdening hospitals with medical record requests.

Specifically, we proposed to identify sampled hospitals' three quarterly potential CLABSI charts using a two-step selection process that would target intensive care unit patients with bloodstream infection (positive blood culture results) and a Central Venous Catheter (CVC) provided by sampled hospitals to CMS. In the first step of this process, a CMS contractor would require the 800 randomly sampled hospitals to provide a quarterly list of all blood cultures positive for infection status taken from intensive care units conducting CLABSI surveillance during the discharge quarter. We are aware that this list will include both reported CLABSI events and many non-CLABSI events, including patients with and without CVCs. In clinical terms, our intent in reviewing these positive blood culture lists is to identify the information needed to determine whether the blood culture isolate is a likely pathogen found at least once, or a common skin commensal (CSC) found in two or more positive blood cultures drawn on separate occasions. CSC's are microorganisms that are commonly found on the skin and often indicate contamination of the blood culture media rather than infection by the microorganism when it is identified in a single blood culture test. Two sets of blood cultures are needed to differentiate true infection from contamination. The list of CSCs is comprised of the following organisms: diphtheroids (*Corynebacterium* spp.); *Bacillus* spp. (not *B. anthracis*); *Priopionibacterium* spp.; coagulase negative staphylococci including *S. epidermidis*; viridans group streptococci; *Aerococcus* spp.; and *Micrococcus* spp. This list of CSCs is also found at the NHSN Web site, *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf*. We would also require hospitals to self-identify intensive care unit patients with a CVC that are on this blood culture list. Using all of this information, we would be able to identify intensive care unit patients with a bloodstream infection and with a CVC (that is, candidate CLABSI events) for subsequent sampling.

In the second step of this process, we would randomly sample these candidate CLABSI events (ICU patients with a CVC and where a pathogen was recovered at least once or the same CSC was cultured from 2 or more blood cultures drawn on separate occasions). Specifically, the CMS CDAC would require hospitals to submit up to 3 medical records each quarter meeting these criteria, randomly selected by

CMS from among eligible charts. This number of medical records is sufficient to detect unreported CLABSI events based on our sample size analysis and experience from State health department validation efforts. This proposed process utilizes the validation experience from at least ten current State health department validation initiatives. In addition, we proposed to randomly validate CLABSI data by abstracting all necessary quality data from the 12 quarterly medical records in our AMI, HF, PN, and SCIP targets already collected for Hospital IQR Program validation as well as the 3 additional records we later propose to collect for ED throughput/ Immunization. Our intent in validating all currently requested quarterly medical records for CLABSI is to assess reliability of CLABSI measure rates from a random sample of patients independent from the proposed 3 record sample selected using blood culture lists and CVC presence to target underreporting of CLABSI events to the CDC's NHSN. In our proposed 12 record random sample of CLABSI events, we will not use blood culture list and CVC presence in our sampling, since this sample is already drawn from the AMI, HF, PN, and SCIP hospital reported data reported to CMS. By combining a random and targeted sampling approach using two independent sources to validate CLABSI data, we believe that we are adequately assessing the accuracy and reliability of the CLABSI measure in accordance with section 1886(b)(3)(B)(viii)(XI) of the Act.

We proposed to determine the CLABSI validation score using a process that begins with the CMS contractor validation coordinator comparing the CDAC's CLABSI infection status to the hospital's event data reported to NHSN for the applicable quarter. For each medical record reviewed, a hospital would receive a match only if the CMS contractor validation coordinator determines equivalency between the CMS contractor's determination of infection status and the infection status reported to NHSN. For example, if one of the CMS-requested validation medical records revealed CLABSI and the event was not reported to the NHSN, then the hospital would receive a zero score for the CLABSI measure for that validated record. If the CMS contractor discovered that a second record in the CMS validation sample indicated no CLABSI event, but a CLABSI was reported to the NHSN for the record, the hospital would also receive a zero score for the CLABSI measure for that validation record. Thus, hospitals would only receive a 100 percent CLABSI validation score for individual records if their CMS validation records' CLABSI status was consistent with the information reported, or not reported, to NHSN. In the above example, if the CMS quarterly validation process identified that 13 out of 15 total sampled records accurately reported the presence of a CLABSI or did not report a CLABSI where none was present, then the hospital's CLABSI validation score would be 13/15, or about 87 percent.

Comment: One commenter suggested that the CLABSI chart validation process, which uses CDC criteria for identification of CLABSI events, requires experienced interpretation and is more subjective than current validation measure criteria. The commenter believed that CMS should validate mismatches using a Certified Infection Control Practitioner. The commenter recommended excluding the validation results for CLABSI from the overall score for the initial year of validation and allowing hospitals to appeal CLABSI mismatches regardless of the overall score in order to educate hospitals on CLABSI mismatches.

Response: We appreciate the comment, and plan to provide educational feedback on all validated CLABSI cases on match status and abstracted reasons for CLABSI event status to hospitals. Based on the relatively rare nature of CLABSI events, we anticipate a relatively high match rate among hospitals surpassing the current 75 percent passing threshold. Based on this information, we believe that the proposed approach to validate CLABSI data is the least burdensome and most statistically sound approach. We also believe that providing hospitals with the opportunity to appeal validated cases that do not affect the overall score would delay completion of the entire appeals process.

Comment: Some commenters did not support what they believed to be a manual and time consuming record identification process and expressed concerned that CMS has not identified exactly what data elements should be on the quarterly list of blood cultures positive for infection or what format would be used for submitting the list to CMS.

Response: We appreciate the input and are aware of the additional time required by this process. We included this burden in our Paperwork Reduction Act burden request for public review and OMB consideration. However, we believe the need to ensure that information reported to the public is accurate and validated outweighs the additional burden. We will provide additional information regarding the exact data elements and format for submission of the quarterly list of blood cultures positive for infection in future communications.

Comment: One commenter expressed concern that the proposed CLABSI validation sample of three charts is not a sufficient sample.

Response: We appreciate the commenter's concern about the sample size for validation. However, the number of charts to be validated for CLABSI is actually 18 charts, not 3 charts. As stated above, in addition to validating the 3 CLABSI charts submitted by hospitals as part of the targeted CLABSI sample, we will also validate CLABSI data elements on the other 15 quarterly charts that are submitted for the AMI, HF, PN, SCIP and ED throughput/Immunization measures. Our intent in including three additional quarterly charts in the CLABSI validation sample is to target CLABSI events unreported to NHSN by using blood culture lists and ICU status to increase targeting efficiency. In addition, we weighed the burden to hospitals, the reliability of hospital validation results in the sample size, and the program costs of validation expenses when proposing the sample size. We believe these considerations support our proposal to use a three-chart validation sample for CLABSI.

Comment: One commenter expressed concern that the process of requiring hospitals to submit two additional lists and three charts has the potential to introduce new errors into the system and additional penalties for hospitals. The commenter recommended that the proposal be piloted and the burden assessed.

Response: We appreciate the input and are aware of the additional time required by this process. However, we believe that this process will allow us to validate the CLABSI measure in the most efficient way possible. Although a pilot was not conducted, we collaborated with CDC and used the experience of State hospital health departments in validating CLABSI information in formulating this proposal.

Comment: One commenter was concerned that CMS has not estimated the burden of work required for 800 hospitals to provide a quarterly list of blood cultures positive for infection status taken from ICUs conducting CLABSI surveillance during the discharge quarter. The commenter believed that additional consideration should be given to the time burdens on hospitals should they have to note on this list which samples came from

patients with CVCs in the ICUs under surveillance. The commenter believed that the practice of looking for unreported CLABSI cases among charts sent for AMI, HF, PN and SCIP measures may not be fruitful because only a small proportion of these patients will be in the ICU with CVCs. The commenter also questioned whether the proposed scoring model has been tested, if there has been any direct pilot experience with matching this data against NHSN data, and if there are reasons why cases omitted from NHSN would show up on the ICU blood culture list (or vice versa).

Response: We appreciate the input and are aware of the additional time required by this process. We included this burden in our Paperwork Reduction Act burden request for public review and OMB consideration. However, we believe the need to ensure that information reported to the public is accurate and validated outweighs the additional burden. Although a pilot was not conducted, we collaborated with CDC and used the experience of State hospital health departments in validating CLABSI information in formulating this proposal. We believe that this process is less burdensome to hospitals than other options considered, including CMS onsite chart review and larger samples. We recognize that only a small proportion of cases for AMI, HF, PN, and SCIP patients will be in the ICU, however, we believe that validating the existence or absence of CLABSI and the associated match in NHSN for those limited cases will result in an appropriately validated quality measure.

Comment: Several commenters urged CMS to evaluate whether or not the list can be procured from information that is stored in the NHSN.

Response: The intent of the supplemental CLABSI sample of three quarterly charts is to target CLABSI events unreported to NHSN by using blood culture lists and ICU status to increase targeting efficiency. We believe that using reported NHSN events as the sole validation sample list would ignore the possibility of unreported CLABSI events. We intend to continue our collaboration with CDC in the future to assess and improve our validation process.

After consideration of the public comments we received, we are adopting as final the proposal to identify sampled hospitals' three quarterly potential CLABSI charts using the two-step selection process outlined above as well as abstracting all necessary quality data from the 15 quarterly medical records in our AMI, HF, PN, SCIP and ED Throughput/Immunization charts already collected for Hospital IQR Program validation.

Starting with the FY 2014 payment determination, we also proposed to add a sixth quarterly sample, which would enable us to validate the EDT measures and the Immunization for Influenza and Immunization for Pneumonia global measures that we added to the Hospital IQR Program measure set. We proposed to modify the current process (75 FR 50225–75 FR 50229) for these measures in two ways. First, we proposed to select 3 additional records each quarter from the records submitted by the 800 annually sampled hospitals. These records would only include 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. Second, we would abstract EDT and the Immunization for Influenza and Immunization for Pneumonia global measure data from the 15 quarterly AMI, HF, PN, SCIP and CLABSI records already submitted by hospitals for Hospital IQR Program validation. We would validate 18 records per quarter for these measures. With the addition of this sample of three records, we would ensure that all hospitals that reported chart-abstracted Hospital IQR data in all principal procedure and diagnosis codes would be eligible for sample selection for these global measures, thus, starting in FY 2014, we would be validating a total of 18 records per quarter per validated hospital in 6 strata (1) SCIP, (2) AMI, (3) HF, (4) PN, (5) CLABSI, and (6) EDT/immunization measures.

Comment: Several commenters supported the increased number of charts for validation in the Hospital IQR Program and believe the additional charts will enhance the validation process.

Response: We appreciate the commenters' support for this proposal.

After consideration of the public comments we received, starting with FY 2014, we are adding a sixth quarterly sample to validate the EDT measures and the Immunization for Influenza and Immunization for Pneumonia global measures and to modify the current process as described above.

7. QIO Regulation Changes for Provider Medical Record Deadlines Possibly Including Serious Reportable Events

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25922 through 25923), we proposed changes to the QIO regulation text to require submission of medical records within 21 days of serious reportable events. Our State QIOs use information collected under the provision we proposed to change, 42 CFR 476.78, to educate hospitals on medical record abstraction accuracy, and to identify potential opportunities for quality improvement through medical record review. It is our goal to improve QIO work, such as quality improvement assistance, beneficiary (or beneficiary representative) requested QIO quality of care reviews, and QIO medical necessity reviews to achieve the following three aims: (1) Improve individual care; (2) improve health for populations; and (3) lower cost through improvement. QIOs serve a critical role in advancing these three aims through their work with Medicare providers and beneficiaries to advance quality care and health.

To assist us in achieving these aims, we proposed changes to 42 CFR 476.78(b), along with minor editorial revisions. Specifically, we proposed to add a new § 476.78(b)(2)(ii) that would require the submission of medical information within 21 days in those situations in which a ''serious reportable event'' or other circumstance has been identified during the course of a QIO review. For purposes of this subsection, we proposed to define the term ''serious reportable event'' to be consistent with the NQF's definition of a serious reportable event in its report ''Serious Reportable Events in Healthcare 2006 Update.'' These events include the following:

Surgical Events

- Surgery performed on the wrong body part.
- Surgery performed on the wrong patient.
- Wrong surgical procedure performed on a patient.
- Unintended retention of a foreign object in a patient after surgery or other procedure.
- Intraoperative or immediately postoperative death in an ASA Class I patient.

Product or Device Events

- Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility.
- Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended.
- Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.

Patient Protection Events

- Infant discharged to the wrong person.

• Patient death or serious disability associated with patient leaving the facility without permission.

• Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility.

Care Management Events

• Patient death or serious disability associated with a medication error (for example, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration).

• Patient death or serious disability associated with a hemolytic reaction (abnormal breakdown of red blood cells) due to the administration of ABO/HLA—incompatible blood or blood products.

• Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility.

• Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.

• Death or serious disability associated with failure to identify and treat hyperbilirubinemia (condition where there is a high amount of bilirubin in the blood) in newborns.

• Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.

• Patient death or serious disability due to spinal manipulative therapy.

• Artificial insemination with the wrong donor sperm or wrong egg.

Environmental Events

• Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility.

• Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.

• Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility.

• Patient death or serious disability associated with a fall while being cared for in a healthcare facility.

• Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.

Criminal Events

• Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.

• Abduction of a patient of any age.

• Sexual assault on a patient within or on the grounds of a healthcare facility.

• Death or significant injury of a patient or staff member resulting from a physical assault (that is, battery) that occurs within or on the grounds of a healthcare facility.

This proposed 21 day medical record deadline would be used when, for example, in the QIO's judgment, delays in receiving medical information could negatively undermine its efforts to evaluate the quality of care provided or the facility's adherence to payment policies. It also would enable QIOs to better utilize, and respond to, information about adverse events gained from the quality reporting program, in a timely fashion so that QIOs can have an improved and more immediate impact on the quality of health care.

We also proposed a technical correction to 42 CFR 476.78(a) to correct a cross-reference.

We invited public comment on our proposal to improve patient care through QIO access to more rapid provider information about ''serious reportable events'' and our proposed technical correction to 42 CFR 476.78(a).

Comment: One commenter supported the regulation changes to require submission of medical information within 21 days of serious reportable events and wanted the investigation of these most serious and NQF-defined events to quickly evaluate the quality of care, to have a more immediate impact, and to prevent other such terrible events from occurring in a facility again.

Response: We agree with the commenter and appreciate the support for this proposal.

Comment: One commenter expressed concern that asking hospitals to report serious reportable events to both Patient Safety Organizations and to QIOs would create a duplication and undue burden on hospitals.

Response: We appreciate the commenter's concern but wish to clarify that this proposal does not change any existing requirements for reporting serious reportable events. This proposal would simply reduce the current submission requirement from 30 days to 21 days.

Comment: One commenter asked that CMS clarify the term ''medical information.'' The commenter asked whether this term refers to the complete medical record or to portions of the medical record. The commenter also asked what CMS requires if the medical record is not yet complete.

Response: We thank the commenter for these questions and refer the commenter to 42 CFR 476.78(b) and 42 CFR 482.24. Hospitals, under these regulations in our conditions of participation, are required to provide patient care data and other pertinent information to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. This information includes, but is not limited to, the medical record.

After consideration of the public comments we received, we are adopting the requirement that hospitals submit medical information within 21 days in those situations in which a ''serious reportable event'' or other circumstance has been identified during the course of a QIO review. We also are finalizing our proposed technical correction to 42 CFR 476.78(a) to correct a cross-reference.

8. Data Accuracy and Completeness Acknowledgement Requirements for the FY 2012 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25923), we proposed to require hospitals to continue to electronically acknowledge their data accuracy and completeness once annually. However, we proposed to change the submission deadline to be used for the FY 2013 Hospital IQR Program payment determination and subsequent years.[35] This proposal will allow us to align the submission deadline with the final quarter of the chart-abstracted measures. Hospitals will continue to submit the required electronic acknowledgment that the data provided to meet the FY 2013 Hospital IQR Program data submission requirements is accurate and complete to the best of the hospital's knowledge at the time of data submission.[36] We proposed to make the submission deadline for the Data Accuracy and Completeness Acknowledgement May 15, 2012 with respect to the time period of January 1, 2011 through December 31, 2011. We invited public comment on this proposal.

Comment: A few commenters supported the alignment of the Data

[35] In a correction notice published at (76 FR 34633), we corrected an erroneous reference in the proposed rule to the fiscal year for which it proposed to change the submission deadline for the Data Accuracy and Completeness Acknowledgement. The reference to this period in this sentence was changed from FY 2012 to FY 2013.

[36] In a correction notice published at (76 FR 34633), we corrected an erroneous reference in the proposed rule to the fiscal year for which it proposed to change the submission deadline for the Data Accuracy and Completeness Acknowledgement. The reference to this period in this sentence was changed from FY 2012 to FY 2013.

Accuracy and Completeness Acknowledgement with the data submission deadline for the fourth quarter of the chart-abstracted measures.

Response: We appreciate the commenters' support on this proposal.

After consideration of the public comments we received, we are adopting the submission deadline for the Data Accuracy and Completeness Acknowledgement of May 15, 2012 with respect to the time period of January 1, 2011 through December 31, 2011.

9. Public Display Requirements for the FY 2014 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25923), we proposed to continue, 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.

The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* Web site *http://www.hospitalcompare.hhs.gov,* but on occasion are reported on other CMS Web sites. 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.

We invited public comment on this proposal.

We did not receive any comments related to this proposal and are, therefore, finalizing it.

10. Reconsideration and Appeal Procedures for the FY 2012 Payment Determination

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25923 through 25925), we proposed to continue, for the FY 2012 payment determination and subsequent years, the general approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) for reconsideration and appeal procedures for the FY 2011 payment determination. We also proposed to codify the requirements under this process at 42 CFR 412.140(e). We discuss each of the regulatory provisions that we proposed, as well as specific changes, below.

We proposed that the general deadline for submitting a request for reconsideration in connection with the FY 2012 payment determination will be 30 days from the date of receipt of the payment determination notification. Historically, most reconsideration requests are based on the failure to meet established data submission deadlines. While we want to ensure that hospitals have an opportunity to request reconsiderations when warranted, we also need to balance this goal with our need to complete the reconsideration process in a timely manner and with the hospitals' desire to obtain final decisions on their requests in a timely manner. Therefore, we proposed to reduce the reconsideration and appeal period from a deadline of November 1st 2012 to 30 days after hospital receipt of the payment determination notification. Notifications will be sent via a trackable mail option such as certified U.S. mail or registered mail. We include this change in the proposed § 412.140(e)(1).

As discussed more fully below, we proposed that all hospitals submit a request for reconsideration and receive a decision on that request before they can file an appeal with the Provider Reimbursement Review Board (PRRB). For the FY 2012 payment determination, we proposed to continue utilizing many of the same procedures that we used for the FY 2011 requests for reconsideration. However, we clarified that a hospital must submit all documentation and evidence that supports its request for reconsideration at the time that it submits its request. This includes copies of any communications, such as e-mails that the hospital believes demonstrate its compliance with the program requirements, as well as all paper medical records that support the hospital's rationale for seeking reconsideration. The information that must be included when a hospital submits a reconsideration request has been listed in proposed § 412.140(e)(2). Under these proposed procedures, the hospital must:

—Submit to CMS, via QualityNet, a Reconsideration Request form (available on the QualityNet Web site) containing the following information:
—Hospital CMS Certification number (CCN).
—Hospital Name.
—CMS-identified reason for failure (as provided in the CMS notification of failure letter to the hospital).
—Hospital basis for requesting reconsideration. This must identify the hospital's specific reason(s) for believing it met the Hospital IQR Program requirements and should receive the full update to the standardized amount.
—CEO contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box). We note that to the extent a hospital can submit a request for reconsideration on-line, the burden on our staff would be reduced and, as a result, we can more quickly review the request.
—QualityNet System Administrator contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box).
—Paper medical record requirement for reconsideration requests involving validation. We proposed that if a hospital asks us to reconsider an adverse Hospital IQR Program payment decision made because the hospital failed the validation requirement, the hospital must submit paper copies of all the medical records that it submitted to the CDAC contractor each quarter for purposes of the validation. Hospitals must submit this documentation to a CMS contractor. The contractor will be a QIO support contractor, which has authority to review patient level information under 42 CFR Part 480. We proposed to post the address where hospitals can ship the paper charts on the QualityNet Web site after we issue the FY 2012 IPPS/LTCH PPS final rule.

Hospitals submitting a Hospital IQR Program validation reconsideration request will have all data elements to be reconsidered reviewed by CMS, and not their State QIO. (The State QIO is available to conduct a quarterly validation appeal if requested to do so by a hospital.)

Hospitals must provide a written justification for each appealed data element classified during the validation process as a mismatch. We will review the data elements that were labeled as mismatched, as well as the written justifications provided by the hospitals, and make a decision on the reconsideration request.

As we mentioned above, a hospital that submits a reconsideration request to CMS must receive a decision on that request prior to submitting a PRRB appeal. We believe that the reconsideration process is less costly for

both CMS and hospitals, and that it decreases the number of PRRB appeals by resolving issues earlier in the reconsideration and appeals process. We proposed language at § 412.140(e)(3) stating that a hospital that receives an adverse decision on its reconsideration request may appeal that decision to the PRRB.

Following receipt of a request for reconsideration, we will—

• Provide an e-mail acknowledgement, using the contact information provided in the reconsideration request, to the CEO and the QualityNet Administrator that the request has been received.

• Provide written notification to the hospital CEO, using the contact information provided in the reconsideration request, regarding our decision. We expect the process to take approximately 90 days from the receipt of the reconsideration request.

We proposed to continue for the FY 2012 Hospital IQR Program reconsideration and future years the scope of review when a hospital requests reconsideration because it failed our validation requirements, which we adopted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43892). The scope of this review will be as follows:

1. *Hospital requests reconsideration for CDAC contractor-abstracted data elements classified as mismatches affecting validation scores.* Hospitals must timely submit a copy of the entire requested medical record to the CDAC contractor during the quarterly validation process for the requested case to be eligible to be reconsidered on the basis of mismatched data elements. Only hospitals that fail to meet the passing threshold for the quarterly validation would receive an opportunity to appeal the validation results to their State QIO.

2. *Hospital requests reconsideration for medical record copies submitted during the quarterly validation process and classified as invalid record selections.* Invalid record selections are defined as medical records submitted by hospitals during the quarterly validation process that do not match the patient's episode of care information as determined by the CDAC contractor (in other words, the contractor determines that the hospital returned a medical record that is different from that which was requested). If the CDAC contractor determines that the hospital has submitted an invalid record selection case, it awards a zero validation score for the case because the hospital did not submit the entire copy of the medical record for that requested case. During the reconsideration process, our review of invalid record selections will initially be limited to determining whether the record submitted to the CDAC contractor was actually an entire copy of the requested medical record. If we determine during reconsideration that the hospital did submit the entire copy of the requested medical record, then we would abstract data elements from the medical record submitted by the hospital.

3. *Hospital requests reconsideration for medical records not submitted to the CDAC contractor within the proposed 30 calendar day deadline.* Our review will initially be limited to determining whether the CDAC contractor received the requested record within the proposed 30 calendar days, and whether the hospital received the initial medical record request. If we determine during reconsideration that the CDAC contractor did receive a paper copy of the requested medical record within the proposed 30 calendar days, then we would abstract data elements from the medical record submitted by the hospital. If we determine that the hospital received a request for medical records and did not submit the requested records within the proposed 30 day period, CMS will not accept these records as part of the reconsideration. CMS will not abstract data from charts not received timely by the CMS contractor. Please note that this proposed language is also designed to address those instances where the hospital's request is based on ''invalid record selections,'' which we have defined as medical records submitted during the quarterly validation process that do not match the patient's episode of care information as determined by the CMS contractor as described above in situation 2, above ''Hospital requests reconsideration for medical record copies submitted during the quarterly validation process and classified as invalid record selections.''

In sum, we proposed to continue to initially limit the scope of our reconsideration reviews involving validation to information already submitted by the hospital during the quarterly validation process, and we will not abstract medical records that were not submitted to the CMS contractor during the quarterly validation process. We would expand the scope of our review only if we find during the initial review that the hospital correctly and timely submitted the requested medical records. In that case, we would abstract data elements from the medical record submitted by the hospital as part of our review of its reconsideration request.

If a hospital is dissatisfied with the result of a Hospital IQR Program reconsideration decision, the hospital may file an appeal under 42 CFR Part 405, Subpart R (a PRRB appeal). We invited public comment on the extent to which these proposed procedures will be less costly for hospitals, and whether they will lead to fewer PRRB appeals.

Comment: Several commenters supported CMS' proposal to reduce the timeframe for appeals from November 1st to 30 days from the date of receipt of the payment determination notification because it would shorten the reconsideration and appeals process, thereby allowing hospitals who successfully appeal CMS' decision to receive their full annual payment update in a more expedited manner.

Response: We agree and appreciate the commenters support for this proposal.

Comment: One commenter opposed the proposal to shorten the timeframe and argued that because many hospitals may decide to retain an attorney for a reconsideration request, and because of the time it takes to coordinate an appeal with an attorney, the deadline should remain at November 1 annually.

Response: We appreciate the commenter's input regarding the time necessary to coordinate a reconsideration request. However, we believe that hospitals will have adequate time to evaluate whether to request reconsideration under this proposal and that the benefits of a faster reconsideration process outweigh any potential inconvenience to hospitals.

In summary, we thank the commenters for their input. We believe our reconsideration process, including the proposed shorter timeframe for requesting reconsideration, is minimally burdensome. The form for reconsiderations and a detailed description of the reconsideration process are available at *http://qualitynet.org* >Hospitals-Inpatient> APU Reconsideration.

After consideration of the public comments we received, we are finalizing the reconsideration process we proposed, including the proposal that the general deadline for submitting a request for reconsideration in connection with the FY 2012 payment determination will be 30 days from the date of receipt of the payment determination notification.

11. Hospital IQR Program Disaster Waivers

In our experience, there have been times when hospitals have been unable to submit required quality data due to extraordinary circumstances that are not

within their control. It is our goal to not penalize hospitals for such circumstances or unduly increase their burden during these times. Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25925) we proposed to continue, for the FY 2014 and subsequent years payment determinations, the process we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225), for hospitals 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 hospital. Under the process, in the event of extraordinary circumstances, such as a natural disaster, not within the control of the hospital, for the hospital to receive consideration for an extension or waiver of the requirement to submit quality data for one or more quarters, a hospital 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:

- Hospital CCN;
- Hospital Name;
- CEO and any other designated personnel contact information, including name, e-mail address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);
- Hospital's reason for requesting an extension or waiver;
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the hospital will again be able to submit Hospital IQR Program data, and a justification for the proposed date.

The request form must be signed by the hospital's CEO. We proposed that a request form must be submitted within 30, rather than 45, days of the date that the extraordinary circumstance occurred. The QIO in the hospital's State will forward the request form to CMS. Following receipt of the request form, CMS will: (1) Provide a written acknowledgement using the contact information provided in the request, to the CEO and any additional designated hospital personnel, notifying them that the hospital's request has been received; and (2) provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of our decision.

This proposal does not preclude CMS from granting waivers or extensions to hospitals that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane), affects an entire region or locale. If CMS makes the determination to grant a waiver or extension to hospitals in a region or locale, CMS proposes to communicate this decision through routine communication channels to hospitals, vendors and QIOs, including but not limited to issuing memos, e-mails and notices on the QualityNet Web site. We proposed to include an overview of this process in proposed 42 CFR 412.140(c)(2). We invited public comment on this proposal.

Comment: One commenter expressed concern with the proposed reduction in the timeframe for submission noting that during truly devastating events, it may take more than 30 days for complete restoration of electronic communication that CMS depends upon to post forms, post notices, and issue e-mails. The commenter recommended that the waiver process not only be permitted electronically, but also through use of U.S. Postal Service where electronic communications have not been established.

Response: We appreciate the commenter's input and recognize that during truly devastating events complete restoration of electronic communication could take more than 30 days. However, the form can be completed and submitted using the U.S. Postal Service, fax or electronic submission. In addition, a hospital can request the assistance of their State QIO to complete and submit the form. We also note that we may grant an extension or waiver, to hospitals that have not requested them, of one or more submission deadlines in extraordinary circumstances that affect an entire region or locale.

Comment: Many commenters stated they had no objections to reducing the timeframe for waiver submissions.

Response: We appreciate the commenters' support for the proposal.

After consideration of the public comments we received, we are adopting as final the process that requires that a request form must be submitted within 30, rather than 45, days of the date that the extraordinary circumstance occurred.

12. Electronic Health Records (EHRs)

a. Background

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of EHRs (also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from the EHRs directly to a CMS data repository (70 FR 47420 through 47421). We sought to prepare for future EHR submission of quality measures by sponsoring the creation of electronic specifications for quality measures under consideration for the Hospital IQR Program.

b. HITECH Act EHR Provisions

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes payment incentives under Medicare for the adoption and use of certified EHR technology beginning in FY 2011. Hospitals are eligible for these payment incentives if they meet requirements for meaningful use of certified EHR technology, which include reporting on quality measures using certified EHR technology. With respect to the selection of quality measures for this purpose, under section 1886(n)(3)(A)(iii) of the Act, as added by section 4102 of the HITECH Act, the Secretary shall select measures, including clinical quality measures, that hospitals must provide to CMS in order to be eligible for the EHR incentive payments. With respect to the clinical quality measures, section 1886(n)(3)(B)(i) of the Act requires the Secretary to give preference to those clinical quality measures that have been selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. All measures must be proposed for public comment prior to their selection, except in the case of measures previously selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act. The final rule for the Medicare and Medicaid EHR Incentive Programs includes 15 clinical quality measures for eligible hospitals and critical access hospitals (75 FR 44418), 2 of which were previously selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act. The remaining 13 measures for these incentive programs are being proposed for the Hospital IQR Program for the FY 2015 payment determination.

We continue to believe there are important synergies with respect to the two programs. We believe the financial incentives under the HITECH Act for the adoption and meaningful use of certified EHR technology by hospitals will encourage the adoption and use of certified EHRs for the reporting of clinical quality measures under the Hospital IQR Program. Through the EHR Incentive Programs we expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to

send, and for CMS to receive, quality measures via hospital EHRs for Hospital IQR Program measures in the future.

The HITECH Act requires that the Secretary seek to avoid redundant and duplicative reporting, with specific reference to the Hospital IQR Program for eligible hospitals. To the extent that quality measures are included in both the Hospital IQR Program and the EHR Incentive Programs, this would mean that Hospital IQR Program would need to transition to use of certified EHR technology rather than manual chart abstraction. We are considering what the most practical approach to effect such a transition might be. One option is to select a date after which chart-abstracted data would no longer be used in the Hospital IQR Program. This would require sufficient advance notice to hospitals for hospitals to report the data via certified EHR technology. At that point, we believe that it is likely that nearly all IPPS hospitals will have implemented certified EHR technology as incentivized by the HITECH Act. Another option would be to allow hospitals to submit the same measure for the Hospital IQR Program based on either chart-abstraction or EHR-based reporting. This would require extensive testing to ensure equivalence given that the data for the Hospital IQR Program supports both the public reporting of such information and the Hospital VBP Program. We are concerned that this option would not be feasible. We invited public comment on the approach of selecting calendar year 2015 after which chart-abstracted data would no longer be accepted for the Hospital IQR Program.

Comment: Many commenters overwhelmingly supported the alignment of Hospital IQR Program measures with the EHR Incentive Programs' meaningful use criteria for objective/measure. Some commenters recommended that CMS monitor the adoption rate of EHRs in the EHR Incentive Programs in order to gauge a target date for complete transition. A few commenters supported the FY 2015 target date for complete transition from chart-abstraction to EHR-based data collection while several commenters doubted the EHR-readiness of some hospitals and believed that 2020 is probably a more realistic date for a complete transition. A commenter recommended the maintaining chart-abstraction for small hospitals which may not be able to afford EHR technology.

Response: We thank the commenters for supporting our goal to advance the Hospital IQR Program toward EHR-based reporting. As we state in section IV.A.3.a of this final rule, we anticipate that most hospitals will have the capability to report quality measures electronically by 2015 because of the upcoming payment adjustments for eligible hospitals that do not meet the criteria as meaningful users of certified EHR technology.

Comment: Commenters also noted complete electronic measure testing, validation, and comparison of measure outcomes obtained from chart-abstraction and electronic specifications are crucial in the transition process.

Response: As we move towards alignment and harmonization of clinical quality measures reporting among federal reporting initiatives, we plan to test, compare, and align these reporting specifications to ensure consistency.

We thank the commenters for the comments and suggestions and we will take them into account as we develop future proposals regarding the transfer to EHR technology for chart-abstracted records under the Hospital IQR Program.

Ultimately, we anticipate that all of the Hospital IQR measures that are chart-abstracted will be e-specified and also included in the EHR Incentive Programs. We envision a single reporting infrastructure for electronic submission of these measures in the future, and will strive to align the hospital quality initiative programs to seek to avoid redundant and duplicative reporting of quality measures for hospitals. We note that some important Hospital IQR Program quality measures such as HCAHPS experience of care measures are based on survey data and do not lend themselves to EHR reporting. Similarly, certain outcome quality measures, such as the current Hospital IQR Program readmission measures, are based on claims data rather than clinical data. Thus, not all Hospital IQR quality measures will necessarily be capable of being submitted through EHRs. As a consequence, not all Hospital IQR Program measures would necessarily be appropriate for inclusion in the EHR Incentive Programs.

We again note that the provisions in this FY 2012 IPPS/LTCH PPS proposed rule do not implicate or implement any HITECH statutory provisions. Those provisions are the subject of separate rulemaking and public comment.

B. Hospital Value-Based Purchasing (VBP) Program

1. Background

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals 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.

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 for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to the FY 2013 base operating MS–DRG payment for each discharge of 1 percent, as required by section 1886(o)(7)(B)(i) of the Act.

Section 1886(o)(1)(C) of the Act provides that the Hospital VBP Program applies to subsection (d) hospitals (as 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 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 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 Hospital Inpatient VBP Program

On April 29, 2011, we issued the Hospital Inpatient VBP Program final rule to implement section 1886(o) of the Act (76 FR 26490, May 6, 2011). As described more fully in the Hospital Inpatient VBP Program final rule, we adopted for the FY 2013 Hospital VBP Program 13 measures that we have already adopted for the Hospital IQR Program, categorized into two domains (76 FR 26495 through 26511). We grouped 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). To determine whether a hospital meets the proposed performance standards for these measures, we will compare each hospital's performance during this performance period to its performance

during a 3-quarter baseline period from July 1, 2009 through March 31, 2010 (76 FR 26493 through 26495).

We also finalized a methodology for assessing the total performance of each hospital based on performance standards under which we will score each hospital based on achievement and improvement ranges for each applicable measure. We will calculate a Total Performance Score 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 will be clinical process of care = 70 percent, patient experience of care = 30 percent), and adding together the weighted domain scores. We will convert each hospital's Total Performance Score into a value-based incentive payment using a linear exchange function. We refer readers to the Hospital Inpatient VBP Program final rule for further explanation of the details of the FY 2013 Hospital VBP Program (76 FR 26490 through 26547).

For FY 2014, we also adopted in the Hospital Inpatient VBP Program final rule 13 outcome measures comprised of 3 mortality measures, 2 AHRQ composite measures, and 8 hospital-acquired condition (HAC) measures (76 FR 26511). These measures are set forth below.

FINALIZED OUTCOME MEASURES FOR THE FY 2014 HOSPITAL VBP PROGRAM

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.
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) Composite Measures.	• Complication/patient safety for selected indicators (composite). • 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.

3. Additional FY 2014 Hospital VBP Program Measure

a. Background

Section 1886(o)(2)(A) of the Act requires the Secretary to select for the Hospital VBP Program measures, other than readmission measures, from the measures specified under section 1886(b)(3)(B)(viii) of the Act for the Hospital IQR Program. Section 1886(o)(2)(B)(i) of the Act requires the Secretary, with respect to value-based incentive payments made for discharges occurring during FY 2013, to ensure that the selected measures cover at least the following specified conditions or topics: Acute Myocardial Infarction (AMI); Heart Failure (HF); Pneumonia (PN); Surgeries, as measured by the Surgical Care Improvement Project (SCIP); Healthcare-Associated Infections (HAIs), as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent HAIs (available at: *http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html*) (or any successor plan); and HCAHPS. Section 1886(o)(2)(B)(ii) of the Act requires the Secretary, with respect to value-based incentive payments made for discharges occurring during FY 2014 or a subsequent year, to ensure that Hospital VBP Program measures include efficiency measures, including measures of Medicare spending per beneficiary.

Section 1886(o)(2)(C)(i) of the Act provides that the Secretary may not select a measure with respect to a performance period for a fiscal year unless the measure has been specified under the Hospital IQR Program and included on the *Hospital Compare* Web site for at least one year prior to the beginning of the performance period. Section 1886(o)(2)(C)(ii) of the Act provides that a measure selected under section 1886(o)(2)(A) of the Act shall not apply to a hospital if the hospital does not furnish services appropriate to the measure.

b. Efficiency Measure—Medicare Spending Per Beneficiary Measure—for the FY 2014 Hospital VBP Program

(1) Introduction

Section 1886(o)(2)(B)(ii) of the Act requires the Secretary to ensure that, for Hospital VBP discharges occurring during FY 2014 or a subsequent year, the measures selected ''include efficiency measures, including measures of 'Medicare spending per beneficiary' * * *.'' Therefore, for the FY 2014 Hospital VBP Program, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25927 through 25928), we proposed to adopt a Medicare spending per beneficiary measure. We also proposed this measure for inclusion in the Hospital IQR Program in the proposed rule and we described it in detail in section IV.A.3.b.(2)(B) of the proposed rule (76 FR 25896 through 25897). Our proposed and final approaches to scoring this measure and including it in the Hospital VBP Program are discussed below.

(2) Scoring the Medicare Spending per Beneficiary Measure

Section 1886(o)(5)(B)(ii) of the Act requires that the hospital performance score be determined using the higher of its achievement or improvement score for each measure. Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25927 through 25928), we proposed to calculate each hospital's achievement score and improvement score on the proposed Medicare spending per beneficiary measure, in order to determine which score will be used to calculate the Total Performance Score for the hospital.

We proposed this scoring methodology because it is generally similar to the methodology proposed for scoring the clinical process of care and outcome measures in the Hospital Inpatient VBP Program proposed rule (76 FR 2465 through 2471).

(A) Scoring Based on Achievement

We proposed to calculate a Medicare per beneficiary spending ratio of the Medicare spending per beneficiary amount for each hospital to the median Medicare spending per beneficiary amount across all hospitals during the performance period. We proposed that a hospital would earn between 1 and 10 achievement points on the Medicare

spending per beneficiary measure if its individual Medicare spending per beneficiary ratio during the performance period falls at or between the achievement threshold and the achievement benchmark for the measure. We proposed to set the achievement threshold at the median Medicare spending per beneficiary ratio across all hospitals during the performance period. We proposed to set the benchmark at the mean of the lowest decile of Medicare spending per beneficiary ratios during the performance period. We proposed that a hospital whose individual Medicare spending per beneficiary ratio fell below the achievement threshold would score 0 achievement points on the measure, and that a hospital whose individual Medicare spending per beneficiary ratio falls at or above the achievement benchmark would score the maximum of 10 achievement points on the measure. We have clarified the scoring language, as detailed below, to indicate that a hospital whose Medicare spending per beneficiary ratio falls above the achievement threshold would not score achievement points, because a lower ratio, within the achievement range, results in higher points on this measure. We also provided a narrative formula to illustrate the proposed calculation of achievement points, which we have clarified below.

(B) Scoring Based on Improvement

In the FY 2012 IPPS/LTCH PPS proposed rule 76 FR 25927 through 25928), we proposed that a hospital would earn between 1 and 9 improvement points on the proposed Medicare spending per beneficiary measure if its individual Medicare spending per beneficiary ratio during the performance period falls within the improvement range. We proposed to set the threshold for improvement at the hospital's own Medicare spending per beneficiary ratio, as calculated during the baseline period. We proposed a baseline period of May 15, 2010 through February 14, 2011 for the Medicare spending per beneficiary measure and discussed this proposal in section IV.B.3.b.(4) of the preamble of the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25928). We proposed that the improvement benchmark would be equal to the achievement benchmark for the performance period, which is the mean of the lowest decile of Medicare spending per beneficiary ratios across all hospitals. We proposed that a hospital whose Medicare spending per beneficiary ratio is equal to or lower than its baseline period Medicare spending per beneficiary ratio would score 0 improvement points on the measure We have clarified the scoring language, as detailed below, to indicate that a hospital whose Medicare spending per beneficiary ratio falls above the improvement threshold (the hospital's own Medicare spending per beneficiary during the baseline period) would not score improvement points, because a lower ratio, within the improvement range, results in higher points on this measure.

Comment: Several commenters suggested that the narrative scoring examples included in the proposed rule were incorrect, because they were similar to those used for scoring other quality measures. The commenters believed the formulas did not apply to the spending per beneficiary measure. One commenter noted that the scoring process description should be clarified to indicate that a lower Medicare spending per beneficiary ratio would result in a higher score on the measure than would a higher Medicare spending per beneficiary ratio.

Response: We disagree that the narrative scoring examples were incorrect. However, we agree that it would be beneficial to clarify the examples, for consistency with the numeric examples. The narrative examples in the proposed rule appeared in a different order than the numeric examples, resulting in a negative number being divided by a negative number and yielding a positive number. The numeric examples result in a positive number being divided by a positive number, which is again a positive number. In this final rule, we are clarifying the narrative examples. We are clarifying the description of the scoring process to indicate that a lower Medicare spending per beneficiary ratio would result in a higher score on the measure, if it falls within the achievement or improvement range, as suggested by a commenter.

Comment: One commenter requested clarification of the purpose of calculating a ratio to the median spending amount rather than giving consideration to the distribution of scores, and suggested evaluating the distribution of scores by geographic region.

Response: The purpose of using a ratio in the Medicare spending per beneficiary measure is to quantify a hospital's individual Medicare spending per beneficiary amount, as compared to spending nationally. The use of a ratio also facilitates our comparison of a hospital's baseline Medicare spending per beneficiary, relative to national Medicare spending per beneficiary, during the baseline period, to the hospital's performance period Medicare spending per beneficiary, relative to the national Medicare spending per beneficiary during the performance period. We believe that comparison of standardized Medicare spending per beneficiary ratios on a national level is the best way to help hospitals understand where opportunities for improved efficiencies lie.

After considering all public comments on scoring of the Medicare spending per beneficiary measure, we are finalizing our proposal that a hospital will earn between 1 and 10 achievement points on the Medicare spending per beneficiary measure if its individual Medicare spending per beneficiary ratio during the performance period falls at or between the achievement threshold and the achievement benchmark for the measure. We are finalizing the achievement threshold at the median Medicare spending per beneficiary ratio across all hospitals during the performance period. We are finalizing the benchmark at the mean of the lowest decile of Medicare spending per beneficiary ratios during the performance period. A hospital whose individual Medicare spending per beneficiary ratio falls above the achievement threshold will score 0 achievement points on the measure, and a hospital whose individual Medicare spending per beneficiary ratio falls at or below the achievement benchmark will score the maximum of 10 achievement points on the measure. A hospital whose individual Medicare spending per beneficiary ratio falls at or below the achievement threshold, but above the benchmark, will score between 1 and 9 points according to the following formula:

[9 * ((achievement threshold − Hospital's performance period Medicare spending per beneficiary ratio)/(achievement threshold − benchmark))] + .5

We are finalizing our proposal that a hospital will earn between 1 and 9 improvement points on the proposed Medicare spending per beneficiary measure if its individual Medicare spending per beneficiary ratio during the performance period falls within the improvement range. We are finalizing the threshold for improvement at the hospital's own Medicare spending per beneficiary ratio, as calculated during the baseline period. We are finalizing the baseline period of May 15, 2010 through February 14, 2011 for the Medicare spending per beneficiary measure. We are finalizing that the improvement benchmark would be equal to the achievement benchmark for

the performance period, which is the mean of the lowest decile of Medicare spending per beneficiary ratios across all hospitals. A hospital whose Medicare spending per beneficiary ratio is equal to or higher than its baseline period Medicare spending per beneficiary ratio will score 0 improvement points on the measure. If a hospital's score on the measure during the performance period is less than its baseline period score but above the benchmark (within the improvement range), the hospital will receive a score of 0–9 according to the following formula:

[10 * ((Hospital baseline period Medicare spending per beneficiary ratio − Hospital performance period Medicare spending per beneficiary ratio)/(Hospital baseline period Medicare spending per beneficiary ratio − Benchmark)] − .5

(C) Example of Scoring the Medicare Spending per Beneficiary Measure

In the proposed rule, we provided the following numeric example of scoring this measure:

If Hospital A had the following spending per beneficiary amounts during the baseline and performance period:

Baseline = $10,105
Performance = $9,125;
and the median spending per beneficiary amounts across all hospitals for the baseline and performance periods were:
Median Baseline = $11,672
Median Performance = $12,467;
then the Medicare spending per beneficiary ratios for Hospital A in the baseline and performance periods would be:
Baseline Ratio = 0.866
Performance Ratio = 0.732.

The achievement threshold is the median ratio across all hospitals, which would be 1.0. In this example, we assume a benchmark of 0.712. We would calculate achievement and improvement points for Hospital A as follows:

Achievement Points = 9 * (1.0 − 0.732) / (1.0 − 0.712) + 0.5 = 8.868
Improvement Points = 10 * (0.866 − 0.732) / (0.866 − 0.712) − 0.5 = 8.185

These points are rounded to yield 9 attainment points and 8 improvement points.

Because section 1886(o)(5)(B)(ii) of the Act, as added by section 3001 of the Affordable Care Act, requires that the hospital performance score will be determined using the higher of attainment or improvement score for each measure, the hospital in this example would receive 9 points on the Medicare spending per beneficiary measure.

Comment: One commenter stated that the scoring example was correct.

Response: We agree that this example is correct, and we have clarified the narrative formulas, for consistency with this example, as suggested by other commenters.

(D) Incorporation of Medicare Spending Per Beneficiary Measure Score into the Overall Hospital Total Performance Score

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25928), we proposed to incorporate the Medicare spending per beneficiary measure score into the FY 2014 Hospital VBP Program as part of a new domain: the ''Efficiency'' domain. The Medicare spending per beneficiary measure score would be the Efficiency domain score for purposes of the FY 2014 Hospital VBP Program. Consistent with the domain scoring method in the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547), we proposed to determine the total earned points for the Efficiency domain in general by adding the points earned for each domain measure and dividing by the total possible points, then multiplying that number by 100 percent. However, because we proposed to adopt only one measure for the Efficiency domain for the FY 2014 Hospital VBP Program, the total points earned for the domain would be the points earned on the Medicare spending per beneficiary measure. We proposed that the total possible points that a hospital could earn for the Efficiency domain for FY 2014 would be 10, which is equal to the total possible points that the hospital could earn for the Medicare spending per beneficiary measure. We proposed that the Efficiency domain percentage score would be calculated for FY 2014 as follows: Efficiency domain score = Total points earned on the Medicare spending per beneficiary measure divided by 10, then multiplied by 100 percent.

Once the Efficiency domain score has been determined, we proposed to assign it a weight for use in the calculation of the Total Performance Score. We proposed FY 2014 domain weighting, additional FY 2014 measures, and other proposals for the FY 2014 Hospital VBP Program in the CY 2012 OPPS/ASC proposed rule (76 FR 42354 through 42365).

Comment: Two commenters requested clarification of the proposed weighting of the Efficiency domain.

Response: We proposed to weight the Efficiency domain at 20 percent in the CY 2012 OPPS/ASC proposed rule (76 FR 42362 through 42363).

After considering the public comments we received on the proposals for incorporation of Medicare spending per beneficiary measure score into the overall hospital Total Performance Score, we are finalizing our proposal to incorporate the Medicare spending per beneficiary measure score into the FY 2014 Hospital VBP Program as part of a new domain: The ''Efficiency'' domain. We are finalizing that the Medicare spending per beneficiary measure score will be the Efficiency domain score for purposes of the FY 2014 Hospital VBP Program. We are finalizing our proposal to determine the total earned points for the Efficiency domain by adding the points earned for each domain measure and dividing by the total possible points, then multiplying that number by 100 percent. For the FY 2014 payment adjustment, there is only 1 measure in the Efficiency domain, the Medicare spending per beneficiary measure, and the total possible points are 10. We are finalizing that the Efficiency domain percentage score would be calculated for FY 2014 as follows: Efficiency domain score = Total points earned on the Medicare spending per beneficiary measure divided by 10, then multiplied by 100 percent.

We are finalizing our proposal to assign a weight to the Efficiency domain, for use in the calculation of the Total Performance Score. We note that we proposed FY 2014 domain weighting, additional FY 2014 measures, and other proposals for the FY 2014 Hospital VBP Program in the CY 2012 OPPS/ASC proposed rule (76 FR 42354 through 42365).

4. Efficiency Domain (Medicare Spending per Beneficiary Measure) Performance Period and Baseline Period

Section 1886(o)(2)(C)(i) of the Act prohibits the Secretary from selecting a measure for the Hospital VBP Program with respect to a performance period unless it has been specified under the Hospital IQR Program and included on the *Hospital Compare* Web site for at least 1 year prior to the beginning of such performance period. Section 1886(o)(8) of the Act requires that hospitals be notified of the calculation of their value-based incentive payment no later than 60 days prior to the fiscal year involved. In order to comply with these statutory requirements for the FY 2014 Hospital VBP Program, in the FY

2012 IPPS/LTCH PPS proposed rule (76 FR 25928), we proposed to adopt a 9-month period of performance from May 15, 2012 through February 14, 2013 for the proposed Medicare spending per beneficiary measure. If the measure is adopted, this would allow for a 1-year display period on *Hospital Compare,* a 60-day notification period, and would allow the time needed for administrative processes. We noted that this would have meant that only IPPS discharges occurring from May 15, 2012 through 90 days prior to February 14, 2013 would count as index stays for purposes of creating the Medicare spending per beneficiary episodes. This was because, as proposed, the Medicare spending per beneficiary measure would have included a Medicare spending per beneficiary episode spanning from 3 days prior to admission through 90-days post-discharge. However, we have finalized a shorter Medicare spending per beneficiary episode, which spans from 3 days prior to admission through 30 days post-discharge. Therefore, discharges occurring within 30 days of the end of the performance period will be counted as index admissions, as described in section IV.A.3.b.(2)(B) of this final rule. The Medicare spending per beneficiary episode is described in section IV.A.3.b.(2)(B) of the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25896 through 25897), and in section IV.A.3.b.(2)(B) of this final rule.

For the purposes of calculating improvement points on the proposed Medicare spending per beneficiary measure, it is necessary to establish the baseline period to which the performance period score will be compared. For purposes of the FY 2014 Hospital VBP Program, we proposed to adopt a baseline period of May 15, 2010 through 90 days prior to February 14, 2011 for this proposed measure. This proposal was intended to indicate that only discharges occurring 90 days prior to the end of the performance period would be counted as index admissions, because, as proposed, the Medicare spending per beneficiary measure would have included a Medicare spending per beneficiary episode spanning from 3 days prior to admission through 90-days post-discharge. However, we have finalized a shorter Medicare spending per beneficiary episode, which spans from 3 days prior to admission through 30 days post-discharge. Therefore, discharges occurring within 30 days of the end of the baseline period will be counted as index admissions, as described in section IV.A.3.b.(2)(B) of this final rule. The proposed baseline period is consistent with the baseline period that has been proposed for the FY 2013 clinical process of care and patient experience of care measures in the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547) because it precedes the performance period by 2 years.

We invited public comment on all of our proposals related to the Efficiency Domain and Medicare spending per beneficiary measure.

Comment: A large number of commenters addressed the proposed period of performance for the Medicare spending per beneficiary measure. All but one of those commenters stated that implementation should be delayed. Most commenters stated that the Medicare spending per beneficiary measure was not posted on *Hospital Compare* in time to meet the requirement of the Affordable Care Act that it be displayed there for 1 year prior to the start of the performance period and that therefore, CMS must choose another performance period for the measure. A number of commenters specifically noted the language in section 3001 of the Affordable Care Act requiring measures of Medicare spending per beneficiary be included in the calculation of value-based incentive payments made for discharges occurring during fiscal year 2014 or a subsequent fiscal year. Nine commenters stated that the measure should be delayed pending the outcome of NQF study or endorsement. A few commenters stated that the measure should be delayed until results of IOM work can be incorporated, and several commenters suggested that CMS wait for the outcome of its GROUPER study. A few commenters stated that implementation should be delayed so that further analysis and testing should be performed. One commenter stated that the performance period was inappropriate, because it precedes the payment year, making it impossible for hospitals to improve performance during the payment year. That commenter further questioned the association of a baseline year with the performance year. A few commenters suggested that the Medicare spending per beneficiary measure should utilize a 12-month performance period, similar to other VBP measures. One commenter stated that the proposed period of performance should be implemented without revision.

Response: We disagree with comments that this measure was not included on *Hospital Compare* in a timely manner. The measure was included on April 21, 2011, which is more than 1 year before the proposed performance period start date of May 15, 2012. We disagree with comments that we should use the Affordable Care Act language regarding inclusion of a Medicare spending per beneficiary measure for discharges occurring in ''a subsequent fiscal year'' to delay the implementation of this measure. We believe that the Medicare spending per beneficiary measure is an important step in encouraging hospitals to redesign and coordinate care with other providers and suppliers of care, and that its timely implementation is critical to incentivizing hospitals to provide the highest-quality, most efficient care possible to Medicare beneficiaries. We acknowledge that movement toward consistency in performance periods across Hospital VBP Program measures, to the extent possible, is an important goal. However we note that some measures within the Hospital VBP Program, including the Medicare spending per beneficiary measure, cannot initially have 12-month periods of performance, due to statutory constraints on display and notification timeframes.

In order to implement this measure for FY 2014, and to display it on *Hospital Compare* for 1 year prior to the start of the performance period, as required by statute, a 9-month period of performance is the longest we are able to implement for the FY 2014 payment adjustment. We note that all hospitals will have the same 9-month performance period during which their Medicare spending per beneficiary ratios will be compared. Therefore, we do not believe that any hospital will be unfairly disadvantaged by this performance period. We will analyze and consider the possibility of moving to a 12-month period of performance for the Medicare spending per beneficiary measure in the future. In response to the comment which questions the use of a performance period which precedes the payment adjustment year, we note that the section 1886(o)(4) of the Act, as added by section 3001 of the Affordable Care Act requires that the performance period for a fiscal year begin and end prior to the beginning of that fiscal year. Section 1886(o)(5)(B)(ii) of the Act, as added by section 3001(a) of the Affordable Care Act, requires that the hospital performance score be determined using the higher of achievement or improvement points, and we believe that the use of a baseline period is the best means of comparison, in order to determine how much hospitals have improved on this measure and calculate improvement

points. We disagree with comments in favor of delaying the implementation of the Medicare spending per beneficiary measure for further refinement or endorsement. We believe that the measure provides an accurate comparison of hospital-specific Medicare spending per beneficiary. We intend to perform ongoing analysis of this measure, in order to continually improve it, but we believe that its prompt implementation is an important step in ensuring that Medicare beneficiaries receive high-quality, coordinated, and efficient care. We appreciate the commenter's support for the implementation of this measure as proposed.

Comment: A few commenters stated that the measure could first be implemented for public reporting purposes, but not be attributed to specific hospitals. Another commenter suggested that CMS could implement the measure by first publishing spending on a per-region basis.

Response: As stated above, we believe that the Medicare spending per beneficiary measure is an important step in encouraging hospitals to redesign and coordinate care with other providers and suppliers of care, and that its prompt implementation is critical to incentivizing hospitals to provide the highest-quality, most efficient care possible to Medicare beneficiaries. This measure would be incorporated as one component of the hospital's Total Performance Score for the Hospital VBP Program.

In summary, after consideration of the public comments we received, we are finalizing the following proposals, with regard to inclusion of the Medicare spending per beneficiary measure in the FY 2014 Hospital VBP Program. We are finalizing our proposal to include of the Medicare spending per beneficiary measure in the FY 2014 Hospital VBP Program. We are finalizing our proposal that a hospital will earn between 1 and 10 achievement points on the Medicare spending per beneficiary measure if its individual Medicare spending per beneficiary ratio during the performance period falls at or between the achievement threshold and the achievement benchmark for the measure. We are finalizing the achievement threshold at the median Medicare spending per beneficiary ratio across all hospitals during the performance period. We are finalizing the benchmark at the mean of the lowest decile of Medicare spending per beneficiary ratios during the performance period. A hospital whose individual Medicare spending per beneficiary ratio falls above the achievement threshold will score 0 achievement points on the measure, and a hospital whose individual Medicare spending per beneficiary ratio falls at or below the achievement benchmark will score the maximum of 10 achievement points on the measure. A hospital whose individual Medicare spending per beneficiary ratio falls at or below the achievement threshold, but above the benchmark, will score between 1–9 points according to the following formula: [9 * ((achievement threshold-Hospital's performance period Medicare spending per beneficiary ratio)/(achievement threshold-benchmark))] + 0.5.

We are finalizing our proposal that a hospital will earn between 1 and 9 improvement points on the proposed Medicare spending per beneficiary measure if its individual Medicare spending per beneficiary ratio during the performance period falls within the improvement range. We are finalizing the threshold for improvement at the hospital's own Medicare spending per beneficiary ratio, as calculated during the baseline period. We are finalizing the baseline period of May 15, 2010 through February 14, 2011 for the Medicare spending per beneficiary measure. We are finalizing the improvement benchmark would be equal to the achievement benchmark for the performance period, which is the mean of the lowest decile of Medicare spending per beneficiary ratios across all hospitals. A hospital whose Medicare spending per beneficiary ratio is equal to or higher than its baseline period Medicare spending per beneficiary ratio will score 0 improvement points on the measure. If a hospital's score on the measure during the performance period is less than its baseline period score but above the benchmark (within the improvement range), the hospital will receive a score of 0–9 according to the following formula:

[10 * ((Hospital baseline period Medicare spending per beneficiary ratio − Hospital performance period Medicare spending per beneficiary ratio)/(Hospital baseline period Medicare spending per beneficiary ratio − Benchmark)] − 0.5.

We are finalizing our proposal to incorporate the Medicare spending per beneficiary measure score into the FY 2014 Hospital VBP Program as part of a new domain: the ''Efficiency'' domain. We are finalizing that the Medicare spending per beneficiary measure score will be the Efficiency domain score for purposes of the FY 2014 Hospital VBP Program. We are finalizing our proposal to determine the total earned points for the Efficiency domain by adding the points earned for each domain measure and dividing by the total possible points, then multiplying that number by 100 percent. For the FY 2014 payment adjustment, there is only 1 measure in the Efficiency domain, the Medicare spending per beneficiary measure, and the total possible points are 10. We are finalizing that the Efficiency domain percentage score would be calculated for FY 2014 as follows: Efficiency domain score = Total points earned on the Medicare spending per beneficiary measure divided by 10, then multiplied by 100 percent.

We are finalizing our proposal to assign a weight to the Efficiency domain, for use in the calculation of the Total Performance Score. We note that we proposed FY 2014 domain weighting, additional FY 2014 measures, and other proposals for the FY 2014 Hospital VBP Program in the CY 2012 OPPS/ASC proposed rule (76 FR 42354 through 42365).

We are finalizing a 9-month period of performance from May 15, 2012 through February 14, 2013 for the Medicare spending per beneficiary measure. We are finalizing a 9-month baseline period of May 15, 2010 through February 14, 2011. We are finalizing that only discharges occurring within 30 days of the end of the baseline period will be counted as index admissions for the purposes of establishing baseline period Medicare spending per beneficiary episodes.

5. Simultaneous Specification of Additional Measures for the Hospital VBP Program and the Hospital IQR Program

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25928), we proposed to simultaneously specify additional measures for the Hospital VBP Program and the Hospital IQR Program, as appropriate, for use in both programs. Our rationale is to improve patient safety and quality of care in an expedited manner that is compliant with applicable statutory guidance. We noted that we used this approach in the FY 2012 IPPS/LTCH PPS proposed rule by proposing to add the Medicare spending per beneficiary measure to both the Hospital VBP and Hospital IQR Programs. We also stated that we would provide all associated regulatory impact and policy rationale in future proposals for both programs. We stated our belief that this proposal notifies stakeholders through rulemaking and welcomed comments on this proposal.

Comment: Several commenters objected to the proposal to

simultaneously adopt measures for both the Hospital VBP Program and the Hospital IQR Program. The commenters believed that such an approach is inconsistent with section 1886(o)(2)(C)(i) of the Act, because they believed that CMS is statutorily required to add measures to the Hospital VBP Program only if they are specified under the Hospital IQR Program and included on the *Hospital Compare* Web site for at least one year prior to the beginning of the Hospital VBP performance period that applies for the fiscal year.

Response: We believe that our proposal is consistent with section 1886(o)(2)(C)(i) of the Act. That provision prohibits the Secretary from selecting a measure for the Hospital VBP Program unless the measure ''has been specified under the Hospital IQR Program and included on the *Hospital Compare* Web site for at least one year prior to the beginning of the applicable performance period.'' This provision does not require that a measure be specified for the Hospital IQR Program before it is included on the *Hospital Compare* Web site, nor does it require that we include on the *Hospital Compare* Web site performance data on the measure prior to selecting the measure for the Hospital VBP Program. We believe that by including measures on *Hospital Compare,* we are providing the public with sufficient notice that we might choose to select any or all of them for the Hospital IQR Program measure set and, possibly simultaneously, for the Hospital VBP Program measure set (provided the performance period for these measures begins at least one year after their initial *Hospital Compare* inclusion and other statutory requirements are met).

Comment: Some commenters supported CMS' proposal to simultaneously specify measures in the Hospital IQR and Hospital VBP Programs. Some commenters generally supported the alignment of Hospital IQR Program and Hospital VBP Program measures.

Response: We appreciate the commenters' support of our proposal. We believe that this policy will enable us to expand the measure set as quickly as possible.

We note that we intend to provide as much notice as is feasibly possible before proposing to select any measure for the Hospital VBP Program. However, as we stated in the proposed rule, one of our main goals is to adopt measures as expeditiously as possible for the purpose of improving patient safety and the quality of care. After consideration of the public comments received, we are finalizing our proposal to adopt a policy under which we can simultaneously propose to adopt measures for use in both the Hospital IQR and Hospital VBP Programs.

6. Responses to Additional Hospital VBP Program Comments

We received additional comments regarding other aspects of the Hospital VBP Program for which we did not make proposals in the FY 2012 IPPS/LTCH PPS proposed rule. We offer the following clarifications and references in response to these comments.

Comment: Several commenters stated that the performance period for the 8 HAC measures adopted for the FY 2014 Hospital VBP Program is incorrect because the measures were not displayed on *Hospital Compare* on March 3, 2011. These commenters further suggest that CMS must select a new performance period to meet the statutory requirements.

Response: We disagree with commenters' assertion that we must change the performance period for these measures. The 8 finalized HAC measures were first included on *Hospital Compare* on March 3, 2011 in the ''Highlights'' section and the Hospital Compare ''Glossary.'' We believe that this display meets the requirement in section 1886(o)(2)(C)(i) that measures be included on the *Hospital Compare* Web site for at least one year prior to the beginning of the performance period that applies to the FY 2014 Hospital VBP Program. As stated in the Hospital Inpatient VBP Program final rule (76 FR 26495), the FY 2014 performance period for the 8 finalized HAC measures will begin on March 3, 2012.

Comment: Some commenters opposed the use of HAC measures in the Hospital VBP Program, and argued that hospitals will be penalized on those measures under two separate payment policies.

Response: As we stated in the Hospital Inpatient VBP Program final rule, we view the Hospital VBP Program and the program authorized under section 3008 of the Affordable Care Act as related but separate efforts to reduce HACs. We intend to monitor the various interactions of programs authorized by the Affordable Care Act and their overall impact on providers and suppliers (76 FR 26504).

Comment: Some commenters suggested that CMS change the finalized domain weighting scheme for the FY 2013 Hospital VBP Program and weight all domains equally, arguing that doing so would help ''bend the cost curve'' and create a more equitable payment system. Other commenters expressed specific concern with the patient experience domain's weighting at 30 percent, arguing that cultural, regional, and educational differences can affect a patient's perspective of care.

Response: We disagree with the comments' suggestions that we alter the domain weighting scheme we finalized for the FY 2013 Hospital VBP Program. As we explained in the Hospital Inpatient VBP Program final rule (76 FR 26526), we considered many factors when determining the appropriate weight for the FY 2013 Hospital VBP Program, including the number of measures in each domain, the reliability of individual measure data, systematic effects of alternative weighting schemes on hospitals according to their location and characteristics, and HHS quality improvement priorities. We also believe that delivery of high-quality, patient-centered care requires us to carefully consider the patient's experience in the hospital inpatient setting.

Taking all of these considerations into account, we finalized the use of a 70 percent clinical process of care and 30 percent patient experience of care (HCAHPS) weighting scheme for the FY 2013 Hospital VBP Program. We believe that assigning a 30 percent weight to the patient experience of care domain is appropriate because the HCAHPS measure is comprised of eight dimensions that address different aspects of patient satisfaction. We believe the finalized 30 percent weight appropriately balances hospitals' incentives to perform well on both the clinical process measures and the HCAHPS survey.

We also refer readers to the CY 2012 OPPS/ASC proposed rule (76 FR 42362 through 76 FR 42363) for our proposed weighting scheme for the FY 2014 Hospital VBP Program.

We adopted a number of HCAHPS dimensions for the FY 2013 Hospital VBP Program that assess the patient's communication experience with hospital staff (including doctors and nurses), and communication regarding medicines and discharge information. We believe that the communication experience of all patients is a critical aspect of quality of care, and one that should be measured and publicly reported for all hospitals. Accordingly, the communication items have been an integral part of HCAHPS since its national implementation in 2006, have been included in the Hospital IQR Program since 2007, have been publicly reported since 2008, and have been adopted in the Hospital VBP Program in a manner that rewards hospitals for either their performance compared to other hospitals, or their improvement

compared to their own previous performance.

Comment: One commenter argued that because urban safety net hospitals typically serve a diverse patient population, these hospitals are likely to score poorly on the communication dimensions of the HCAHPS survey, and that for this reason, the use of HCAHPS in the Hospital VBP Program would be detrimental to them. Several commenters stated that CMS should distinguish safety net and urban safety net hospitals from other hospitals because of the distinct challenges faced by such hospitals and because such hospitals are disadvantaged by the Hospital VBP Program, particularly the HCAHPS domain.

Response: We thank the commenters for their input. As we discussed in the Hospital Inpatient VBP Program final rule (76 FR 26502), we recognize that urban hospitals, particularly large ones, have historically not performed as well on HCAHPS as rural hospitals. However, our internal studies of HCAHPS results show that hospitals in some urban areas scored in the top 25 percent of hospitals overall. We believe that those results suggest that urban hospitals can achieve high scores under the HCAHPS domain.

''Safety net'' hospital is not an official CMS term or category. However, we are aware of several differing definitions of this term. Employing a definition of ''Safety Net hospital'' created by the AHRQ, we looked into the ability of safety net hospitals to score well on HCAHPS in the Hospital VBP Program. We found 30 hospitals that meet all three of AHRQ's criteria for Safety Net hospital: (1) high Medicaid percentage; (2) high percentage of uncompensated care; and (3) located in a high poverty county. Of these 30 hospitals, 3 hospitals (10 percent) fall in the top 10 percent of all hospitals in terms of projected earned total HCAHPS points for the Hospital VBP Program. This suggests that safety net hospitals can achieve the highest HCAHPS Hospital VBP Program scores and at a similar rate to non-safety net hospitals.

Comment: One commenter requested that CMS publicly report the patient mix characteristics of each hospital, and publicly report the non-patient-mix adjusted HCAHPS scores to allow hospitals to determine the impact of patient-mix adjustment in Hospital VBP Program payments.

Response: We thank the commenter for the suggestion. We currently provide patient-mix adjustment coefficients for HCAHPS measures on our HCAHPS On-Line Web site, *http://www.hcahpsonline.org,* along with instructions on how hospitals can derive the adjustments that apply to their scores. We will consider the benefits of publicly reporting the patient mix characteristics and the pre- and post-patient-mix adjusted HCAHPS scores of participating hospitals.

C. Hospital Readmissions Reduction Program

1. Background

a. Overview

CMS is committed to promoting high quality health care and improving patient health outcomes. Readmission to a hospital may be an adverse event for patients and many times imposes a financial burden on the health care system. Successful efforts to reduce preventable readmission rates will improve quality of care while simultaneously decreasing costs. Hospitals can work with their communities to lower readmission rates and improve patient care in a number of ways, such as ensuring patients are clinically ready to be discharged, reducing infection risk, reconciling medications, improving communication with community providers responsible for post-discharge patient care, improving care transitions, and ensuring that patients understand their care plans upon discharge.

Many studies have demonstrated the effectiveness of these types of in-hospital and post-discharge interventions in reducing the risk of readmission, confirming that hospitals and their partners have the ability to lower readmission rates.[37 38 39] These types of efforts taken during and after a hospitalization have been shown to be effective in reducing readmission rates in geriatric populations generally,[40 41] as well as for multiple specific conditions. Moreover, such interventions can be cost saving. For example, in the case of heart failure, improved hospital[42] and post-discharge care,[43 44] including pre-discharge planning,[45 46] home-based follow-up, and patient education,[47 48] have been shown to lower heart failure readmission rates, suggesting that heart failure readmission rates might be reduced if proven interventions were more widely adopted. Financial incentives to reduce readmissions will in turn promote improvement in care transitions and care coordination, as these are important means of reducing preventable readmissions.[49]

In its 2007 ''Report to Congress: Promoting Better Efficiency in Medicare,''[50] MedPAC noted the potential benefit to patients of lowering readmissions and suggested payment strategies that would incentivize hospitals to reduce these rates. MedPAC identified 7 conditions and procedures that accounted for almost 30 percent of potentially preventable readmissions: Heart failure; chronic obstructive pulmonary disease; pneumonia; acute myocardial infarction; coronary artery bypass graft surgery; percutaneous transluminal coronary angioplasty; and other vascular procedures.

To promote quality of care, CMS developed hospital quality of care

[37] Gwadry-Sridhar FH, Flintoft V, Lee DS, Lee H, Guyatt GH: A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. Arch Intern Med. 2004;164(21):2315–2320.

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[39] Krumholz HM, Amatruda J, Smith GL, et al.: Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. J Am Coll Cardiol. 2002;39(1):83–89.

[40] Coleman EA, Parry C, Chalmers S, Min SJ.: The care transitions intervention: Results of a randomized controlled trial. Arch Intern Med. 2006;166:1822–8.

[41] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS.: Comprehensive discharge planning and home follow-up of hospitalized elders: A randomized clinical trial. JAMA. 1999;281:613–20.

[42] Gwadry-Sridhar FH, Flintoft V, Lee DS, Lee H, Guyatt GH.: A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. Arch Intern Med. 2004;164(21):2315–2320.

[43] Lappe JM, Muhlestein JB, Lappe´ DL, et al.: Improvements in 1-year cardiovascular clinical outcomes associated with a hospital-based discharge medication program. Ann Intern Med. 2004;141(6):446–453.

[44] Phillips CO, Wright SM, Kern DE, Singa RM, Shepperd S, Rubin HR.: Comprehensive discharge planning with postdischarge support for older patients with congestive heart failure: A metaanalysis [published correction appears in JAMA. 2004;292(9):1022]. JAMA. 2004;291(11): 1358–1367.

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[47] Koelling TM, Johnson ML, Cody RJ, Aaronson KD.: Discharge education improves clinical outcomes in patients with chronic heart failure. Circulation. 2005;111(2):179–185.

[48] Krumholz HM, Amatruda J, Smith GL, *et al.:* Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. J Am Coll Cardiol. 2002;39(1):83–89.

[49] Coleman EA.: 2005. Background Paper on Transitional Care Performance Measurement. Appendix I. In: Institute of Medicine, Performance Measurement: Accelerating Improvement. Washington, DC: National Academy Press.

[50] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at *http://www.medpac.gov/documents/Jun07_EntireReport.pdf.* Accessed January 10, 2011.

measures that compare patient outcomes across different hospitals. These measures, including hospital risk-standardized readmission measures for Acute Myocardial Infarction (AMI), Heart Failure (HF) and Pneumonia (PN), were originally developed for public reporting as a part of the Hospital IQR Program. We adopted the HF readmission measure for the Hospital IQR Program in the FY 2009 IPPS final rule for the FY 2010 payment determination (73 FR 48606) and the AMI and PN readmission measures in the CY 2009 OPPS/ASC final rule with comment period for the FY 2010 payment determination (73 FR 68781). Details about the methodology used for these measures may be found on the Web site at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

As described above, readmission rates are important markers of quality of care, particularly of the care of a patient in transition from an acute care setting to a non-acute care setting, and improving readmissions can positively influence patient outcomes and the cost of care. The above hospital risk-standardized readmission measures are endorsed by the National Quality Forum (NQF) and have been publicly reported on *Hospital Compare* Web site since 2009 (*http://www.hospitalcompare.hhs.gov*) to encourage quality improvement and lower readmission rates. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25928 through 25937), we proposed that the readmission measures for these three conditions be used for the Hospital Readmissions Reduction Program under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act. Below is a discussion of the proposals we included regarding these measures, the public comments we received regarding these proposals, our response to these public comments, and our final policy decisions.

b. 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 hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions.

In this year's IPPS rulemaking, we address: (i) Those aspects of the Hospital Readmissions Reduction Program that relate to the conditions and readmissions to which the Hospital Readmissions Reduction Program will apply for the first program year beginning October 1, 2012; (ii) the readmission measures and related methodology used for those measures, as well as the calculation of the readmission rates; and (iii) public reporting of the readmission data. Specific information regarding the payment adjustment required under section 1886(q) of the Act will be proposed in next year's IPPS/LTCH PPS proposed rule. Although we did not propose specific policies regarding the payment adjustment under the Hospital Readmissions Reduction Program in the FY 2012 IPPS/LTCH PPS proposed rule, we believe that it is still important to set forth the general framework of the Hospital Readmissions Reduction Program, including the payment adjustment provisions, in order for the public to understand how the measures discussed and finalized in this rulemaking will affect certain hospital payments beginning in FY 2013.

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, the ''base operating DRG payments'' are reduced by an adjustment factor that accounts for excess readmissions. Section 1886(q)(1) of the Act requires the Secretary to make payments for a discharge in an amount equal to the product of ''the base operating DRG payment amount'' and ''the adjustment factor'' for the hospital in a given fiscal year. 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 payments, and 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).'' We intend to propose regulations to implement the statutory provisions related to the definition of ''base operating DRG payment amount'' in the FY 2013 IPPS/LTCH PPS proposed rule.

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 ''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 we addressed in detail below in section IV.C.3.a. of this preamble, 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).'' The term ''expansion of the applicable condition'' refers to the Secretary's authority, beginning with 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 by 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 proposed rule and in this 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 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. Implementation of the Hospital Readmissions Reduction Program

a. Overview

We intend to implement the requirements of the Hospital Readmissions Reduction Program in the FY 2012, FY 2013, and future IPPS/LTCH PPS rulemaking cycles.

Comment: A few commenters supported CMS' implementation of the Hospital Readmissions Reduction Program and CMS's implementation approach. One commenter specifically appreciated the phased-in approach for implementation.

Response: We appreciate the commenters' support for the Hospital Readmissions Reduction Program and the phased-in approach we have taken.

Comment: Some commenters urged that, prior to next year's rulemaking in which CMS will discuss and implement the provisions related to the payment adjustment and other outstanding issues, CMS hold a series of stakeholder calls to solicit input in the development of the Hospital Readmissions Reduction Program.

Response: We appreciate the comments on our implementation process of the Hospital Readmissions Reduction Program. We intend to solicit formal public input on our proposal related to the readmissions reduction through rulemaking. In addition, the public can provide input on proposals related to the Hospital Readmissions Reduction Program through the Hospital Open Door Forums calls that we hold periodically to provide hospitals with information on various issues and to listen to questions and concerns from hospitals. The public can find out more information about the Hospital Open Door Forums, including when they will be held, on the CMS Web site: *http://www.cms.gov/OpenDoorForums/18_ODF_Hospitals.asp#TopOfPage.*

Comment: One commenter expressed concern that the Hospital Readmissions Reduction Program's payment adjustments are likely to have a disproportionate impact on rural hospitals.

Response: We appreciate the comment on the impact of the Hospital Readmissions Reduction Program on rural hospitals. We note that we did not propose policies related to the Hospital Readmissions Reduction Program payment adjustment in the proposed rule. Therefore, this comment is outside the scope of the issues addressed in the proposed rule. As discussed in more detail below, we plan to propose policies related to the implementation of the payment adjustment set forth in section 1886(q) of the Act in the FY 2013 IPPS/LTCH PPS proposed rule. We will consider this comment when formulating these policies.

Comment: One commenter stated that the simultaneous implementation of the readmissions reduction measures for AMI, HF, and PN in the Hospital Readmissions Reduction Program and the Hospital IQR Program would cause ''double jeopardy,'' that is, the hospital would be penalized twice for care provided to the same patients.

Response: While the readmissions measures that we proposed for the Hospital Readmissions Reduction Program are also part of the Hospital IQR Program, hospitals are not assessed under the Hospital IQR Program based on their performance on the measures. Rather, under the Hospital IQR Program, hospitals are only required to participate in the program and to report the measure in order to avoid a payment reduction, regardless of their performance on the reported measures. Moreover, the readmission measures included in the Hospital IQR Program are not eligible to be included in the Hospital VBP Program. In the case of the three proposed NQF-endorsed 30-day risk standardized readmissions measures for AMI, HF, and PN, no additional information is required of hospitals because we use information that is already submitted on Medicare Part A and Part B claims for payment purposes. The Hospital Readmissions Reduction Program includes a payment adjustment based on the hospital's performance with regard to the claims-based readmissions measures. Therefore, in this situation, we do not believe hospitals will be penalized twice based on the same readmissions measures. However, we intend to monitor any potential interactions that the Hospital Readmissions Reduction Program may have with other programs. We anticipate implementing the readmissions payment adjustment through future rulemaking.

Comment: One commenter expressed concern about a number of potential unintended consequences that could result from the Hospital Readmissions Reduction Program, including premature discharge of patients, providers avoiding certain types of patients who are more ill or complicated and therefore likely to be readmitted. Another commenter suggested that the Hospital Readmissions Reduction Program resulted in increased pressure on emergency physicians not to readmit

patients within the 30-day window. This commenter also expressed concerns that physicians in emergency departments do not have access to the patient's record if they have had a recent inpatient stay at another hospital.

Response: We appreciate the commenters pointing out these potential unintended consequences of the Hospital Readmissions Reduction Program. As part of our implementation of the Hospital Readmissions Reduction Program, we will monitor trends to determine if there are unintended consequences of the policy, such as systematic shifting, diversion, and delays in care, in order to assess and take appropriate action to minimize any such unintended consequences.

Comment: One commenter stated that it is important to ensure that transplant centers are not unduly penalized by the Hospital Readmissions Reduction Program, when transplant patients are readmitted for infections caused by the transplantation of organs from marginal donors.

Response: The three applicable conditions for readmission measures only apply to patients discharged with a primary diagnosis code for AMI, HF, and PN, and do not apply to transplant patients who have contracted infections from the transplantation of infected organs. Therefore, patient admissions for transplants and corresponding discharges with those primary codes are not included in the index hospitalizations counted for these measures. However, if a transplant recipient is subsequently admitted with AMI, HF or PN and is readmitted within 30 days, the readmission would be included in the readmissions methodology. Therefore, we do not believe that transplant centers would be disproportionately penalized by the Hospital Readmissions Reduction Program.

Comment: One commenter stated that it is important for hospitals to be able to track patients who are subsequently admitted to other hospitals and requested that CMS develop patient identifiers that would allow for this tracking. Two commenters stated that hospitals need a mechanism to track and understand patient readmissions in real time.

Response: We recognize the value in being able to track patients' readmissions to other hospitals real time both for a hospital's internal quality improvement purpose, and for validating our readmission measure criteria. We thank the commenters for their suggestions, and we will consider whether it is operationally possible to provide these data to hospitals and whether sharing these data would be consistent with patient privacy considerations.

Comment: One commenter recommended that CMS provide hospitals with their expected readmission ratio and actual readmission counts on a quarterly basis, as well as claims data for the prior 12 months for any readmission attributed to them.

Response: To provide the measures quarterly, including the expected readmission rates and the actual counts of readmissions, is resource intensive. We thank the commenters for their suggestions and will consider them if resources allow us to do so in the future. The readmission measures are calculated using the data from the claims that hospitals submitted to CMS for payment. Therefore, hospitals should have access to at least their own facility's patient claims data for the prior 12 months for any readmission attributed to them.

We thank the commenters for these suggestions. We will consider whether it is operationally possible to provide hospitals with these measures quarterly and the patient data for any readmission attributed to the hospitals. In addition we will look into whether sharing these patient data would be consistent with patient privacy considerations.

Comment: Two commenters requested that data be made available to advocacy and watchdog organizations so that the proposed measures can be replicated and validated independently prior to the end of the comment period. One commenter recommended that CMS' calculations, including its methodology for all risk adjustments and how it calculates hospital-specific observed and expected rates be made available to the public so that CMS' work can be replicated and verified.

Response: We have made the methodology reports for risk-adjusting the proposed measures and the software (in SAS format) to calculate the measures publicly available through *https://www.Qualitynet.org.* However, because of the comparative nature inherent to the calculating the measures, we note that the statistical models used to calculate the measures require data from all applicable hospitals, and cannot be replicated using only a single hospital's data. With regard to providing data to advocacy and watchdog groups for independent validation, we have provided the downloadable files on the *Hospital Compare* Web site. The downloadable files contain the aggregate-level data that we publicly reported. As we noted above, we will consider whether it is operationally possible to provide additional data to third parties and whether sharing these data would be consistent with patient privacy considerations.

b. Provisions in the FY 2012 IPPS/LTCH PPS Final Rule

As explained above, the adjustment factor set forth in section 1886(q) of the Act does not apply to discharges until FY 2013. Therefore, we are able to implement the Hospital Readmissions Reduction Program over two years. We are first addressing issues such as the selection of readmission measures and the calculation of the Excess Readmission Ratio, which will then be used, in part, to calculate the readmission payment adjustment factor. Specifically, in the FY 2012 IPPS/LTCH PPS proposed rule and in this final rule, we addressed 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;
- Public reporting of the readmission data; 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 are specifically addressing the following:

- Index hospitalizations;
- Risk Adjustment;
- Risk Standardized Readmission Rate;
- Data sources; and
- Exclusion of Certain Readmissions.

c. Provisions To Be Included in the FY 2013 IPPS/LTCH PPS Proposed Rule

In the FY 2013 IPPS/LTCH PPS rulemaking, we will address the provisions in section 1886(q) of the Act that are related to the payment adjustment, as well as the rest of the provisions in section 1886(q) of the Act that are not addressed in the FY 2012 IPPS/LTCH PPS rulemaking. Specifically, in the FY 2013 IPPS/LTCH PPS proposed rule, we plan to address section 1886(q) of the Act related to the following provisions:

- Base operating DRG payment amount, including policies for SCHs and MDHs;
- Adjustment factor (both the ratio and floor adjustment factor);
- Aggregate payments for excess readmissions;
- Applicable hospital.

We believe it is appropriate to first address the readmission measures and

the calculation of the Excess Readmission Ratio that will be used, in part, to calculate the readmission payment adjustment factor and the application of the readmission payment adjustment factor to inpatient hospital payments. We believe the 2-year rulemaking schedule provides adequate time and opportunities for careful consideration of the various aspects of the Hospital Readmissions Reduction Program by both CMS and stakeholders prior to implementation of the Hospital Readmissions Reduction Program in FY 2013.

Comment: One commenter asked that cancer hospitals payment based on limits set by the Tax Equity and Fiscal Responsibility Act of 1982 be exempt from the Hospital Readmissions Reduction Program.

Response: We appreciate the comment, but we note that this comment is not within the scope of the proposals in the FY 2012 IPPS/LTCH PPS proposed rule regarding the Hospital Readmissions Reduction Program. In the proposed rule, we noted that we plan to address the provisions of section 1886(q)(5)(C) of the Act related to the definition of ''applicable hospital'' in the FY 2013 IPPS/LTCH PPS proposed rule.

Comment: Several comments addressed the payment adjustment under section 1886(q) of the Act. One commenter expressed appreciation that the readmission payment adjustment factor would not be applied to Medicare DSH, IME, or outlier payments. Some commenters believed that the readmission payment adjustment factor should only be applied to discharges following readmissions and not all discharges. Other commenters believed that the formula set forth in the statute to calculate the aggregate payments due to excess readmissions would result in a payment penalty that is too severe. Commenters also stated that the formula to calculate the aggregate payments due to excess readmissions should be the product of the Excess Readmission Ratio, the average base DRG operating payment, and the expected number of readmissions, rather than the current statutory language that defines aggregate payments for excess readmissions as the product of the total number of admissions for the condition, the average base DRG payment for the condition, and the Excess Readmission Ratio.

Commenters also stated that the statutory formula is inconsistent and combines quantities that are not comparable because the Excess Readmission Ratio is based on the ratio of risk-adjusted actual readmissions to risk-adjusted expected readmissions and that ratio, which is based on readmissions, is applied to the total number of admissions. Commenters believed that the statutory formula is contrary to Congressional intent, because the monetary savings if the formula were implemented consistent with the statute is far greater than the CBO score of the provision. Commenters suggested that CMS adopt a less literal and rigid interpretation of the statute or seek a technical amendment to the law.

Response: We appreciate the comments on the readmission payment adjustment factor, but we again note that we did not propose policies related to the Hospital Readmissions Reduction Program payment adjustment in the proposed rule. Therefore, these comments are not within the scope of issues discussed in the FY 2012 IPPS/LTCH PPS proposed rule. We will consider these comments when formulating policies related to the Hospital Readmissions Reduction Program payment adjustment in next year's IPPS/LTCH PPS rulemaking.

d. Expansion of the Applicable Conditions To Be Included in the Future Rulemaking

Pursuant to section 1886(q)(5)(B) of the Act, beginning in FY 2015, the Secretary ''shall, to the extent practicable,'' expand the list of applicable conditions for the Hospital Readmissions Reduction Program beyond the three conditions described in section 1886(q)(5)(A) of the Act to include additional conditions that have been identified by MedPAC as high cost or high volume in its 2007 Report to Congress, as well as other conditions as determined appropriate by the Secretary. We plan to implement this provision of the Hospital Readmissions Reduction Program in future rulemaking.

Comment: A few commenters expressed support for the future expansion of applicable conditions for the Hospital Readmissions Reduction Program. One commenter requested that CMS consider some often undertreated clinical conditions that commonly afflict hospital patients (such as disorders associated with abnormal sodium level). Some commenters urged CMS to provide details about expansion of the applicable conditions soon so that they can begin interventions to improve readmissions for these conditions.

Response: We appreciate the commenters' support and their proactive approach to reduce hospital readmissions. We will take these suggestions into account as we continue to implement the Hospital Readmissions Reduction Program in the future. We plan to consider the remaining four conditions that accounted for almost 12 percent of potentially preventable readmissions as identified by the MedPAC in its 2007 ''Report to Congress'' as well as other conditions as determined appropriate by the Secretary.[51]

Comment: One commenter stated that complying with the Hospital Readmissions Reduction Program measure requirements and concurrently undergoing the adoption of EHR technology is overwhelming. The commenter requested delaying the expansion of applicable conditions until after 2015, when the EHR transition is projected to be complete.

Response: We appreciate the commenter's concerns. The Secretary is authorized under section 1886(q)(5)(B) of the Act to expand the list of applicable conditions beginning in FY 2015. Therefore, we believe hospitals would have sufficient time to prepare to address both the HITECH EHR Incentive Program and the Hospital Readmissions Reduction Program. We will collaborate with stakeholders to assess the impact of expanding the list of applicable conditions as 2015 approaches.

Comment: Another commenter suggested that, if CMS were to adopt the Healthcare Associated Infection (HAI) measure of Clostridium *Difficile* infection proposed for the Hospital IQR Program, it should consider adopting a readmission measure for Clostridium *Difficile* infection for the Hospital Readmissions Reduction Program for FY 2013 or a subsequent year because doing so would help to achieve the goals of the HHS Action Plan to Prevent HAIs.

Response: We appreciate the commenter's suggestion. However, we want to clarify that there is currently no NQF-endorsed readmission measure that covers the condition of Clostridium *Difficile* infection that could have been considered as an applicable condition for FY 2013. For the FY 2013 payment determination for the Hospital Readmissions Reduction Program, we are required to adopt NQF-endorsed measures for the high cost/high expenditure conditions that are selected.

For the Hospital IQR Program, we proposed and are finalizing the clostridium *Difficile* infection measure that was listed among the targeted metrics in the HHS Action Plan to Prevent HAIs, and we believe that doing

[51] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at *http://www.medpac.gov/documents/Jun07_EntireReport.pdf.* Accessed January 10, 2011.

so will further the goals of the Action Plan. In the future, should this condition meet the statutory criteria and should a readmission measure for the condition be established that also meets the statutory criteria, we will consider it for future expansion of the Hospital Readmissions Reduction Program in accordance with the applicable condition requirements set forth in section 1886(q)(5) of the Act.

3. Provisions for the Hospital Readmissions Reduction Program

a. Applicable Conditions for the FY 2013 Hospital Readmissions Reduction Program

Section 1886(q) of the Act sets forth payment adjustments for applicable hospitals to account for excess readmissions, for applicable conditions, that are high volume or high expenditure, in the hospital. These payment adjustments are determined based on the occurrence of readmissions for ''applicable conditions.'' When selecting ''applicable conditions,'' the Secretary must select among conditions and procedures for which (1) readmissions are ''high volume or high expenditure''; and (2) ''measures of such readmissions'' have been endorsed by the entity with a contract under section 1890(a) of the Act'' (currently NQF) and (3) 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).'' Consistent with these requirements, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25931), we proposed to include AMI, HF, and PN as ''applicable conditions'' for the FY 2013 Hospital Readmissions Reduction Program. As set forth below, we believe these conditions meet the criteria for ''applicable conditions'' under section 1886(q)(5)(A) of the Act. We also note that in MedPAC's 2007 Report to Congress that we discussed in section IV.C.1.a. of this preamble, MedPAC listed three conditions (AMI, HF, and PN) as priorities for hospital-specific public reporting of readmission rates.

With regards to the first criterion, that readmissions of ''applicable conditions'' be ''high volume or high expenditure,'' MedPAC identified AMI, HF, and PN as being among the seven conditions and procedures associated with approximately 30 percent of potentially preventable readmissions, based on an 3M analysis conducted for MedPAC of 2005 MedPAR (Medicare FFS hospital claims). Of these seven conditions and procedures, HF and PN were the highest in terms of volume and expenditures.

In addition, in our analysis of the 235 diagnostic categories for hospitalization based on 2008 Medicare hospital claims data, HF and PN were first and second, respectively, as the most frequent diagnostic category for both total admissions and total readmissions. AMI was ninth among the 235 conditions in terms of frequency of admission and 8th in frequency of readmission. Therefore, we believe that AMI, HF and PN consitute high volume and high expenditure conditions particularly as this term relates to hospital admission and readmission.

With regards to the second criterion, we believe that measures of readmissions for these applicable conditions also meet the statutory requirements. Section 1886(q)(5)(A)(ii) of the Act requires that each ''applicable condition'' have ''measures of readmissions'' that ''(I) have been endorsed by the entity with a contract under section 1890(a) [of the Act]; and (II) 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).'' As discussed in section IV.C.3.c. of this preamble, we believe selecting AMI, HF, and PN as ''applicable conditions'' is consistent with this statutory requirement. The NQF (the entity with a contract under section 1890(a) of the Act) has endorsed ''measures of readmissions'' for each of these three conditions, and those NQF-endorsed measures ''have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).''

We believe AMI, HF, and PN meet both prongs of the definition of ''applicable condition.'' Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to include AMI, HF, and PN as ''applicable conditions'' for the Hospital Readmissions Reduction Program for FY 2013. We invited public comment on this proposal.

Comment: One commenter encouraged CMS to carefully review and address the selection of applicable conditions. One commenter urged CMS to exercise caution in implementing financial incentives to reduce readmission of patients for pneumonia and COPD because of the clinical variability and uncertainty involving the effectiveness of interventions for such patients.

Response: We note that we did not propose a COPD-based measure in the FY 2012 IPPS/LTCH PPS proposed rule, but we will take the comment into consideration should we consider proposing COPD as an applicable condition in future rulemaking. In the case of pneumonia, we note that studies suggest optimal care for pneumonia during the index hospitalization may reduce the risk of subsequent readmission.[52] [53] Furthermore, as we discussed above, pneumonia meets all of the statutory criteria to be included as a readmissions measure for the Hospital Readmissions Reduction Program for FY 2013.

As we discussed in the proposed rule, we believe the three applicable conditions that we have selected for the Hospital Readmissions Reduction Program for FY 2013 meet the stringent selection criteria as laid out in the statute and are conditions for which hospital interventions can lead to reduced readmissions. Specific interventions evaluated under the QIO 9th Statement of Work for reducing readmissions are listed at: *http://www.cfmc.org/caretransitions/files/toolkit/intervention/QIO%20Developed%20Tools/Interventions_by_Driver_031011.pdf.* We believe these three applicable conditions are most appropriate for the Hospital Readmissions Reduction Program.

Comment: One commenter stated that using only three applicable conditions in the FY 2013 Hospital Readmissions Reduction Program will create opportunities for gaming.

Response: We believe that the commenter was suggesting that hospitals might change coding practices to avoid identifying patients with AMI, HF, or PN. We plan to monitor trends in admissions and readmissions to ensure there no systematic shift in patients' primary discharge diagnoses codes occurs as a result of implementation of the Hospital Readmissions Reduction Program.

After consideration of the public comments we received, we are finalizing the proposed applicable

[52] Dean NC, Bateman KA, Donnelly SM, *et al.* 2006. Improved clinical outcomes with utilization of a community-acquired pneumonia guideline. Chest 130(3):794–799.

[53] Gleason PP, Meehan TP, Fine JM, *et al.* 1999. Associations between initial antimicrobial therapy and medical outcomes for hospitalized elderly patients with pneumonia. Arch Intern Med 159(21):2562–2572.

[54] Benbassat J, Taragin M. 2000. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Intern Med 160(8):1074–1081.

[55] Benbassat J, Taragin M. 2000. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Intern Med 160(8):1074–1081.

[56] Jonas M, Grossman E, Boyko V, *et al.* 1999. Relation of early and one-year outcome after acute myocardial infarction to systemic arterial blood pressure on admission. Am J Cardiol 84:162–165.

conditions of AMI, HF, and PN for use in the Hospital Readmissions Reduction Program for FY 2013.

b. Definition of ''Readmission''

Section 1886(q)(5)(E) of the Act defines ''readmission'' as, ''in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge.'' The definition further states that ''[i]nsofar as the discharge relates to an applicable condition for which there is an endorsed measure * * * such time period (such as 30 days) shall be consistent with the time period specified for such measure.''

The three NQF-endorsed readmission measures define a readmission as occurring when a patient is discharged from the applicable hospital to a non-acute setting (for example, home health, skilled nursing, rehabilitation or home) and then is admitted to the same or another acute care hospital within a specified time period from the time of discharge from the index hospitalization (*http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841*. The time period specified for these measures is 30 days. Because the measures as endorsed by NQF are calculated based on readmissions occurring within 30 days, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25931 through 25932), we proposed 30 days as the time period specified from the date of discharge for the purpose of defining readmission for the Hospital Readmissions Reduction Program. The 30-day time period also meets the requirement set forth in section 1886(q)(5)(E) of the Act that the time period specified by the Secretary for defining a readmission be consistent with the time period specified for the endorsed measures. We invited public comment on our proposal to adopt, without revision, a proposed definition of readmission with a time period of 30 days from the date of discharge from the index hospitalization as set forth in the existing NQF-endorsed measures.

Comment: One commenter asked how multiple readmissions will be calculated.

Response: The readmissions measures are designed to measure whether a patient experienced at least one readmission within 30 days of an initial (or ''index'') discharge as a single binary (yes/no) event, rather than counting the number of readmissions experienced within 30 days of discharge as a separate readmissions. For any given patient, only the first readmission they have will be counted for the Hospital Readmissions Reduction Program. In addition, only one readmission during the 30 days following the discharge from the initial hospitalization will count as a readmission for purposes of calculating the ratios set forth in section 1886(q) of the Act. For any given patient, none of the subsequent readmissions they experience within 30 days after discharge would be counted as a new ''index'' admission (that is, an admission evaluated in the measure for a subsequent readmission). Any eligible admission after the 30-day time period will be considered a new index admission.

Comment: One commenter recommended defining ''readmission'' to mean ''readmission to the same hospital'' because hospitals cannot control the admitting practices of other institutions.

Response: Section 1886(q)(5)(E) of the Act, as added by the Affordable Care Act, defines ''readmission'' as ''in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital.'' We do not believe that the commenter's suggestion to limit the definition of readmission to only those readmissions to the same hospital is consistent with the statutory definition of ''readmission.'' The statutory definition, which is consistent with the definition of ''readmission'' in the NQF-endorsed measures, captures the more than 20 percent of readmissions that occur at a hospital that is different from the hospital where the initial admission took place. We believe this is the appropriate approach. Although hospitals may not have influence over the admitting practices of outside institutions, we believe that hospitals can communicate effectively with post-acute care providers and take other measures that can better prepare a patient for discharge to reduce the risk of readmission.

After consideration of the public comments we received, we are finalizing our proposal to adopt the definition of readmission as occurring when a patient is discharged from the applicable hospital and then is admitted to the same or another acute care hospital within a specified time period from the time of discharge from the index hospitalization.

c. Readmission Measures and Related Methodology

(1) Readmission Measures for Applicable Conditions

As explained above, section 1886(q)(5)(A)(ii) of the Act requires that each ''applicable condition'' selected by the Secretary has ''measures of readmissions'' that ''have been endorsed by the entity with a contract under section 1890(a) [of the Act]'' and that ''such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge.'' In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25932), we proposed to adopt three NQF-endorsed, hospital risk-standardized readmission measures for AMI, HF, and PN which are currently included in the Hospital IQR Program. These existing measures are:

- Acute Myocardial Infarction [AMI] 30-day Risk Standardized Readmission Measure (NQF #0505);
- Heart Failure [HF] 30-day Risk Standardized Readmission Measure (NQF #0330); and
- Pneumonia [PN] 30-day Risk Standardized Readmission Measure (NQF #0506).

CMS adopted these measures for the Hospital IQR Program in the FY 2009 IPPS/LTCH PPS final rule for the FY 2010 payment determination (73 FR 48606) and the CY 2009 OPPS/ASC final rule with comment period (73 FR 68781). The NQF (the entity with a contract under section 1890(a) of the Act) has endorsed each of these ''measures of readmissions'' and, as explained in more detail below, those NQF-endorsed measures ''have exclusions for readmissions that are unrelated to the prior discharge.'' Therefore, we believe these measures meet the statutory requirements for selection for the Hospital Readmissions Reduction Program, and we proposed them, without modification, as measures for the program.

Comment: Many commenters suggested changes to specific aspects of the three NQF-endorsed 30-day readmission measures for AMI, HF, and PN (for example, exclusions for unrelated readmissions and risk-adjustment of the readmission measures). These comments are summarized and included in the sections of this document that discuss those specific aspects of the measures.

Response: For the FY 2013 Hospital Readmission Reduction Program, the statute requires us to adopt NQF-endorsed measures for the 3 conditions selected. We have proposed to use the three measures as currently NQF endorsed. As we discuss below in the

section regarding NQF endorsement of the measures, we believe that altering specific aspects of the measures that are part of the NQF endorsed methodology (such as exclusions and risk adjustment) would be inconsistent with the statutory requirement to use NQF-endorsed readmission measures.

Comment: One commenter supported CMS' proposal to adopt, without alteration, the three NQF-endorsed 30-day readmission measures for AMI, HF, and PN.

Response: We appreciate the commenter's support of the readmission measures.

After consideration of the public comments we received, we are finalizing three readmission reduction measures for the FY 2013 Hospital Readmissions Reduction Program: AMI 30-day risk standardized readmission measure, HF 30-day risk standardized readmission measure, and PN 30-day risk standardized readmission measure.

(2) NQF Endorsement of Measures of Readmissions

We note that these measures and their underlying methodologies were NQF-endorsed. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25932), we proposed to adopt, for purposes of the Hospital Readmissions Reduction Program, the measures and related methodologies as they are currently endorsed by NQF. This includes the currently endorsed 30-day time window, risk-adjustment methodology, and exclusions for certain readmissions that comprise the measures. We stated our belief that our proposal to adopt, without modification, these measures of readmission is consistent with the statutory language, which requires the measures of readmissions to be ''endorsed by the entity with a contract under section 1890(a) [of the Act].'' If we were to modify the endorsed measures, we are concerned that they would no longer be considered ''endorsed.'' If the NQF were to later endorse a revised measure for one of these conditions, we would then propose through notice and comment rulemaking that the revised measure be used prospectively for purposes of the Hospital Readmissions Reduction Program.

We welcomed public comment on our proposal to use, for each of the proposed applicable conditions, existing measures as endorsed by the NQF.

We did not receive any public comments specifically on the NQF-endorsement of the three proposed readmission measures. Therefore, we are finalizing the three NQF-endorsed Hospital Readmissions Reduction Program measures as proposed for the FY 2013 Hospital Readmissions Reduction Program.

(3) Endorsed Measures With Exclusions for Unrelated Readmissions

Section 1886(q)(5)(A)(i)(ii)(II) of the Act requires that each of the readmission measures also have ''exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).'' The three NQF-endorsed readmission measures that we proposed in the FY 2012 IPPS/LTCH PPS proposed rule for inclusion in the Hospital Readmissions Reduction Program have exclusions that meet this statutory requirement. Under each measure, certain unrelated readmissions are not taken into account when determining the number of readmissions under the measures.

The AMI 30-day risk standardized readmission measure, as endorsed by the NQF and as proposed in the FY 2012 IPPS/LTCH PPS proposed rule, has exclusions for certain unrelated readmissions. Because admissions for Percutaneous Transluminal Coronary Angioplasty (PTCA) or Coronary Artery Bypass Graft (CABG) may be staged or are typically scheduled readmissions for patients initially admitted for AMI, the AMI 30-day risk standardized readmission measure does not count as readmissions those admissions after discharge that include PTCA or CABG procedures, unless the principal discharge diagnosis for the readmission is one of the following diagnoses that are not consistent with a scheduled readmission: Heart failure, acute myocardial infarction, unstable angina, arrhythmia, and cardiac arrest (that is, readmissions with these diagnoses and a PTCA or CABG procedure are counted as readmissions). We adopted this approach when first developing this measure after consultation with clinical experts, including cardiologists, and review of relevant readmissions data.

During the development of the readmission measures for both HF and PN, we similarly asked clinical experts to identify planned readmissions for these conditions, that is, those which would not count as a readmission, after an admission for HF or PN. Specifically, the clinical experts were asked whether there were common follow-up causes of readmissions for a scheduled procedure that represented a continuation of care after either a HF or PN admission, respectively. No such related, planned procedures were identified as occurring commonly after the index admissions for HF or PN at the time of the development of the Hospital IQR Program measures. Therefore, no similar exclusions exist for the HF and PN measures of readmissions as they are currently endorsed.

The three NQF-endorsed risk-standardized readmission measures that we proposed in the FY 2012 IPPS/LTCH PPS proposed rule exclude transfers to other acute care facilities from each of the readmission measures. The NQF-endorsed proposed measures consider these multiple contiguous hospitalizations to be a single acute episode of care. The measures attribute the readmission for transferred patients to the hospital that ultimately discharges the patient to a non-acute care setting (for example, to home or a skilled nursing facility). Thus, in the case of a patient who is transferred between two or more hospitals, if the patient is readmitted in the 30 days following the final hospitalization, the measures attribute such a readmission to the hospital that discharged the patient to a non-acute care setting. We believe that the exclusion of transfers to other applicable hospitals under the measures is sufficient to meet the requirement set forth in section 1886(q)(5)(A)(ii)(II) of the Act that certain ''unrelated'' readmissions be excluded from the measures selected for use in the program.

Comment: Many commenters stated that the current set of existing exclusions for unrelated readmissions did not meet Congress' intent, which they believed requires additional exclusions for certain readmissions. These commenters noted that although the AMI measure contains exclusion for certain planned procedures, neither the heart failure nor the pneumonia measures contain such exclusions.

Response: We thank the commenters for sharing their views on exclusions for the proposed readmission measures. Section 1886(q)(5)(A) of the Act requires us to select as the initial readmission measures those that are endorsed by the entity with a contract under section 1890(a) (currently the NQF), and that have exclusions for readmissions that are unrelated to the prior discharges (such as a planned readmission or transfer to another applicable hospital). The statute does not state that the measures must account for all possible unrelated readmissions. Moreover, adding exclusions would be inconsistent with the statute, which requires us to adopt the measures as endorsed by the NQF, and the endorsements currently include specific exclusions for unrelated readmissions, which include transfers.

We recognize that there could conceivably be additional readmissions

that could properly be excluded from the readmission measures, and we intend to further explore if there are any such readmissions. If we determine that changes should be made to the measures used for the Hospital Readmissions Reduction Program in FY 2013, we will bring them to NQF for review for continued endorsement for the measures and would subsequently propose the revised measure for use in the Hospital Readmissions Reduction Program in future rulemaking.

Comment: Several commenters urged CMS to ''* * * conduct a study to thoroughly determine the common reasons for planned readmissions, as well as determine a subset of readmissions that are unrelated to a patient's initial admission. * * *'' These commenters also recommended three possible interim steps: (1) Not counting readmissions for certain patients (cancer, trauma, burns, end-stage renal disease, psychiatric disorders, substance abuse, and rehabilitation); (2) allowing a coding modifier on hospital claims to identify planned readmissions; or (3) using existing classification schemes such as MS–DRGs or AHRQ's classification system (*http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp*), the clinical classification software, which ''groups diagnoses and procedure codes into clinically meaningful groups'' to identify related readmissions (and to exclude readmissions that are not identified as related).

Response: We appreciate the commenters' suggestions. As part of our ongoing implementation of the Hospital Readmissions Reduction Program, we intend to further explore whether there are other readmissions that could be excluded from the readmission measures finalized in this rule, and we expect that we will solicit public input on this issue in future rulemaking. However, again we note that because the FY 2013 measures must be NQF-endorsed, any changes to the measures used for the program in FY 2013 would have to be brought to NQF for review for continued endorsement before we could, in future rulemaking, propose the measures for use in the Hospital Readmissions Reduction Program.

Comment: Some commenters expressed concern that inappropriate transfers from acute care hospitals to a different acute care hospital might occur. Several of these commenters requested that CMS monitor transfers to ensure that potentially high-risk patients are not unnecessarily transferred in an attempt to artificially reduce hospital readmission rates.

Response: We note that the NQF-endorsed readmission measures as finalized in this rule are designed to count all readmissions unless they meet the planned procedure definition for AMI or involve a transfer to another acute care hospital. This approach is consistent with section 1886(q)(5)(ii)(II) of the Act which requires that ''endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).''

With regard to the commenters' concerns about hospitals transferring patients to another acute care institution to avoid being accountable for readmissions, we will consider future monitoring of transfer rates to assess if there are any unexpected changes in transfer patterns in response to the Hospital Readmissions Reduction Program.

Comment: Two commenters expressed concern regarding the appropriateness of the exclusion criteria for unrelated readmissions for use in measures when applied to hospitals that treat specialized patient populations, such as LTCHs and IPPS-exempt cancer hospitals. One commenter emphasized the importance to rural hospitals of not counting unrelated or planned readmissions. Another commenter suggested that CMS not count readmissions related to random events such as falls or readmissions that occur during natural disasters or states of emergency. One commenter suggested a method of reporting ''nonreportable'' admissions via the claims payment system. One commenter believed that the upcoming implementation of ICD–10 would enhance CMS' ability to identify and remove readmissions related to random events.

Response: We thank the commenters for their input on exclusion criteria, and we will consider these suggestions as we continue to implement the Hospital Readmissions Reduction Program. The proposed NQF-endorsed readmission measures were designed as ''all-cause'' readmission measures (that is, they count readmission regardless of the reason for readmission) because, from a patient perspective, readmission from any cause is an adverse event. Similarly, as we discussed above, many cases of seemingly unrelated diagnoses may, in fact, correspond to the original hospitalization, and differentiation is not always possible solely on the basis of the admitting diagnosis for the readmission. For instance, a patient with heart failure who develops a hospital-acquired infection may ultimately be readmitted with sepsis. In this context, we believe that the NQF-endorsed readmission measure for heart failure appropriately considers the readmission to be related to the care the patient received for heart failure during the first hospitalization.

In our view, readmissions that are truly unrelated to the hospitalization should not affect some hospitals more than others, because these readmissions should have the same probability of occurring for similarly situated patients, regardless of where the patient was initially hospitalized. We also note that planned readmissions are easier to identify, especially those that are elective and scheduled in advance either as follow-on care for a procedure following a hospitalization or that have been scheduled by outpatient providers, and are not indicative of care quality.

Comment: One commenter stated there is another readmission measure available that has excludes greater numbers of unrelated readmissions and is in use in a State.

Response: The readmissions measure referred to by the commenter is 3M's Potentially Preventable Readmission measure and is in use in the State of Florida. This measure was reviewed by NQF in 2009 and was not endorsed (NQF # HOE–007–08). It is our understanding that the NQF's Steering Committee's decision not to endorse the measure reflected the Committee's concern about the measure's approach to identifying preventable readmissions. The measure developer specified over 98,000 admission–readmission diagnoses pairs (for example, a heart failure admission followed by readmission for a fall) as either clinically related and therefore preventable or not related and therefore not preventable. The NQF Steering Committee did not think these judgments were reliable, and it rejected the measure in part on this basis. We agree with the Steering Committee that this measure did not accurately specify what is related or unrelated simply by looking at the diagnoses for the admission and the readmission.

After consideration of the public comments we received, we are finalizing the NQF-endorsed measures with exclusions for unrelated conditions, as proposed.

(4) Methodology of Readmission Measures

In the following section, we describe the major components of the measure methodology of the three NQF-endorsed risk-standardized readmission measures for AMI, HF and PN that we proposed for the implementation of the Hospital Readmissions Reduction Program.

Additional details about each of these measures may be found online at *http://www.QualityNet.org*>Hospital-Inpatient>Readmission Measures>methodologies. This Web page is located at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

Briefly, as is described in more detail in the sections below, the measures are risk-standardized rates of readmission. For each hospital, qualifying index hospitalizations are identified based on the principal discharge diagnosis of the patient and the inclusion/exclusion criteria (section IV.C.3.c.(4)(A) of this preamble on index hospitalizations). Each hospitalization is evaluated for whether the patient had a readmission to an acute care setting in the 30-days following discharge (section IV.C.3.c.(4)(B) of this preamble on readmission). Patient-risk factors, including age, and chronic medical conditions are also identified from inpatient and outpatient claims for the 12-months prior to the hospitalization for risk-adjustment (section IV.C.3.c.(4)(D) of this preamble on risk-adjustment). The readmissions, sample size for each hospital, and patient risk-factors are then used to calculate a risk-standardized readmission ratio for each hospital. For the purposes of publicly-reporting the measures, this risk-standardized readmission ratio is then multiplied by the national crude rate of readmission for the given condition to produce a risk-standardized readmission rate (RSRR) (section IV.C.3.c.(5)(B) of this preamble).

(A) Index Hospitalization

An index hospitalization for each of the readmission measures is the hospitalization from which we evaluate the 30 days after discharge for possible readmissions. The measures, as endorsed by the NQF, evaluate eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital (as defined by section 1886(q)(5)(C) of the Act) having a principal discharge diagnosis for the measured condition in an applicable period. The NQF-endorsed measures, as specified, exclude patients under 65 year of age.

The discharge diagnoses for each applicable condition are based on a list of specific ICD–9–CM codes for that condition. These codes are listed in the *2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30-Day Risk-Standardized Readmission Measures.* They also are posted on the QualityNet Web site: *http://www.QualityNet.org*>Hospital-Inpatient>Readmission Measures>methodologies. See *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=Qnet Public%2FPage%2FQnetTier4&cid=1219069855841.*

The current NQF-endorsed CMS 30-day risk standardized readmission measures exclude the following admissions from the group of index hospitalizations:

- Hospitalizations for patients with an in-hospital death (because they are not eligible for readmission);
- Hospitalizations for patients without at least 30 days post-discharge enrollment in Medicare FFS (because the 30-day readmission outcome cannot be assessed in this group);
- Hospitalizations for patients discharged against medical advice (because providers did not have the opportunity to deliver full care and prepare the patient for discharge).
- Hospitalizations for patients under the age of 65.

Comment: One commenter noted that admissions related to disaster preparedness or recovery should be excluded from the measures. One commenter noted that the nature of traumatic injuries is such that certain medical conditions are not always readily apparent upon admission and lead to the need for readmission.

Response: We appreciate the commenter's recommendation, and we intend to consider whether to it would be appropriate to allow waivers for extraordinary regional or local circumstances, such as natural disasters that are not in the control of the hospital. Any such process would be proposed in a future rulemaking.

(B) Readmission

As explained above, the initial hospitalization assessed for a readmission is called the index hospitalization. The proposed measures, as endorsed by the NQF, define readmission as a second admission to another acute care hospital within 30 days of the index hospitalization. Under the proposed measures, as endorsed by the NQF, a patient who is readmitted twice within 30 days simply is counted as having been readmitted; this patient's readmissions are not counted differently than a patient with a single readmission within 30 days of discharge.

With the exception of the exclusions discussed previously (transfers and planned readmissions, as discussed in the Exclusions for Unrelated Readmissions section above), the proposed measures, as currently endorsed by the NQF, include readmissions for all causes, without regard to the principal diagnosis of the readmission. There are several reasons for this approach. First, from the patient's perspective, readmission from any cause is an adverse event. Second, although we would expect few hospitals to use gaming strategies, we strive to make sure that measures do not create incentives for hospitals to do so. Limiting the readmissions to particular diagnoses creates an opportunity for hospitals to potentially avoid having readmissions counted by changing coding practices. Further, doing so could create a perverse incentive whereby hospitals begin to avoid patients with conditions that are part of the readmissions measures. Third, as discussed above, there are not currently any clinically and technically sound and accepted strategies for accurately identifying readmission that are unrelated to hospital quality based on the documented cause of readmission. Finally, we believe it is important that hospitals strive to reduce readmissions from all causes, not just for patients with conditions that happen to be readmissions measures. While the measures do not presume that each readmission is preventable, interventions have generally shown reductions in all types of readmissions (including both related and unrelated readmissions). The NQF measures are intended to provide incentives for hospitals to reduce readmissions and not to achieve zero readmissions.

(C) Time Window

The three proposed measures, as endorsed by the NQF, count readmissions within a 30-day period from the date of the initial discharge from the index hospitalization. The timeframe of 30 days is a clinically meaningful period for hospitals, in collaboration with their medical communities, to reduce readmission risk. This time period for assessing readmission is an accepted standard in research and measurement. We believe that during this 30-day time period, hospital and community partners can take steps to reduce risk by ensuring patients are clinically ready to be discharged, improving communication across providers, reducing risks of infections, and educating patients on symptoms to monitor whom to contact with questions and where and when to seek follow-up care can influence readmission rates.

Comment: One commenter suggested the proposed 30-day time period (time window) is too long and should be reduced to 15 days. Another commenter

supported the 30-day time window, but indicated that they preferred 15 days.

Response: The proposed timeframe of 30 days from the date of the initial discharge from the index hospitalization is the timeframe that has been NQF-endorsed as part of the three readmission measures. The timeframe of 30 days is considered an acceptable standard in both the research and measurement communities as this time period is long enough to capture a substantial proportion of readmissions attributable to an index hospitalization, a greater proportion than captured in just 15 days, and yet it is short enough that outcomes can be attributed to and influenced by hospital care and the early transition to the outpatient setting. The use of the 30-day timeframe is also a clinically meaningful period for hospitals to collaborate with their communities in an effort to reduce readmissions. Multiple studies have shown that interventions by hospitals can make an impact on 30-day readmission rates.[54] [55] [56] Finally, we again note that, as required under the Act, we proposed the measures as they were endorsed by the NQF. Since the NQF-endorsed measures use a 30-day time period, we are finalizing our proposal to count readmissions within a 30-day period from the date of the initial discharge from the index hospitalization.

(D) Risk Adjustment

Section 1886(q)(4)(C)(i)(I) of the Act requires that the number of readmissions used in the Excess Readmission Ratio be risk adjusted. This language requires us, when comparing hospitals' readmission rates, to account for differences in the severity of illnesses of the patients that hospitals treat. Risk adjustment essentially ''levels the playing field'' for comparing hospital performance by taking into account that some hospitals' patients are sicker than others on admission and therefore have a higher risk of readmission.

The methodology for calculating the RSRRs under the NQF-endorsed measures that we proposed adjusts for key factors that are clinically relevant and have strong relationships with the outcome (for example, patient demographic factors, patient co-existing medical conditions, and indicators of patient frailty). Under the current NQF-endorsed methodology, these covariates are obtained from Medicare claims extending 12 months prior to, and including, the index admission. This risk-adjustment approach adjusts for differences in the clinical status of the patient at the time of the index admission as well as for demographic variables.

A complete list of the variables used for risk adjustment and the clinical and statistical process for selecting the variables for each NQF-endorsed measure, as proposed, is available in the publicly-available technical documentation of the existing measures for AMI, HF, and PN. The risk adjustment variables for each condition are presented in the 2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30-Day Risk-Standardized Readmissions Measures that are posted on *http://www.QualityNet.org*>Hospital-Inpatient>Readmission Measures>Resources. The variables used are Condition Categories that group ICD–9–CM codes into clinically coherent variables. The 2010 Condition Category-ICD–9–CM Crosswalk provides a map to the specific ICD–9–CM codes in each variable and is also posted on *http://www.QualityNet.org*>Hospital-Inpatient>Readmission Measures>Measure Calculation Methodology or readers may use the following Web site address: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

Comment: Many commenters argued that CMS should risk-adjust for patient characteristics beyond the medical diagnosis, age and gender currently included in the NQF-endorsed risk adjustment methodology. Specifically, commenters believed that patient race, language, life circumstances, environmental factors, and socioeconomic status (SES) should be included in the risk-adjustment methodology, because these factors also have an impact on health outcomes. Commenters expressed concern that without adding these adjustment factors, the Hospital Readmissions Reduction Program may disproportionately affect hospitals serving a large number of minorities, and by penalizing these hospitals, the program could in turn disproportionately harm minority patients. Commenters stated that failure to account for these factors could result in ''disparate-impact discrimination,'' potentially violating Title VI of Civil Rights Act and 45 CFR 80.3.

Response: We do not agree that the use of the current NQF-endorsed risk adjustment methodology in the Hospital Readmissions Reduction Program will harm minorities. The proposed readmission measures are risk-standardized readmission measures that adjust for case-mix differences based on the clinical status of the patient at the time of admission to the hospital. That is, they are risk-adjusted for certain key variables (for example, age, sex, co-morbid diseases and indicators of patient frailty) that are clinically relevant and/or have been found to have strong relationships with the outcome. To the extent that race or SES results in certain patient groups having a greater disease burden, those factors are accounted for in the measure. A more complete description of the risk adjustment model and its development is available on the QualityNet Web site (*http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841*).

However, these measures are not adjusted for other factors such as race, English language proficiency or SES. We believe such additional adjustments are not appropriate because the association between such patient factors and health outcomes can be due, in part, to differences in the quality of health care received by groups of patients with varying race/language/SES. Differences in the quality of health care received by certain racial and ethnic groups may be obscured if the measures risk-adjust for race and ethnicity. Additionally, risk-adjusting for patient race, for instance, may suggest that hospitals with a high proportion of minority patients are held to different standards of quality than hospitals treating fewer minority patients.

We appreciate the concerns of hospitals that care for disproportionately large numbers of disadvantaged populations. Our analysis indicates that better quality of care is achievable regardless of the demographics of the hospital's patients. (See: *Medicare Hospital Quality Chartbook 2010*).

Although we believe the current risk-adjustment methodology properly accounts for different patient circumstances, we will monitor whether the Hospital Readmissions Reduction Program has a disparate impact on

[54] Benbassat J, Taragin M. 2000. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Intern Med 160(8):1074–1081.

[55] Benbassat J, Taragin M. 2000. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Intern Med 160(8):1074–1081.

[56] Jonas M, Grossman E, Boyko V, *et al.* 1999. Relation of early and one-year outcome after acute myocardial infarction to systemic arterial blood pressure on admission. Am J Cardiol 84:162–165.

[57] *http://www.cms.gov/HospitalQualityInits/20_OutcomeMeasures.asp#TopOfPage.*

hospitals that care for large numbers of disadvantaged patients. If such an impact is found, we will consider whether additional program modifications would be appropriate and consistent with the statutory requirements and intent of the program. For example, one option might be to refine the measures themselves to include factors such as SES in the risk adjustment. We also note that there are programs that provide technical and financial support that may assist hospitals in improving performance on the readmission measures included in the Hospital Readmissions Reduction Program such as the Community Based Care Transitions program authorized under section 3026 of the Affordable Care Act and the Partnership for Patients, a new public-private partnership that will help improve the quality, safety and affordability of health care. In addition, assistance in lowering readmission rates is available from the Quality Improvement Organizations.

Comment: Several commenters suggested that trauma hospitals and safety-net hospitals are at increased risk of being subject to a payment adjustment under the Hospital Readmissions Reduction Program because of insufficient risk-adjustment for ''case-mix'' or the fact that their patients are sicker, lack access to appropriate post-discharge care, may suffer numerous chronic conditions, and may have substance abuse or behavioral problems. Another commenter expressed concern that coding does not capture patients in palliative care or those readmitted from hospice, but acknowledged that CMS risk adjustment methodology is the state of the art at present.

Response: We thank the commenters for their input. As noted above, our analyses suggest that trauma and safety net hospitals caring for high proportions of at-risk patients can, and frequently do, perform as well on the readmission measures as those hospitals with fewer at-risk patients (see: *Medicare Hospital Quality Chartbook 2010,* pp 14–19).

We do not exclude hospice patients or those who have elected palliative care from the readmission measures because we do not believe that it is appropriate to differentiate, as to the appropriateness of care provided, between patients who have elected hospice or palliative care and those who have not.

After consideration of the public comments we received, we are finalizing the risk-adjustment methodology as proposed and endorsed by the NQF.

(E) Applicable Period

Section 1886 (q)(5)(D) of the Act authorizes the Secretary to specify the ''applicable period'' with respect to a fiscal year. Currently, for Hospital IQR Program public reporting purposes, we use 3 years of data (three 12-month increments) to calculate the three proposed readmission measures. This provides substantially more data than a 1- or 2-year timeframe and increases the precision of the measure in distinguishing performance among hospitals. Additionally, it is advantageous to have three years worth of data for purposes of displaying the three proposed readmission measures on *Hospital Compare* where we categorize hospital performance into one of three discrete categories: ''Better than the US national rate,'' ''No different than the US national rate,'' and ''Worse than the US national rate.''

For the FY 2013 Hospital Readmissions Reduction Program, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25934), we proposed to use 3 years of data for discharges from July 1, 2008 through June 30, 2011 as the applicable period upon which to calculate Excess Readmission Ratios for each of the three proposed measures. Based on our experience with the Hospital IQR Program, we believe that this timeframe increases the precision of the measures in distinguishing performance among hospitals. However, for purposes of the Hospital Readmissions Reduction Program, we will not be categorizing hospital performance in three categories; rather, we will be using the measures to calculate Excess Readmission Ratios for the three conditions. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25934), we proposed to use a 3-year data period spanning July 1, 2008 through June 30, 2011, as the applicable period for determining the FY 2013 Hospital Readmissions Reduction Program payment adjustment. We indicated that we are currently conducting analyses to determine an appropriate data period (for example, 1 year, 2 years, 3 years) that will yield reliable Excess Readmission Ratios for the three proposed measures, and that we intend to consider both the positive and negative consequences of using longer or shorter data periods for this program. We also indicated that should our analysis or public comment indicate that a shorter data period yields Excess Readmission Ratios with acceptable reliability, we may consider finalizing a shorter time period.

We invited public comment and suggestions on the topic of an appropriate length for the applicable period to consider for the three proposed readmission measures for FY 2013.

Comment: Many commenters recommended that CMS shorten the proposed applicable period of 3 years so that only more recent data would be used for the Hospital Readmissions Reduction Program. Some commenters urged CMS to shorten the timeframe because the commenters believed it was unfair to assess hospital performance on data that occurred during 2008, which is ''long before [the Hospital Readmissions Reduction Program provision] was passed * * *''

Response: We thank the commenters' for their views regarding the data used for the measures. We proposed 3 years as the applicable period because we believe that this time period would ensure the proposed measures covers a sufficient number of applicable patients for hospital performance to be fairly portrayed. For example, from 2006 through 2008, only 2,500 of the 4,500 qualifying hospitals for the Hospital Readmissions Reduction Program reported at least 25 discharges for AMI during that time period.

As stated above, we indicated that we are currently conducting analyses to determine if a different data period (for example, 1 or 2 years) might also yield reliable Excess Readmission Ratios for the three proposed measures. We intend to consider both the positive and negative consequences of using longer or shorter data periods for this program. If our analysis or public comments indicate that a shorter data period yields Excess Readmission Ratios with acceptable reliability, we may consider finalizing a shorter time period.

Because we did not receive any public comments demonstrating that a shorter period would yield reliable and meaningful results upon which differences in hospital performance could be appropriately distinguished, and because our own analysis indicated that 3 years continues to be an appropriate period, we are finalizing 3 years as the applicable period for the FY 2013 Hospital Readmissions Reduction Program.

(F) Data Sources

As discussed above, the adjustment under section 1886(q) of the Act is made to the ''base operating DRG payment amount,'' and components of the ratio used to determine a hospital's adjustment factor also use that payment amount. Payments under section 1886 of the Act, including the ''base operating DRG payment amount,'' are made for services furnished to Medicare's fee-for-

service population under part A. Therefore, for purposes of implementing the Hospital Readmissions Reduction Program under section 1886(q) of the Act, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25934), we proposed to use Medicare claims data for the Medicare FFS population over the age of 65 only. This is the same universe of claims used for calculating the NQF-endorsed measures for the purposes of the Hospital IQR Program.

The administrative data sources for the risk adjustment analyses are Medicare administrative claims datasets that contain FFS inpatient and outpatient (Medicare Parts A and B) claims information in the prior 12 months and subsequent one month for patients admitted in each of these years. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25934), we proposed to use claims from the index hospitalization included the measure and from the prior 12 months from all of these data sources to gather risk factors. If the patient does not have any claims in the 12 months prior to the index hospitalization admission, only comorbidities from the included admission are used.

We welcomed public comment on this proposal.

We did not receive any public comments on this proposal. Therefore, we are finalizing the data sources used for the Hospital Readmissions Reduction Program as proposed in the FY 2012 IPPS/LTCH PPS proposed rule.

(G) Minimum Number of Discharges for Applicable Conditions

Section 1886(q)(4)(C)(II)(ii) of the Act authorizes the Secretary to exclude readmissions for an applicable condition for which there are ''fewer than a minimum number (as determined by the Secretary).'' Currently, for public reporting purposes under the Hospital IQR Program, only hospitals with at least 25 discharges for each of the three proposed applicable conditions are included in the display of the three proposed readmission measures on *Hospital Compare.* We chose this number of discharges for the Hospital IQR Program based on our findings that using fewer cases did not provide sufficiently reliable information on hospital performance. In general, the larger the number of cases, the more reliable the information. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25935), we indicated that we are currently conducting additional analyses to further evaluate the appropriate minimum number of discharges needed to yield reliable Excess Readmission Ratios for the three proposed measures. However, based on our experience with the Hospital IQR Program, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25934 through 25935), we proposed to use the current threshold of 25 discharges for each of the three measures for the Hospital Readmissions Reduction Program. However, we indicated that should our analysis or public comment indicate that a different minimum number of discharges would be more appropriate for this program, we would consider finalizing a different number.

We invited public comment and suggestions on the topic of appropriate minimum number of discharges to consider for the three proposed readmission measures.

Comment: Several commenters supported the proposed minimum number of 25 discharges. Other commenters stated that 25 discharges is too small a number to reliably profile hospitals.

Response: We appreciate hearing from commenters regarding the proposed minimum number of discharges. We continue to believe that 25 discharges is the appropriate cut-off. As noted in the proposed rule, we have been using 25 cases as the minimum sample size for publicly reporting hospital quality measures on *Hospital Compare* Web site for the Hospital IQR Program. Hospitals are familiar with this threshold. We also proposed to use this threshold of 25 discharges for each of the three measures to calculate the Excess Readmission Ratios because we believe this number helps maximize hospital participation and at the same time ensures that we achieve reasonable reliability for profiling hospital performance.

After consideration of the public comments we received, we are finalizing our proposal to use 25 discharges as the minimum number of discharges for applicable conditions for the FY 2013 Hospital Readmissions Reduction Program. We note that analyses to determine appropriate sample size to yield reliable Excess Readmission Ratios for the three readmission measures are ongoing. If the results of our analyses suggest that a different minimum number of discharges would be more appropriate, we will propose to revise the minimum number accordingly through future rulemaking.

(H) Reporting Hospital-Specific Readmission Rates

Section 1886(q)(6)(A) of the Act requires the Secretary to ''make information available to the public regarding readmission rates of each subsection (d) hospital under the [readmissions reduction] program.'' Section 1886(q)(6)(B) of the Act requires the Secretary to ''ensure that a subsection (d) hospital has the opportunity to review and submit corrections for, the information to be made public with respect to the hospital * * * prior to such information being made public.'' Section 1886(q)(6)(C) of the Act requires the Secretary to post the hospital-specific readmission information on the *Hospital Compare* Web site in an easily understandable format.

We currently report information on the three readmission rates that we are finalizing in this rule on the *Hospital Compare* Web site for each subsection (d) hospital. We provide hospitals with an opportunity to preview their readmission rates for 30 days prior to posting on the Web site. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25935), we proposed to use a similar process and timeframe for the rates calculated for the Hospital Readmissions Reduction Program. Through this process, hospitals will be able to review the information and submit to CMS corrections in advance of the information to be made public. We will review all such correction submissions and determine the appropriateness of any revisions. We will inform the hospital requesting corrections of our findings, and we will make any appropriate revisions to the information to be made available to the public regarding the hospital's readmission rates.

We invited public comment on this proposal.

Comment: Several commenters supported our proposal to use a preview period and public reporting process that is similar to that used in the Hospital IQR Program. Two commenters requested more information about how the information will be presented on the *Hospital Compare* Web site. One recommended that more specific data on actual readmission rates be portrayed.

Response: We appreciate the commenters' support for the proposed reporting procedure for hospital-specific readmission rates. This reporting procedure will be different from what is reported with the Hospital IQR Program. The Hospital IQR Program identifies hospitals on *Hospital Compare* as being better than, no different than, or worse than the national rate for readmission. However, the Hospital Readmissions Reduction Program will include hospital-specific readmission rates.

Comment: One commenter requested clarification on ''what grounds and with

what data'' a hospital might appeal its calculated expected readmissions ratio.

Response: As stated earlier, hospitals will be able to review the information and submit to CMS corrections related to their readmission rate in advance of the information to be made public. We will review all such correction submissions and determine the appropriateness of any revisions. The policies regarding what aspects of the readmission rates are subject to corrections, as well as specifics regarding the review and correction process will be proposed in future rulemaking. We will consider the commenter's concern as we develop our proposal.

After consideration of the public comments we received, we are finalizing the proposed reporting procedure for hospital-specific readmission rates for the FY 2013 Hospital Readmissions Reduction Program.

(I) Readmission Rates for All Patients

Section 1886(q)(8)(A) of the Act requires the Secretary to calculate readmission rates for all patients for a ''specified hospital'' for an applicable condition and ''other conditions deemed appropriate by the Secretary for an applicable period.'' Section 1886(q)(8)(D)(ii) of the Act defines ''specified hospital'' as: ''a subsection (d) hospital; hospitals described in clauses (i) through (v) of subsection (d)(1)(B) (psychiatric hospitals, rehabilitation hospitals, children's hospitals, LTCHs, and cancer hospitals); and, as determined feasible and appropriate by the Secretary, other hospitals not otherwise described. * * *'' Such information is to be calculated in the same manner as used to calculate readmission rates for hospitals with respect to the postings on the CMS *Hospital Compare* Web site.

Section 1886(q)(8)(C) of the Act requires specified hospitals, or a State or an appropriate entity on behalf of the hospitals, to submit to the Secretary, in a form, manner and time specified by the Secretary, data and information determined necessary to calculate the all patient readmission rates. Section 1886(q)(8)(D) of the Act defines ''all patients'' to mean patients who are treated on an inpatient basis and discharged from a specified hospital. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25935), we did not propose any specific policies to implement section 1886(q)(8) of the Act, but we invited public comment and suggestions for issues related to implementation of these provisions, such as the mechanisms to collect the all-patient data, the collection of patient identifiers to track patient care history across multiple settings to conduct risk adjustment for outcome measures, what entities could submit all patient data on behalf of hospitals, and more generally, the requirement for all patient data submission.

Comment: One commenter supported the calculation of all-patient readmission rates. Another commenter supported the decision to defer proposals for the collection of data necessary for readmission rates of all patients to allow CMS enough time to put the underlying infrastructure in place. One commenter suggested allowing hospitals to either submit data directly to CMS, or through a third party that is not another payer.

Response: We appreciate the comments provided on this issue. As we stated in the proposed rule, we will take them into account in the calculation and reporting of readmission rates for all patients in future rulemaking.

(5) Excess Readmission Ratio

(A) Statutory Background

Section 1886(q)(4)(C) of the Act requires the Secretary to develop a risk-adjusted ''Excess Readmission Ratio.'' The Excess Readmission Ratio will be used in the calculation of ''aggregate payments for excess readmissions'' as required under section 1886(q)(4)(A)(iii) of the Act, which, in turn, is used to determine the adjustment factor under section 1886(q)(3) of the Act. Specifically, section 1886(q)(4)(C)(i) of the Act states that the term '' 'excess readmission ratio' means, with respect to an applicable condition for a hospital for an applicable period, the ratio * * * of * * * the risk adjusted readmissions based on actual readmissions * * * to * * * the risk adjusted expected readmissions. * * *'' The Act also requires that the numerator and denominator of the ratio, that is, ''risk adjusted readmissions based on actual readmissions'' and the ''risk adjusted expected readmissions,'' be determined ''consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I) [of the Act].''

(B) Excess Readmission Ratio Methodology

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25935 through 25936), we proposed to use the risk-standardized ratio calculated for the NQF-endorsed measures for AMI, HF, and PN as the ''Excess Readmission Ratio.'' This risk-standardized ratio (Excess Readmission Ratio), as required by the Act, is a ratio of ''risk adjusted readmission based on actual'' to ''risk adjusted expected readmissions.'' Moreover, use of this ratio meets the statutory requirement that the numerator and denominator of the ratio be determined in a manner that is ''consistent with'' an NQF-endorsed readmission measure methodology.

The proposed ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (that is, patients with the same risk factors for readmission such as age and comorbidities), the ratio will be less than one. If a hospital performs worse than average, the ratio will be greater than one. Hospitals with a ratio greater than one have excess readmissions relative to average quality hospitals with similar types of patients.

As part of the Hospital IQR Program, the risk-standardized ratio is used to generate the measure results for these three measures that are reported on *Hospital Compare* Web site. The risk-standardized ratio is the unique result produced by the measures for each hospital for each condition to assess relative hospital performance. Hospitals may not be familiar with this ratio because the measure result reported on *Hospital Compare* for each hospital and each condition is this ratio multiplied by a constant (the national raw rate of readmission for the condition), and it is currently presented as the risk-standardized readmission rate (RSRR). Multiplying by a constant transforms the ratio into a rate (the risk-standardized readmission rate) that is better understood by the public. Thus *Hospital Compare* results for CMS readmission measures are computed as follows:

[Hospital risk-standardized ratio] X [national raw readmission rate]

(i) Numerator and Denominator of the Risk-Standardized Ratio (Excess Readmission Ratio)

The NQF-endorsed measures, which we are finalizing in this rule for the Hospital Readmissions Reduction Program, calculate this risk-standardized ratio (Excess Readmission Ratio) using hierarchical logistic modeling, which is a widely accepted statistical method that evaluates relative hospital performance based on outcomes such as readmission. The method adjusts for variation across hospitals in how sick their patients are when admitted to the hospital (and therefore variation in hospitals' patients' readmission risk) as well as the variation in the number of patients that a hospital treats to reveal difference in

quality. The detailed methodology for these measures is publicly-available and the calculation ''SAS packs'' are made available upon request. This is the calculation software that permits the measures to be calculated. We describe the key details of the methodology here.

In order to model the extent to which hospitals affect patients' risk of readmission, this statistical model first analyzes data on all the patients discharged from all hospitals for a given condition that indicate for each patient what comorbidities were present when the patient was admitted and whether or not the patient was readmitted and calculates:

- How much variation in hospital readmission rates overall is accounted for by variation across hospitals in patients' individual risk factors (such as age and other medical conditions); a risk weight (beta-coefficient) is calculated for each patient risk factor at all hospitals. The specific approach and variables used in the risk adjustment are discussed below.
- How much variation in readmission rates is accounted for by hospitals' contribution to readmission risk, after adjusting for differences in readmission due to differences in patients' risk factors. The model estimates the amount by which a specific hospital increases or decreases patients' risk of readmission relative to an average hospital based on the hospitals actual readmission relative to hospitals with similar patients. The estimated amount each hospital contributes (or subtracts) from its patients readmission risk compared to hospitals with similar patients is called the ''hospital-specific readmission effect.'' It is used only in the numerator to estimate the adjusted actual readmissions. The hospital-specific effect will be negative for a hospital above the national average (that is, with lower than average adjusted rates of readmissions), positive for a hospital below the national average (that is, with higher than average adjusted rates of readmissions), and close to zero for an average hospital. If there are no quality differences resulting in excess readmissions among hospitals (if all hospitals had the same readmission rates relative to hospitals with similar patients), the hospital-specific effects for all hospitals will be zero and the ratio for all hospitals will be one.

Comment: One commenter expressed concern that multiplying the ratio by the national raw rate of readmissions could inflate the readmission rate for a given hospital.

Response: As discussed above, the Excess Readmission Ratio is calculated using hierarchical logistic regression which produces an adjusted actual (or ''predicted'') number in the numerator and an ''expected'' number in the denominator. The expected calculation is similar to that for logistic regression—it is the sum of all patients' expected probabilities of readmission given their risk factors and the risk of readmission at an average hospital. The excess readmissions ratio is multiplied by the national readmission rate for reporting of risk-standardized readmission rates to the public as a part of the Hospital IQR Program for ease of interpretation. This serves to standardize all hospitals rates to the national rate but should not be interpreted as the unadjusted rate for a given hospitals. Depending on the hospital's performance it may be higher or lower than the hospital's raw readmission rate. The Hospital Readmissions Reduction Program uses the Excess Readmission Ratio rather than the raw readmission rate.

(ii) Numerator Calculation—Adjusted Actual Readmissions

For each hospital, the numerator of the ratio used in the NQF-endorsed methodology (actual adjusted readmissions) is calculated by estimating the probability of readmission for each patient at that hospital and summing up over all the hospital's patients to get the actual adjusted number of readmissions for that hospital. This estimated probability of readmission for each patient is calculated using:

- The hospital-specific effect (probability of readmission relative to the probability of readmission at an average hospital);
- The intercept term for the model (this is the average hospital-specific effect and is the same for all hospitals and for both numerator and denominator equations). The intercept term is the probability of readmission for each patient when the value of all the patient risk factors is zero;
- The probability of readmission contributed by each of the patients' risk factors (risk adjustment coefficients multiplied by the patient's risk factors, X)

Mathematically, the numerator equation can be expressed as:

Mathematically, the numerator equation can be expressed as:

Numerator: Adjusted Actual Readmissions

Step 1:

Calculate each patient's predicted probability of readmission = $\frac{1}{1 + e^{-Za}}$

Z_a = hospital-specific effect + Xβ

intercept + risk-adjustment coefficients

Step 2:

To get the numerator result, add all patients' predicted probabilities of readmission

Comment: One commenter requested clarification on how the numerator calculation of probable readmissions is related to the adjusted actual readmission. The commenter suggested that CMS take actual readmissions (observed) divided by the expected readmission.

Response: As explained in the FY 2012 IPPS/LTCH PPS proposed rule and this final rule, consistent with the requirements in section 1886(q)(4)(C)(i)(I) of the Act, the numerator is the adjusted actual number of readmissions, which is the sum of the probability of readmission for all patients admitted at the particular hospital given the patients' risk factors and the hospitals estimated contribution to readmission risk. This estimated contribution to readmission risk—the hospital-specific effect discussed in the rule—is derived from the hospital's actual readmission rate relative to hospitals with similar patients. Thus, the numerator is each hospital's adjusted actual readmissions. This approach to calculating the numerator, although more complex than that used for logistic regression, is the method traditionally used in hierarchical regression modeling and is statistically more accurate given the type of data being used. Other methods may overestimate the differences between hospitals.

(iii) Denominator Calculation—Expected Readmissions (at an Average Quality Hospital Treating the Same Patients)

The denominator of the risk-standardized ratio (Excess Readmission Ratio) under this NQF-endorsed methodology sums the probability of readmission for each patient at an average hospital. This probability is calculated using:

- The intercept term for the model (the same for all hospitals and for both numerator and denominator equations); and
- The increase or decrease in the probability of readmission contributed by each of the patients' risk factors (risk adjustment coefficients multiplied by the patient's risk factors, X).

This can be expressed mathematically as:

This can be expressed mathematically as:

Denominator: Expected Readmissions

Step 1:

Calculate each patient's expected probability of readmission = $\frac{1}{1 + e^{-Ze}}$

$Z_e = X\beta$

intercept + risk-adjustment coefficients

Step 2:

To get the denominator result, add all patients' expected probabilities of readmission

Thus, the ratio compares the total adjusted actual readmissions at the hospital to the number that would be expected if the hospital's patients were treated at an average hospital with similar patients. Hospitals with more adjusted actual readmissions than expected readmissions will have a risk-standardized ratio (Excess Readmission Ratio) greater than one.

Because the ratio is risk-adjusted, a hospital may have high crude readmission rates (number of 30-day readmissions among patients with the applicable condition divided by number of admissions for patients with the applicable condition) yet have a risk-standardized ratio (Excess Readmission Ratio) less than one. For example, if a hospital with a higher than average raw readmission rate cares for very sick patients, the ratio may show that the adjusted actual number of readmissions (the numerator), which accounts for the case-mix, is actually lower than what would be expected for an average hospital caring for these patients (denominator) and therefore the Excess Readmission Ratio, as proposed, will be less than one, demonstrating that this hospital performs better than average, despite having a high crude readmission rate. Similarly, if a hospital has a seemingly low unadjusted readmission rate but cares for a very low risk population of patients, it may be found to have an adjusted actual number of readmissions that is higher than the expected number of readmissions, and therefore a ratio greater than one.

In summary, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to use the risk-standardized readmission ratio of the NQF-endorsed readmission measures as the Excess Readmission Ratio. The ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (that is, patients with the same risk factors for readmission such as age and comorbidities), the ratio will be less than 1.0. If a hospital performs worse than average, the ratio will be greater than 1.0.

We welcomed public comment on our proposal to use this methodology for

calculating the ''risk adjusted readmissions based on actual readmissions'' as well as the ''risk adjusted expected readmissions'' used to determine the Excess Readmission Ratio, as set forth in section 1886(q)(5)(C) of the Act.

Comment: Some commenters interpreted the Affordable Care Act as requiring CMS to calculate observed and expected rates and, therefore, these commenters suggested that CMS revise the measures to use the calculation of observed and expected rates. Some commenters compared the hierarchical modeling approach to the logistic regression model, which produces an expected rate for the denominator and uses the observed (raw count of readmission) for the numerator. One commenter requested CMS to provide reasons for not using a conventional observed over expected ratio in the methodology.

Response: We appreciate the commenter's thoughts on the Excess Readmission Ratio. Consistent with the statutory requirement that the Secretary must develop a risk-adjusted Excess Readmission Ratio that is the ratio of ''the risk adjusted readmissions based on actual readmission, as determined consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I) * * * to the risk adjusted expected readmissions,'' we proposed to calculate the Excess Readmission Ratio using hierarchical modeling (rather than logistic regression, which produces an observed over expected ratio).

We believe that hierarchical modeling is a more appropriate statistical approach for hospital outcomes measures than the calculation of observed over expected ratio using the logistic regression model for various reasons. First, the hierarchical model meets the requirement under section 1886(q)(4)(C)(i)(I) of the Act for NQF-endorsement and risk-adjustment. Second, we believe that hierarchical modeling is a more appropriate statistical approach given the structure of the data and the underlying assumption of such measures which is that hospital quality of care influences 30-day readmission rates. Patients are clustered within hospitals and, as such, have a shared exposure to the hospital's quality processes. The advantage of using the hierarchical modeling is that it accounts for the clustering of patients within hospitals. Third, hierarchical models distinguish within-hospital variation and between-hospital variation in the estimation of the hospital's contribution to the risk of mortality. The estimation of the hospital's influence on patient outcomes is more noticeable. Finally, within hierarchical models, we can account for both differences in case mix and sample size to more fairly profile hospital performance. If we did not use hierarchical modeling, we may overestimate variation and potentially mischaracterize hospitals' performance with respect to readmissions.

After consideration of the public comments we received, we are finalizing the proposed methodology for readmission measures, including the definitions of ''index hospitalization,'' ''readmission,'' ''time window,'' ''risk adjustment methodology,'' ''applicable periods,'' ''data sources,'' ''minimum number of discharges for applicable conditions,'' and ''reporting hospital-specific readmission rates,'' as proposed, for use in the FY 2013 Hospital Readmissions Reduction Program.

D. Rural Referral Centers (RRCs) (§ 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 an RRC. For discharges that occurred before October 1, 1994, RRCs received the benefit of payment based on the other urban standardized amount rather than the rural standardized amount (as discussed in the FY 1993 IPPS final rule (59 FR 45404 through 45409)). Although the other urban and rural standardized amounts are the same for discharges occurring on or after October 1, 1994, RRCs continue to receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs 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 national median CMI value for FY 2012 includes data from all urban hospitals nationwide, and the regional values for FY 2012 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 values are based on discharges occurring during FY 2010 (October 1, 2009 through September 30, 2010), and include bills posted to CMS' records through March 2011.

For the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25938), we proposed that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2011, they must have a CMI value for FY 2010 that is at least—

- 1.5292; or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2012 IPPS/LTCH PPS proposed rule at 76 FR 25938.)

The final CMI criteria for FY 2012 are based on the latest available data (FY 2010 bills received through March 2011). 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, 2011, they must have a CMI value for FY 2010 that is at least—

- 1.5305; or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The final median CMI values by region are set forth in the following table:

Region	Case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.3237
2. Middle Atlantic (PA, NJ, NY)	1.3745
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.4589
4. East North Central (IL, IN, MI, OH, WI)	1.4620
5. East South Central (AL, KY, MS, TN)	1.3996
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.4456
7. West South Central (AR, LA, OK, TX)	1.5689
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.6277
9. Pacific (AK, CA, HI, OR, WA)	1.5169

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. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25938 and 25939), we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2009 (that is, October 1, 2008 through September 30, 2009), which are the latest cost report data available at the time the proposed rule was developed.

Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25938 and 25939), we proposed that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2011, must have, as the number of discharges for its cost reporting period that began during FY 2009, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2012 IPPS/LTCH PPS proposed rule at 76 FR 25939).)

Based on the latest discharge data available at this time, that is, for cost reporting periods beginning on or after October 1, 2011, the final median numbers of discharges for urban hospitals by census region are set forth in the following table.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,141
2. Middle Atlantic (PA, NJ, NY)	11,919
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	11,422
4. East North Central (IL, IN, MI, OH, WI)	8,981
5. East South Central (AL, KY, MS, TN)	7,528
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	8,116
7. West South Central (AR, LA, OK, TX)	6,426
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	9,608
9. Pacific (AK, CA, HI, OR, WA)	8,900

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 is the minimum criterion for all hospitals under this final rule.

We reiterate that, if an osteopathic hospital is to qualify for RRC status for cost reporting periods beginning on or after October 1, 2011, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2009.

E. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

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 ''in 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 add-on payment amount is based on all other per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outliers. For SCHs and MDHs, the low-volume add-on payment amount is based on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment. Sections 3125 and 10314 of the Affordable Care Act amended the definition of a low-volume hospital under section 1886(d)(12)(C) of the Act. Sections 3125 and 10314 of the Affordable Care Act also revised the methodology for calculating the payment adjustment for low-volume hospitals.

Prior to the amendments made by the Affordable Care Act, 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 that 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, not merely 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. The statute also limits the 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 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 a multivariate analyses supported the existing low-volume adjustment implemented in FY 2005. Therefore, the low-volume adjustment of an additional 25 percent would continue to be provided for qualifying hospitals with less than 200 discharges.

2. Temporary Changes for FYs 2011 and 2012

Section 1886(d)(12) of the Act was amended by sections 3125 and 10314 of the Affordable Care Act. The changes made by these sections of the Affordable Care Act are effective only for discharges occurring during FYs 2011 and 2012. Beginning with FY 2013, the preexisting low-volume hospital payment adjustment and qualifying criteria, as implemented in FY 2005, will resume. Specifically, as discussed above, the provisions of the Affordable Care Act revised the definition of a low-volume hospital and also revised the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2011 and 2012.

Sections 3125(3) and 10314(1) of the Affordable Care Act amended the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act to make it easier for hospitals to qualify for the low-volume adjustment. Specifically, the revised provision specifies that, for FYs 2011 and 2012, a hospital qualifies as a low-volume hospital if it is ''more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Part A during the fiscal year.'' In addition, section 1886(d)(12)(D) of the Act, as added by section 3125(4) and amended by section 10314 of the Affordable Care Act, provides that the payment adjustment (the applicable 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 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year.''

Section 3125(3)(A) of the Affordable Care Act revised the distance requirement of ''25 road miles'' to ''15 road miles'' for FYs 2011 and 2012 such that a low-volume hospital is required to be only more than 15 road miles, rather than more than 25 road miles, from another subsection (d) hospital for purposes of qualifying for the low-volume payment adjustment in FYs 2011 and 2012. The mileage requirement will revert back to ''more than 25 road miles'' for fiscal years after FY 2012.

Sections 3125(3)(B) and 10314(1) of the Affordable Care Act revised the discharge requirement for FYs 2011 and 2012 to less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A during the fiscal year. Prior to enactment of the Affordable Care Act, under section 1886(d)(12) of the Act, as added by section 406(a) of Public Law 108–173, the discharge requirement to qualify as a low-volume hospital is less than 800 total discharges annually, which includes discharges of both Medicare and non-Medicare patients. This discharge requirement will apply also for fiscal years after FY 2012.

Section 3125(4) of the Affordable Care Act added section 1886(d)(12)(D) to the Act, and section 10314(2) of the Affordable Care Act further modified that section of the Act. Section 1886(d)(12)(D) of the Act, as modified, revises the methodology for calculating the payment adjustment under section 1886(d)(12)(A) of the Act for low-volume hospitals for discharges occurring in FYs 2011 and 2012. For FY 2010 and prior fiscal years, and beginning again in FY 2013, sections 1886(d)(12)(A) and (B) of the Act require the Secretary to determine an applicable percentage increase for 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 requires the Secretary to develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals. The statute also limits the adjustment to no more than 25 percent. Based on analyses we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102) and the FY 2006 IPPS final rule (70 FR 47432 through 47434), a 25-percent low-volume 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. However, section 1886(d)(12)(D) of the Act, as added by the Affordable Care Act, provides that, for discharges occurring in FYs 2011 and 2012, the Secretary shall determine the applicable percentage increase using a continuous linear sliding scale ranging from an additional 25-percent payment adjustment for hospitals with 200 or fewer Medicare discharges to a 0-percent additional payment adjustment for hospitals with more than 1,600 Medicare discharges.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), we revised our regulations at 42 CFR 412.101 to reflect the changes to the payment adjustment for low-volume hospitals provided for by the provisions of the Affordable Care Act. We also 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, we established a procedure for a hospital to request low-volume hospital status.

Specifically, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 and

50414), we revised our regulations at § 412.101(b)(2)(ii) to provide that, to qualify for the low-volume payment adjustment in FYs 2011 and 2012, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital. We also defined, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(i). This change in the qualifying criteria from 25 to 15 road miles is applicable only for FYs 2011 and 2012, but the definition of ''road miles'' continues to apply even after the distance requirement reverts to 25 road miles beginning in FY 2013.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50239 and 50414), we revised our regulations at § 412.101(b)(2)(ii) to provide that, to qualify for the low-volume adjustment in FYs 2011 and 2012, a hospital must have fewer than 1,600 ''Medicare discharges'' during the fiscal year based on the hospital's Medicare discharges from the most recently available MedPAR data as determined by CMS. We also revised the regulations to specify at § 412.101(a) that the term ''Medicare discharges'' means a ''discharge of inpatients entitled to Medicare Part A, including discharges associated with individuals whose inpatient benefits are exhausted or whose stay was not covered by Medicare and also discharges of individuals enrolled in a MA organization under Medicare Part C.''

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240 through 50241), we adopted a continuous linear sliding scale equation to determine the low-volume payment adjustment for FYs 2011 and 2012 for eligible low-volume hospitals with Medicare discharges of more than 200 and less than 1,600 (that is, from 201 to 1,599 Medicare discharges). Consistent with the statute, for FYs 2011 and 2012 for eligible low-volume hospitals with 200 or fewer Medicare discharges, we established a low-volume payment adjustment of 25 percent.

Under the regulations at § 412.101(c)(2), for FYs 2011 and 2012, the low-volume adjustment is determined as follows:

- Low-volume hospitals with 200 or fewer Medicare discharges will receive a low-volume adjustment of an additional 25 percent for each discharge.
- Low-volume hospitals with Medicare discharges of more than 200 and fewer than 1,600 will receive for each discharge a low-volume adjustment of an additional percent calculated using the formula: [(4/14) − (Medicare discharges/5600)]. For additional information on the mathematical interpretation of this formula, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50241).

While we revised the qualifying criteria and the payment adjustment for low-volume hospitals for FYs 2011 and 2012, consistent with the amendments made by the Affordable Care Act, we also noted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240) that we did not modify the process for requesting and obtaining the low-volume hospital payment adjustment. In general, in order to qualify for the low-volume hospital payment adjustment, a hospital must provide to its fiscal intermediary or MAC sufficient evidence to document 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 and, if so, the applicable add-on percentage. 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.

3. Discharge Data Source To Identify Qualifying Low-Volume Hospitals and Calculate the Payment Adjustment (Percentage Increase) for FY 2012

As described above, for FYs 2005 through 2010 and FY 2013 and subsequent years, since the discharge determination is made based on the hospital's number of total discharges, the hospital's most recently submitted cost report is used to determine if the hospital meets the criteria to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). For FYs 2011 and 2012, the hospital's Medicare discharges from the most recently available MedPAR data, as determined by CMS, are used to determine if the hospital meets the discharge criteria to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(ii)). As also described above, the applicable low-volume percentage increase is determined using a continuous linear sliding scale equation that results in a low-volume adjustment ranging from an additional 25 percent for hospitals with 200 or fewer Medicare discharges to a 0 percent additional payment adjustment for hospitals with 1,600 or more Medicare discharges.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50241), we established that, for FY 2011, the low-volume payment adjustment would be determined using Medicare discharge data for FY 2009 from the March 2010 update of the MedPAR files, as these were the most recent available data. We also stated that we expected to use Medicare claims data from FY 2010 to determine the low-volume payment adjustment for FY 2012, as these would be the most recent available data at that time.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25941), we proposed that, for FY 2012, qualifying low-volume hospitals and their payment adjustment would be determined using Medicare discharge data from the most recent update of the FY 2010 MedPAR file, that is, the December 2010 update, as these data were the most recent data available at that time. We also proposed that if more recent FY 2010 Medicare discharge data are available (such as data from the March 2011 update of the MedPAR files), we would use such data in the final rule. Table 14 in the proposed rule (which was listed in section VI. of the Addendum to the proposed rule and available via the Internet) listed the ''subsection (d)'' hospitals with fewer than 1,600 Medicare discharges based on the December 2010 update of the FY 2010 MedPAR files and their proposed FY 2012 low-volume payment adjustment. We noted that eligibility for the proposed low-volume payment adjustment for FY 2012 is also dependent upon meeting (if the hospital is qualifying for the low-volume payment adjustment for the first time in FY 2012), or continuing to meet (if the hospital qualified in FY 2011) the mileage criteria specified at § 412.101(b)(2)(ii). In addition, we proposed a procedure for a hospital to request low-volume hospital status for FY 2012 (as described below).

Comment: Commenters supported the proposal to update the Medicare discharge data upon which to base the low-volume hospital adjustment for FY 2012 (we note that there were no public comments opposed to the proposal). In addition, a few commenters urged CMS to explore ways to continue increased payments to the hospitals that received additional payments in FYs 2011 and 2012 under the temporary expansion of the low-volume hospital adjustment provided for by the Affordable Care Act rather than revert to the prior low-volume hospital adjustment policy for FY 2013 and subsequent years.

Response: We appreciate the commenters' support. We are finalizing our proposal to determine the FY 2012 low-volume hospitals and their payment adjustments based on the number of

Medicare discharges from the most recent update of the FY 2010 MedPAR file. Specifically, we will make these determinations using the March 2011 update, as these data are the most recent data available. Table 14, which is referenced in section VI. of the Addendum to this final rule and available via the Internet on the CMS Web site, lists the ''subsection (d)'' hospitals with fewer than 1,600 Medicare discharges based on the March 2011 update of the FY 2010 MedPAR file and their payment adjustments for FY 2012. The eligibility for the low-volume payment adjustment for FY 2012 is also dependent upon meeting (if the hospital is qualifying for the low-volume payment adjustment for the first time in FY 2012), or continuing to meet (if the hospital qualified in FY 2011) the mileage criteria specified at § 412.101(b)(2)(ii).

With regard to commenters who urged CMS to explore ways to continue the enhanced low-volume hospital payment adjustment beyond FYs 2011 and 2012, we note that the statute restricts the temporary increases in the low-volume payment adjustments to FYs 2011 and 2012. Therefore, beginning with FY 2013, the low-volume hospital qualifying criteria and the amount of the payment adjustment to such hospitals will revert back to those policies that were in effect prior to the amendments made by the Affordable Care Act.

We note that the list of hospitals with fewer than 1,600 Medicare discharges in Table 14 does not reflect whether or not the hospital meets the mileage criterion, and a hospital also must be located more than 15 road miles from any other IPPS hospital in order to qualify for a low-volume hospital payment adjustment in FY 2012.

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 mileage criterion. The use of a Web-based mapping tool, such as MapQuest, as part of documenting that the hospital meets the mileage criterion for low-volume hospitals, is acceptable. The fiscal intermediary or MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance (in road miles, as defined in the regulations at § 412.101(a)) from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the fiscal intermediary or MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the low-volume mileage criterion. In addition, the fiscal intermediary or MAC will refer to the hospital's Medicare discharge data determined by CMS (for FY 2012 as shown in Table 14 of this final rule (which is listed in section VI. of the Addendum to this final rule and available via the Internet)), to determine whether or not the hospital meets the discharge criterion, and the amount of the payment adjustment, once it is determined that both the mileage and discharge criteria are met. The Medicare discharge data shown in Table 14, as well as the Medicare discharge data for all ''subsection (d)'' hospitals with claims in the March 2011 update of the FY 2010 MedPAR file, is also available on the CMS Web site for hospitals to check their Medicare discharges to help them to decide whether or not to apply for low-volume hospital status.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25941), we proposed that for FY 2012, a hospital must make its request for low-volume hospital status in writing to its fiscal intermediary or MAC by September 1, 2011, in order for the applicable low-volume percentage add-on to be applied to payments for its discharges beginning on or after October 1, 2011. This proposal is similar to the policy we established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 20574 through 20575). We did not receive any public comments on this proposed procedure. Therefore, in this final rule, we are finalizing this procedure for a hospital to request low-volume hospital status for FY 2012. We also are finalizing our proposal that a hospital that qualified for the low-volume payment adjustment in FY 2011 may continue to receive a low-volume payment adjustment in FY 2012, without reapplying, if it continues to meet the Medicare discharge criterion, based on the latest available FY 2010 MedPAR data (as finalized above and shown in Table 14) and the distance criterion. However, the hospital must verify in writing to its fiscal intermediary or MAC that it continues to be more than 15 miles from any other ''subsection (d)'' hospital no later than September 30, 2011. Further, similar to the policy we established for FY 2011 (Transmittal 2060, Change Request 7134; October 1, 2010), we are finalizing our proposal with regard to requests for low-volume hospital status for FY 2012 received after September 1, 2011. In such cases, if the hospital meets the criteria to qualify as a low-volume hospital, the fiscal intermediary or MAC will apply the applicable low-volume adjustment in determining payments to the hospital's FY 2012 discharges prospectively within 30 days of the date of the fiscal intermediary's or MAC's low-volume status determination.

F. Indirect Medical Education (IME) Adjustment (§ 412.105)

1. Background

Section 1886(d)(5)(B) of the Act provides for an additional payment amount under the IPPS for 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 regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at § 412.105.

Public Law 105–33 (BBA 1987) established a limit on the number of allopathic and osteopathic residents that a hospital may include in its full-time equivalent (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 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 on the FTE resident count for IME purposes is effective for discharges occurring on or after October 1, 1997. Changes to the policies regarding counting residents for both IME and direct GME payment purposes as a result of the implementation of sections 5503 through 5506 of the Affordable Care Act were issued in a final rule published in the **Federal Register** on November 24, 2010 (75 FR 72133).

2. IME Adjustment Factor for FY 2012

The IME adjustment to the MS–DRG payment is based in part on the applicable IME adjustment factor. The IME adjustment factor is calculated by using a hospital's ratio of residents to beds, which is represented as r, and a formula multiplier, which is represented as *c*, in the following equation: $c \times [\{1 + r\}^{.405} - 1]$. The formula is traditionally described in terms of a certain percentage increase in payment for every 10-percent increase in the resident-to-bed ratio.

Section 502(a) of Public Law 108–173 modified the formula multiplier (*c*) to be used in the calculation of the IME

adjustment. Prior to the enactment of Public Law 108–173, the formula multiplier was fixed at 1.35 for discharges occurring during FY 2003 and thereafter. In the FY 2005 IPPS final rule, we announced the schedule of formula multipliers to be used in the calculation of the IME adjustment and incorporated the schedule in our regulations at § 412.105(d)(3)(viii) through (d)(3)(xii). Section 502(a) modified the formula multiplier beginning midway through FY 2004 and provided for a new schedule of formula multipliers for FYs 2005 and thereafter as follows:

- For discharges occurring on or after April 1, 2004, and before October 1, 2004, the formula multiplier is 1.47.
- For discharges occurring during FY 2005, the formula multiplier is 1.42.
- For discharges occurring during FY 2006, the formula multiplier is 1.37.
- For discharges occurring during FY 2007, the formula multiplier is 1.32.
- For discharges occurring during FY 2008 and fiscal years thereafter, the formula multiplier is 1.35.

Accordingly, for discharges occurring during FY 2012, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2012 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.

Comment: Several commenters supported CMS' proposal to maintain the IME formula multiplier at 1.35. Commenters stated they support the continued IME adjustment factor because IME payments are an important part of guaranteeing both a strong cardiothoracic surgery and general surgery workforce, both of which are currently facing increasing shortages. Another commenter stated that it supported maintaining the current level of IME payments because it is an important funding source for safety net teaching hospitals.

Response: We appreciate the commenters' support. We note that the IME formula multiplier is set by Congress; any change to the multiplier would require a legislative change. Therefore, we are finalizing our proposal that the IME formula multiplier for FY 2012 be set at 1.35, which we estimate will result in an increase in IPPS payments of 5.5 percent for every approximately 10-percent increase in the hospital's resident-to-bed ratio.

G. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME) (§§ 412.105 and 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 (including patients who are enrolled in a Medicare Advantage (Part C) plan) 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 (including patients who are enrolled in a Medicare Advantage (Part C) plan). 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).

As we did in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25942), we are combining, under section IV.G.2. of this preamble, our discussion of changes to the policies for counting beds in relation to the calculations for the IME adjustment at § 412.105(b) and the DSH payment adjustment at § 412.106(a)(1)(i) and for counting patient days for purposes of the DSH payment adjustment at § 412.106(a)(1)(ii).

2. Policy Change Relating to the Exclusion of Hospice Beds and Patient Days From the Calculation of the Medicare DSH Payment Adjustment and the IME Payment Adjustment

a. Background

As discussed in the FY 2004 IPPS final rule (68 FR 45415 through 45420), when determining a hospital's Medicare DSH payment, our policy is to include patient days in hospital units or wards that would be directly included in determining the allowable costs of inpatient hospital care payable under the IPPS on the Medicare cost report. Under this policy, CMS uses the level of care generally provided in such a unit or ward as a proxy for determining the level of care provided to a particular patient on a particular day within that unit. As stated in the FY 2004 IPPS final rule, our policy is ''not intended to focus on the level or type of care provided to individual patients in a unit, but rather on the level and type of care provided in the unit as a whole.'' (68 FR 45417) In the FY 2005 IPPS final rule, we amended this policy to specifically exclude observation and swing days from the patient day count. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25942 and 25943), we proposed to establish an additional exclusion with respect to counting bed days and patient days for patients receiving hospice services in an inpatient setting of a hospital.

b. Hospice Inpatient Services

Section 1861(dd)(1) of the Act defines hospice care to include a limited set of ''items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician

and by the medical director.'' Among those items and services specified under section 1861(dd)(1)(G) of the Act is ''short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days.'' Based on these statutory definitions of hospice care, the Secretary, through regulation at § 418.302, has grouped hospice care services into four categories for payment purposes. Two of these payment categories describe hospice services in an inpatient setting: Inpatient respite care day and general inpatient care day.

Section 418.302(b)(3) of the regulations defines an inpatient respite care day as ''a day on which the individual who has elected hospice care receives care in an approved facility on a short-term basis for respite.'' Section 40.2.2 of Chapter 9 of the Medicare Benefit Policy Manual (*https://www.cms.gov/manuals/Downloads/bp102c09.pdf*) further describes an inpatient respite care day as a short-term inpatient day provided only when necessary to relieve family members or other caregivers caring for the individual at home. Under the Act, inpatient respite care is limited to 5 consecutive days for a given stay. Similarly, the regulations at § 418.302(b)(4) describe a general inpatient care day as ''a day on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings.''

Section 40.1.5 of Chapter 9 of the Medicare Benefit Policy Manual provides that general inpatient care is appropriate when care for pain control or acute or chronic symptom management cannot feasibly be provided in another setting. This section of the Medicare Benefit Policy Manual further states that such care is ''not equivalent to a hospital level of care.'' That hospice care is not hospital level care is further supported by the provision at § 418.202(e), which provides that general inpatient care and inpatient respite care hospice services can be ''provided in a participating hospice inpatient unit, or a participating hospital or [skilled nursing facility], that additionally meets the standards in § 418.202(a) and (e) regarding staffing and patient areas * * * [and] must conform to the [hospice provider's] written plan of care.''

Furthermore, hospice services provided in an inpatient hospital setting are not payable under the IPPS. Rather, at this time, these services are payable under two of the four prospectively determined all-inclusive categories of care under the hospice payment system. In the FY 2004 IPPS final rule (68 FR 45418), we stated that we believed it ''reasonable to interpret the phrase 'hospital's patient days,' to mean only the hospital's inpatient days at a level of care that would be covered under the IPPS as a means to determine an IPPS payment adjustment.'' In that rule, we acknowledged that it would be ''administratively inefficient and impracticable'' to calculate a hospital' inpatient days based on a determination of whether a particular patient in a particular inpatient bed for a particular stay is receiving a level of care that would be covered under the IPPS (68 FR 45418). Accordingly, we adopted a policy under which we use the level of care that is generally provided in particular units or wards as a proxy for determining whether the care provided to a particular patient is of a type that would be covered under the IPPS. However, we have recognized exceptions to this policy for certain categories of nonacute care, even if that care is provided in an acute care unit.

Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to revise § 412.106(a)(1)(ii) to exclude patient days associated with hospice patients receiving inpatient hospice services in an inpatient hospital setting from the Medicare and Medicaid fractions of the DPP. We also proposed to amend our cost reporting instructions accordingly. Our proposal to exclude hospice inpatient days was analogous to our decision in the FY 2005 IPPS final rule to exclude observation and swing-bed days from the Medicare and Medicaid fractions of the DPP. In that rule, we stated that our policies to exclude observation days and swing-bed days from the count of patient days ''stem from the fact that although the services are provided in beds that would otherwise be available to provide an IPPS level of services, these days are not payable under the IPPS * * *'' (69 FR 49097). Similarly, our proposal to exclude inpatient hospice days stemmed from the fact that these days are not acute care services generally payable under the IPPS.

We noted in the proposed rule that, on rare occasions, patients receiving care under a third payment category, routine home care, may also receive services in an inpatient hospital setting. Unlike inpatient respite care or general inpatient services, routine home care services are not intended to be provided in a hospital setting. For the same reasons stated above, such days should also be excluded from the Medicare and Medicaid fractions of the DPP.

We also proposed to exclude from the hospital's bed count days associated with hospice patients who receive inpatient hospice services in the hospital for purposes of both the IME payment adjustment and the DSH payment adjustment. The rules for counting hospital beds for the purposes of the IME adjustment are codified in the IME regulations at § 412.105(b), which is cross-referenced in § 412.106(a)(1)(i) for purposes of the DSH payment adjustment. Our bed counting policy is to include bed days available for IPPS-level acute care hospital services. Inpatient hospice services provided in an acute unit or ward are occasional, alternative uses of acute inpatient beds that would otherwise be considered available for IPPS-level acute care hospital services (as long as other criteria for a bed to be considered as an available bed are met under § 412.105(b)). A bed used for inpatient hospice services on a given day is not available to be used for IPPS-level services. Therefore, we proposed to revise § 412.105(b)(4) to state that such hospice days are excluded from the counts of available beds for purposes of the IME payment adjustment. Because the same rules govern the counting of available beds for purposes of the DSH payment adjustment under § 412.106(a)(1)(i), under the proposal, hospice days would also be excluded from the count of available beds for purposes of the DSH payment adjustment.

In the proposed rule, we noted that there is a circumstance in which a hospital will provide IPPS-level acute care hospital services to a hospice patient for which it would receive payment under the IPPS. This occurs when a Medicare beneficiary receiving hospice care under his or her hospice benefit requires acute care hospital services to treat a condition unrelated to his or her hospice plan of care. For example, an individual who has elected the hospice benefit could be treated in the inpatient hospital setting for a condition or illness, such as a broken bone, that is unrelated to his or her terminal illness. Under these circumstances, the patient is receiving acute care hospital services of the sort payable under the IPPS. As such, consistent with § 412.106(a)(1)(ii), we did not propose to exclude these patient

days from the Medicare and Medicaid fractions of the DPP or from the count of available beds under § 412.105(b)(4) and § 412.106(a)(1)(i).

We further noted that hospitals may have hospice units that are separate and distinct from their acute care inpatient units. Under existing regulations at § 412.105(b)(3) and § 412.106(a)(1)(ii)(A), services provided in distinct nonacute care inpatient units are excluded from the patient day and bed day count. Our proposal with respect to inpatient hospice services did not change or affect this policy.

Comment: Several commenters believed that the proposal would have an immaterial impact on providers' DSH payment adjustments while creating an unnecessary administrative burden to the extent that providers would have to take steps to identify the excluded days. The commenters requested that CMS reevaluate the administrative burden created by the need to identify hospice days in light of what the commenters describe as the immaterial impact of hospice days on the DSH payment adjustments.

Response: We do not agree with the commenters that our proposal would create an undue administrative burden for providers. Hospitals already identify hospice patients for the purpose of billing and payment. Because hospice patients in an inpatient setting are already being specifically identified for other purposes, we do not believe it would be an undue administrative burden for hospitals to identify and exclude these patients for purposes of the DSH payment adjustment.

Comment: Commenters requested clarification regarding the effective date of the proposal, including whether the regulation change is intended to be prospective. The commenters also questioned whether the change in policy would be reflected on the cost report.

Response: Our proposal to exclude hospice bed days from the calculation of the DSH payment adjustment is a regulation change that will be effective for cost reporting periods beginning on or after October 1, 2011. As we stated in the proposed rule, we plan to amend the cost reporting instructions to reflect our change in policy.

Comment: A few commenters requested that CMS not apply the intern-to-resident bed (IRB) ratio cap with respect to the proposed removal of hospice bed days from the calculation of the DSH payment adjustment. Instead, the commenters requested that hospitals be allowed to exclude these inpatient hospice days from their prior year's IRB ratio for purposes of applying that ratio as the cap on the hospital's current year IRB ratio.

Response: We believe the commenters are referring to a provision that was included in the Balanced Budget Act of 1997, known as the cap on the intern and resident-to-bed (IRB) ratio that is applicable to the IME payment that teaching hospitals receive under the IPPS. Under section 1886(d)(5)(B)(vi)(I) of the Act, and implemented in the regulations at § 412.105(a)(1)(i), a hospital's IRB ratio in the current cost reporting period generally cannot exceed, or is capped by, the value of the IRB ratio in the preceding cost reporting period. Therefore, if a teaching hospital's IRB ratio increases in the current cost reporting period relative to the prior cost reporting period, its receipt of an increase in IME payment as a result of that increase to the IRB ratio is delayed by 1 year. Because, effective for cost reporting periods beginning on or after October 1, 2011, certain inpatient hospice bed days are to be excluded from the count of available beds under § 412.105(b)(4), assuming there are no changes in the FTE resident count in the numerator of the IRB ratio from the cost reporting period occurring prior to October 1, 2011, a reduced bed count in the cost reporting period that begins on or after October 1, 2011, could cause an increase in the IRB ratio. However, because the prior cost reporting period's bed count would still reflect the inclusion of the inpatient hospital beds, the IRB ratio for the cost reporting period that begins on or after October 1, 2011 will be capped by the lower IRB ratio from the preceding period, thereby limiting the IME payment somewhat for the cost reporting period that begins on or after October 1, 2011.

We do not agree with the commenters' request to not apply the IRB ratio cap with respect to inpatient hospice days by permitting teaching hospitals to exclude the inpatient hospice days from the denominator of the IRB ratio of the prior period. While it is true that the law and regulations permit teaching hospitals to make adjustments to their prior year IRB ratios under certain circumstances such as for Medicare GME affiliation agreements, new programs, or absorption of residents displaced by another hospital's closure, we do not believe a similar exception is warranted under this policy. In this instance, no harm is occurring to either the teaching hospital or residents in the GME programs as a result of not including the bed days of hospice inpatients in the denominator of the IRB ratio. Rather, it is simply a matter of receiving an increased IME payment immediately in the current cost reporting period, or, through application of the IRB ratio cap, on a 1-year delay in the following cost reporting period. In fact, the intent of the IRB ratio cap is to modulate such changes in a hospital's IRB ratio from year to year. Therefore, we are not waiving the IRB ratio cap effective for cost reporting periods that begin on or after October 1, 2011.

Comment: One commenter requested that CMS begin implementation of the Affordable Care Act amendments to the DSH payment adjustment provisions of the Act through this rulemaking.

Response: We believe that this comment is outside of the scope of the proposed rule. The referenced statutory changes made by the Affordable Care Act do not go into effect in FY 2012 and were not addressed in this year's proposed rule.

After consideration of the public comments we received, we are adopting our proposed policies without modifications. In summary, we are excluding inpatient hospice days from the patient day count under § 412.106(a)(1)(ii) (for DSH) and the bed day count under § 412.105(b) (for IME) and under § 412.106(a)(1)(i) (for DSH).

H. Medicare-Dependent, Small Rural Hospitals (MDHs) (§ 412.108)

1. Background

Under the IPPS, separate special payment protections are provided to a Medicare-dependent, small rural hospital (MDH). MDHs are paid for their hospital inpatient services based on the higher of the Federal rate or a blended rate based in part on the Federal rate and in part on the MDH's hospital-specific rate. 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 (that is, not less than 60 percent of its inpatient days or discharges either in its 1987 cost reporting year or in two of its most recent three settled Medicare cost reporting years). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be classified as an MDH.

Although MDHs are paid under an adjusted payment methodology, they are still IPPS hospitals paid under section 1886(d) of the Act. Like all IPPS hospitals paid under section 1886(d) of the Act, MDHs are paid for their discharges based on the DRG weights calculated under section 1886(d)(4) of the Act.

Through and including FY 2006, under section 1886(d)(5)(G) of the Act, MDHs are paid based on the Federal rate or, if higher, the Federal rate plus 50 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate based on the hospital's FY 1982 or FY 1987 costs per discharge, whichever of these hospital-specific rates is higher. Section 5003(b) of Public Law 109–171 (DRA 2005) amended section 1886(d)(5)(G) of the Act to provide that, for discharges occurring on or after October 1, 2006, MDHs are paid based on the Federal rate or, if higher, the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever of these hospital-specific rates is highest.

For each cost reporting period, the fiscal intermediary or MAC determines which of the payment options will yield the highest aggregate payment. Interim payments are automatically made at the highest rate using the best data available at the time the fiscal intermediary or MAC makes the determination. However, it may not be possible for the fiscal intermediary or 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 accurately forecast the outlier payments, the amount of the DSH adjustment or the IME adjustment, all of which are applicable only to payments based on the Federal rate and not to payments based on the hospital-specific rate. The fiscal intermediary or MAC makes a final adjustment at the settlement of the cost report after it determines precisely which of the payment rates would yield the highest aggregate payment to the hospital.

If a hospital disagrees with the fiscal intermediary's or the MAC's determination regarding the final amount of program payment to which it is entitled, it has the right to appeal the determination in accordance with the procedures set forth in 42 CFR Part 405, Subpart R, which govern provider payment determinations and appeals.

2. Extension of the MDH Program

As we discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50286 and 50287), section 3124 of the Affordable Care Act extended 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 from the end of FY 2011 to the end of FY 2012, by striking ''October 1, 2011'' and inserting ''October 1, 2012''. Section 3124(b) of the Affordable Care Act also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act. Section 3124(b)(2) of the Affordable Care Act also amended section 13501(e)(2) of OBRA 1993 to extend the provision permitting hospitals to decline reclassification as an MDH through FY 2012. 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 proposed rule (76 FR 25944), we did not propose any additional changes to this regulatory text for FY 2012.

We did not receive any public comments regarding the extension of the MDH program.

I. Certified Registered Nurse Anesthetist (CRNA) Services Furnished in Rural Hospitals and CAHs (§ 412.113)

Section 2312 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) provided for reimbursement to hospitals on a reasonable cost basis for the costs that certain hospitals incur in connection with the services of certified registered nurse anesthetists (CRNAs). Section 2312(c) provided that pass-through payment of CRNA costs was effective for cost reporting periods beginning on or after October 1, 1984, and before October 1, 1987. Section 9320 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509) (which established a fee schedule for the services of nurse anesthetists) amended section 2312(c) of Public Law 98–369 by extending the CRNA pass-through provision through cost reporting periods beginning before January 1, 1989. In addition, Public Law 99–509 amended section 1861 of the Act to add a new subsection (bb), which provides that CRNA services include anesthesia services and related care furnished by a CRNA. Section 1861(bb)(2) of the Act states that the term ''certified registered nurse anesthetist'' includes an anesthesiologist assistant. Section 608 of the Family Support Act of 1988 (Pub. L. 100–485) extended pass-through payments for CRNA services through 1991 and amended section 9320 of Public Law 99–509 by including language referring to eligibility for pass-through payments for CRNA services if the facility is ''* * * a hospital located in a rural area (as defined for purposes of section 1886(d) of the Social Security Act).'' Reasonable cost-based payment for CRNA services was extended indefinitely by section 6132 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239).

Section 1886(d) of the Act defines ''rural'' as any area outside an urban area. This definition of ''rural'' was in effect when Public Law 100–485 was implemented. In 1999, the Balanced Budget Refinement Act (Pub. L. 106–113) amended section 1886(d)(8) of the Act by adding a new subparagraph (E), which permits a hospital physically located in an urban area to apply for reclassification to be treated as rural. In addition, Public Law 106–113 made a corresponding change to section 1820(c)(2)(B)(i) of the Act, which specifies the rural location requirement for CAH designation, by adding the phrase ''or is treated as being located in a rural area pursuant to section 1886(d)(8)(E).''

The regulations implementing pass-through payments for anesthesia services and related care furnished by qualified nonphysician anesthetists (that is, both CRNAs and anesthesiologist assistants) employed by a hospital or CAH, are located at § 412.113(c). In the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24010), we proposed to revise § 412.113(c)(2)(i)(A) to state that, effective for cost reporting periods beginning on or after October 1, 2010, CAHs and hospitals that have reclassified as rural pursuant to section 1886(d)(8)(E) of the Act and § 412.103 of the regulations also are rural for purposes of section 1886(d) of the Act and, therefore, are eligible to be paid based on reasonable cost for anesthesia services and related care furnished by a qualified nonphysician anesthetist.

After consideration of the public comments, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303), we adopted a policy that would allow otherwise eligible critical access hospitals (CAHs) or hospitals, that have reclassified from urban to rural status under section 1886(d)(8)(E) of the Act and 42 CFR 412.103, to receive reasonable cost payments for anesthesia services and related care furnished by qualified nonphysician anesthetists (also referred to in this section as CRNA pass-through payments), effective for cost reporting periods beginning on or after October 1, 2010. After the issuance of the final rule, we received an inquiry from a public commenter who indicated that CMS had misunderstood its submitted comment on the FY 2011

IPPS/LTCH PPS proposed rule in which the commenter stated that the policy should be effective on the basis of a calendar year, not a cost reporting period, since as a rule a hospital can only begin receiving CRNA pass-through payments at the beginning of a calendar year. Our response to this public comment in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303) indicated that it was unnecessary to modify the effective date in the final rule because ''if the provision is effective for cost reporting periods beginning on or after October 1, 2010, it will also be in effect for the calendar year beginning January 1, 2011.'' While this statement was accurate, it did not take into account that if a hospital's cost reporting period begins on or after January 1, 2011, the hospital would be ineligible to receive CRNA pass-through payments until the beginning of the next calendar year, on January 1, 2012. Under the finalized policy in the FY 2011 IPPS/LTCH PPS final rule, hospitals reclassifying from urban to rural areas with cost reporting periods beginning between October 1, 2010, and December 31, 2010, would be able to first receive CRNA pass-through payments effective January 1, 2011, while hospitals with cost reporting periods beginning on or after January 1, 2011, would not be able to receive CRNA pass-through payments until one year later on January 1, 2012.

In an interim final rule with comment period included in the **Federal Register** on November 24, 2010 (75 FR 72256), we stated that our intention in the FY 2011 IPPS/LTCH PPS final rule was not to make the provision for CRNA pass-through payment for anesthesia services and related care furnished by qualified nonphysician anesthetists effective January 1, 2011, for some hospitals and CAHs and January 1, 2012, for other hospitals and CAHs. We stated our belief that the provision would be more equitable if it had a uniform effective date for all eligible hospitals and CAHs. While we considered changing the effective date to January 1, 2011, for all hospitals and CAHs to begin receiving CRNA pass-through payments under this provision, we noted that our regulations at 42 CFR 412.113(c)(2)(iii) state that the hospital or CAH must demonstrate to its fiscal intermediary *prior* to the start of the calendar year that it meets the requirements for receiving CRNA pass-through payments. For this reason, we stated our belief that the best option was to adopt an effective date of December 2, 2010, for all hospitals and CAHs, which we provided for in the interim final rule with comment period. With an effective date of December 2, 2010, any hospital or CAH, regardless of its specific fiscal year beginning date, was provided the opportunity to demonstrate prior to January 1, 2011, that it met the requirements for receiving CRNA pass-through payments beginning January 1, 2011. In the interim final rule with comment period, we amended the regulations at § 412.113(c)(2)(i)(A) to provide for an effective date of December 2, 2010, for all eligible hospitals and CAHs to receive CRNA pass-through payments for anesthesia services and related care furnished by qualified nonphysician anesthetists.

As we indicated in the FY 2012 IPPS/LTCH PPS proposed rule, in this final rule, we are responding to the one public comment received on the interim final rule with comment period and setting forth our final policy.

Comment: One commenter supported CMS' decision to change the effective date of the policy to December 2, 2010, because this change will allow all eligible hospitals and CAHs to begin receiving CRNA pass-through payments effective January 1, 2011.

Response: We appreciabe the commenter's support. In this final rule, we are finalizing the effective date established in the interim final rule with comment period.

We received two additional comments in response to the FY 2012 IPPS/LTCH PPS proposed rule.

Comment: One commenter suggested that CMS consider, for future rulemaking, an increase in the limit on the number of procedures and FTE hours that a facility may have and remain qualified for reasonable cost-based reimbursement for services furnished by qualified nonphysician anesthetists. The commenter stated that this increase would ensure better coverage for emergency rooms and surgery cases, which would support patient services and improve patient safety and efficiency of treatment. Another commenter stated that while it appreciated and supported changing the regulations to permit CRNA pass-through payments for reclassified hospitals, it urged CMS to permit hospitals in Lugar counties the same benefit.

Response: Because we did not propose any further changes to the CRNA pass-through payment policy in the FY 2012 IPPS/LTCH PPS proposed rule, we consider these comments to be outside the scope of the proposed rule. Therefore, we are not responding to these comments in this final rule. However, we may consider these public comments in the development of future rulemaking.

After consideration of the public comments we received, we are finalizing the effective date of December 2, 2010, that was established in the interim final rule with comment period. Effective December 2, 2010, in addition to hospitals and CAHs geographically located in rural areas, as defined in § 412.62(f), and are not deemed to be located in an urban area under § 412.64(b)(3), hospitals and CAHs that have reclassified as rural under the regulations at § 412.103 are also eligible to receive CRNA pass-through payments.

J. Additional Payments for Qualifying Hospitals With Lowest Per Enrollee Medicare Spending

1. Background

Section 1109 of the Affordable Care Act requires additional payments for FYs 2011 and 2012 for ''qualifying hospitals.'' Section 1109(d) defines a ''qualifying hospital'' as a ''subsection (d) hospital * * * that is located in a county that ranks, based upon its ranking in age, sex and race adjusted spending for benefits under parts A and B * * * per enrollee within the lowest quartile of such counties in the United States.'' Therefore, a ''qualifying hospital'' is one that meets the following conditions: (1) It is a ''subsection (d) hospital'' as defined in section 1886(d)(1)(B) of the Act; and (2) it is located in a county that ranks within the lowest quartile of counties based upon its spending for benefits under Medicare Part A and Part B per enrollee adjusted for age, sex, and race. Section 1109(b) of the Affordable Care Act makes available $400 million to qualifying hospitals for FY 2011 and FY 2012. Section 1109(c) of the Affordable Care Act requires the $400 million to be divided among each qualifying hospital in proportion to the ratio of the individual qualifying hospital's FY 2009 IPPS operating hospital payments to the sum of total FY 2009 IPPS operating hospital payments made to all qualifying hospitals.

Section 1109 is one of several provisions in the Affordable Care Act that addresses concerns about how Medicare makes adjustments for geographic differences in the cost of providing services and geographic variation in the volume and intensity of health care spending. Some other provisions in the Affordable Care Act that relate to concerns about geographic variation in Medicare payments include:

- Section 3102(a), which provides a floor of 1.0 on the physician fee schedule work geographic practice cost

index (GPCI) through the end of CY 2010 (later extended by the Medicare and Medicaid Extension Act of 2010 through the end of CY 2011);

• Section 3102(b), as amended by section 1108 of the Affordable Care Act, which requires that only one-half of the relative cost differences in employee wages and office rents be reflected in the practice expense GPCIs in 2010 and 2011;

• Section 10324, which provides for a floor on the wage index and the practice expense GPCI in frontier States (defined as 50 percent or more of the counties in the State having a population density of less than 6 people per square mile).

These provisions provide temporary adjustments in payments while other initiatives are underway to evaluate geographic adjustment factors that are used in Medicare's payment systems. For instance, section 3101 of the Affordable Care Act requires the Secretary, not later than January 1, 2012, to make appropriate adjustments to the practice expense GPCI considering alternative data sources such as the American Community Survey for the nonphysician employee portion of the GPCI. Section 3137 of the Affordable Care Act requires the Secretary to submit to Congress a report that includes a plan to reform the hospital wage index system under section 1886 of the Act by December 31, 2011. In addition to these provisions, the Secretary has contracted with the Institute of Medicine (IOM) to study the hospital wage index and the physician fee schedule GPCI. The IOM released its first report to CMS on June 1, 2011. The report provides an evaluation and assessment of:

(1) The empirical validity of the adjustment factors (the hospital wage index and physician fee schedule GPCI);

(2) The methodology used to determine the adjustment factors;

(3) Measures used for the adjustment factors, taking into account—

• Timeliness of data and frequency of revisions to such data;

• Sources of data and the degree to which such data are representative of costs; and

• Operational costs of providers who participate in Medicare.

The report includes recommendations for the Secretary to consider. It is available on the Web site at: *http://iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.* We are looking forward to reviewing IOM's report and acting expeditiously on its recommendations to improve Medicare's payment systems and better adjust for geographic differences in the cost of hospital labor as well as the cost of operating a physician practice.

2. Methodology for Identifying Qualifying Hospitals and Eligible Counties

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303 through 50342), we finalized our methodology for distributing the $400 million to qualifying hospitals located in the lowest quartile of counties in per enrollee Medicare spending. First, we provided our methodology for determining the bottom quartile of counties with the lowest Medicare Part A and Part B spending adjusted by age, sex, and race for the purpose of disbursing the available $400 million. We developed an adjustment model by age, sex, and race, as required under the provisions of section 1109. We then applied this adjustment to the county Medicare Part A and Part B spending data to account for the demographics of the Medicare beneficiaries in those counties. After those adjustments were applied, we determined the Medicare Part A and Part B spending by county per enrollee. As we explained in the final rule, our methodology for determining the Medicare Part A and Part B spending per enrollee by county adjusted for age, sex, and race is similar to the methodology we use to calculate risk adjustment models for Medicare Advantage (MA) ratesetting. For more information on the methodology we used to calculate the county Medicare per enrollee spending rates, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303 through 75 FR 50307).

In addition, in the FY 2011 IPPS/LTCH PPS final rule, we developed a methodology to identify the qualifying hospitals located in each of the eligible counties. As we stated earlier, section 1109 defines a qualifying hospital as a ''subsection (d) hospital'' (as defined for purposes of section 1886(d) of the Act) that is ''located in'' an eligible county. 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 50 States or the District of Columbia.'' Therefore, we excluded Puerto Rico hospitals and CAHs from the provisions of section 1109 because they do not meet the definition of a ''subsection (d) hospital.''

In the FY 2011 IPPS/LTCH PPS final rule, we identified ''qualifying hospitals'' based on their Medicare provider number (now referred to as the ''CMS certification number'' (CCN)) because this number is used by hospitals to identify themselves on their Medicare cost reports. We also provided that, in order to meet the definition of a ''qualifying hospital,'' the hospital, as identified by its CCN, must: (1) Have existed as a subsection (d) hospital as of April 1, 2010; (2) be geographically located in an eligible county; and (3) have received IPPS operating payments (in accordance with section 1886(d) of the Act) under its CCN in FY 2009. We used the Online Survey, Certification and Reporting (OSCAR) database to determine a hospital's county location associated with that CCN. We also specified that the address listed for a hospital's CCN must be currently located in a qualifying county in order for a hospital to meet the definition of a ''qualifying hospital.'' For more information on how we identified the qualifying hospitals, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50307 and 50308). We note that we did not propose to clarify, nor in this final rule are we clarifying, the application of our definition in section IV.J.4. of this preamble.

3. Determination of Annual Payment Amounts

The third step in the implementation of section 1109 of the Affordable Care Act required that we determine the payment amount that each qualifying hospital would receive. Specifically, section 1109(c) of the Affordable Care Act required that the payment amount for a qualifying hospital be determined ''in proportion to the portion of the amount of the aggregate payments under section 1886(d) of the Social Security Act to the hospital for fiscal year 2009 bears to the sum of all such payments to all qualifying hospitals for such fiscal year.'' As specified in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50310 through 50312), we determined that a qualifying hospital's payment amount will be based on the proportion of its IPPS operating payments made in FY 2009 under section 1886(d) of the Act relative to the total IPPS operating payments made to all qualifying hospitals in FY 2009 under section 1886(d) of the Act. The FY 2009 IPPS operating payments made under section 1886(d) of the Act includes DRG and wage-adjusted payments made under the IPPS standardized amount with add-on payments for operating DSH, operating IME, operating outliers, and new technology (collectively referred to in this preamble as the IPPS operating payment amount). We used the March 2010 update of the FY 2009 MedPAR hospital inpatient claims data to determine the IPPS operating payment amounts for each qualifying hospital in order to calculate the proportion of money that each qualifying hospital

would receive under this provision. For more information on the methodology we used to calculate the payment determinations, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50310 through 75 FR 50312).

4. Eligible Counties and Qualifying Hospitals

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50312 through 50342), we published the list of eligible counties, that is, the lowest quartile of counties with Medicare Part A and Part B spending per enrollee adjusted for age, sex, and race, the qualifying hospitals located in those counties, and the qualifying hospitals' payment weighting factors, for purposes of making payments under section 1109 for FY 2011 and FY 2012. We identified 3,142 counties in the United States. Therefore, there are 786 eligible counties (rounded from 785.5 eligible counties). Of those 786 eligible counties, there are only 273 counties in which qualifying hospitals are located, using the methodology that we finalized in the FY 2011 IPPS/LTCH PPS final rule. Using CCNs, we identified 416 IPPS hospitals that are currently located in those eligible counties and that received IPPS operating payments in FY 2009.

In response to public comments on the FY 2011 IPPS/LTCH PPS proposed rule, in the FY 2011 IPPS/LTCH PPS final rule, we corrected the list of eligible counties by replacing two counties on our list of eligible counties (adding Crooks County, OR and Bottineu County, ND). However, we did not identify any qualifying hospitals located in those two eligible counties. Therefore, we provided the public an opportunity to notify CMS by August 30, 2010, if there were any qualifying IPPS hospitals located in either of the two newly added counties. We stated that if we added qualifying hospitals in these counties as a result of accurate notification from the public, we would publish a revised list of qualifying hospitals and their payment weighting factors on the CMS Web site after August 30, 2010. We did not receive any public comments that there were qualifying hospitals located in Crooks County, OR or Bottineu County, ND. Therefore, the list of eligible counties and qualifying hospitals that was finalized in Tables 1 and 2 in the FY 2011 IPPS/LTCH PPS final rule remained valid for distribution of payments under section 1109 for FY 2011 and FY 2012.

In auditing our determination of qualifying hospitals prior to the distribution of payments for FY 2011, we found that the following providers on the list of qualifying hospitals which we finalized in the FY 2011 IPPS/LTCH PPS final rule were not subsection (d) hospitals in FY 2011:

CMS Certification No.	Provider name
110231	Landmark Hospital of Athens LLC.
130024	Bonner General Hospital.
130069	SW Idaho Advanced Care.
130070	Complex Care Hospital of Idaho.
160156	Continuing Care Hospital at St. Luke's.
250112	Calhoun Health Services.
260221	Select Specialty Hospital—Springfield Inc.
270002	Holy Rosary Healthcare.
320088	Advanced Care of South New Mexico.
330010	Amsterdam Memorial Hospital.
500143	Providence St. Peter Chemical Dependency Center.

Because these providers were not subsection (d) hospitals in FY 2011, the statute precludes them from being qualifying hospitals eligible to receive section 1109 payments for FY 2011. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25947), we proposed to clarify that, in applying our definition of qualifying hospitals for making payments under section 1109 of the Affordable Care Act, these 11 providers (and other providers that do not meet the statutory definition) are not qualifying hospitals and, therefore, are removed from the list of qualifying hospitals. Furthermore, we proposed to clarify that, in order to meet the definition of ''qualifying hospital'' under section 1109 for FY 2012, a hospital that is on the list of qualifying hospitals in the proposed rule must meet the statutory criteria of a ''qualifying hospital'' for some portion of FY 2012 (a hospital must be a subsection (d) hospital for some part of FY 2012).

In addition, we noted that, prior to the issuance of the FY 2012 final rule and prior to making section 1109 payments for FY 2012, we intend to review providers' status vis-à-vis the statutory definition of qualifying hospital. Accordingly, we noted that, in this FY 2012 final rule and again prior to distribution of section 1109 payments for FY 2012, we would update the list of qualifying hospitals and payment weighting factors based on these findings. We indicated that, in addition to the opportunity to submit comments on the proposed rule, we were proposing to provide hospitals an opportunity after the FY 2012 IPPS rulemaking cycle to notify CMS whether any qualifying hospitals removed from the list have been removed in error and to notify CMS if a hospital is on the list of qualifying hospitals and will not be a qualifying hospital (for example, a subsection (d) hospital) for any or all part of FY 2012. We also stated that the public would be allowed to submit input on these two topics via e-mail to Nisha Bhat, nisha.bhat@cms.hhs.gov. All information, including relevant documentation, must be received by November 1, 2011.

5. Payment Determinations and Distributions for FY 2011 and FY 2012

Under section 1109(b) of the Affordable Care Act, the total pool of payments available to qualifying hospitals for FY 2011 and FY 2012 is $400 million. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50308 through 50310), we stated that we would distribute $150 million for FY 2011 and $250 million for FY 2012. We stated that we would distribute payments to the qualifying hospitals through an annual one-time payment during each of FY 2011 and FY 2012 through their Medicare contractor (fiscal intermediary or MAC). We instructed qualifying hospitals to report these additional payments on their Medicare hospital cost report corresponding to the appropriate cost reporting period that the hospitals receive the payments and that hospitals should report these payments on the ''Other adjustment'' line on Worksheet E, Part A of the Medicare hospital cost report Form 2552. We noted that we require these payments to be reported on the cost report for tracking purposes only and that these additional payments will not be adjusted or settled by the fiscal intermediary or MAC on the cost report.

In the FY 2012 IPPS/LTCH PPS proposed rule, we noted that at the time of the issuance of the proposed rule, we had not yet made the payments to the qualifying hospitals for FY 2011. As we stated in the FY 2011 IPPS/LTCH PPS final rule, and again in the FY 2012 proposed rule, we will make the FY 2011 payments during FY 2011 (that is, by September 30, 2011). However, in the proposed rule, we indicated that we were notifying the public that we intended to change the method we would use to distribute the payment for FY 2011 and FY 2012, in order to ease the reporting burden on hospitals. Rather than making a one-time annual payment to the qualifying hospitals through their Medicare contractor using the Medicare cost report, in the proposed rule, we indicated that we planned to make payments to the qualifying hospitals through a one-time

annual payment made by one Medicare contractor who would directly pay all of the qualifying hospitals. We stated that we would send each qualifying hospital a letter stating the specifics of how the hospital will receive its payments. Because these one-time annual payments would be made through a special process outside of the scope of normal payments by their Medicare contractor, the hospitals' Medicare contractor would no longer need to track the payment amounts made to the hospitals under this provision. We believed this would simplify and expedite the payment process so that one Medicare contractor is responsible for overseeing the distribution of payments. In addition, we believed that this simplified process would ease the administrative burden within CMS to track that payments have been properly made to the qualifying hospitals. In addition, the burden to hospitals is reduced because hospitals would no longer have to report these additional payments on their Medicare hospital cost report corresponding to the appropriate cost reporting period for which the hospitals receive payments in FY 2011 or FY 2012 (as we instructed in the FY 2011 IPPS/LTCH PPS final rule and note above).

In the FY 2011 IPPS/LTCH PPS final rule, we also stated that we would make only one determination of eligible counties and qualifying hospitals for FY 2011 and FY 2012, with the caveat that we would accept additional public input on the limited issue of whether there are any qualifying hospitals in the two newly identified eligible counties. As we stated earlier, we did not receive any public input on qualifying hospitals for the two newly identified eligible counties. However, as we describe above, 11 hospitals that were included on the list of qualifying hospitals do not meet the statutory criteria in section 1109 of the Affordable Care Act. Therefore, in the proposed rule, we proposed to revise our list of qualifying hospitals and their payment weighting factors finalized in the FY 2011 IPPS/LTCH PPS final rule to exclude these 11 hospitals. As explained in the FY 2011 IPPS/LTCH PPS final rule, we finalized in that rule (to the best of our ability) the list of eligible counties and qualifying hospitals once for ease of implementation of the section 1109 provision and to allow hospitals to plan their budgets accordingly. We indicated that the proposed revision of our determination to exclude these 11 hospitals would result in changes to the payment weighting factors. We proposed to update the payment weighting factors accordingly. Therefore, we proposed to distribute the remaining $250 million in FY 2012 to those qualifying hospitals included in the proposed rule based on the payment weighting factors proposed in the proposed rule. In addition, in order to distribute the section 1109 payments for FY 2011 in as timely a manner as possible, we indicated that we intended to make preliminary section 1109 payments for FY 2011 using the proposed list of qualifying providers and payment weighting factors using the payment method described above. We stated that if additional hospitals are deleted from the proposed list of qualifying hospitals for FY 2011 because they do not meet the statutory criteria, the payment weighting factors would need additional revision. If this situation occurs, we proposed to further amend the payment weighting factors for payments to be made in FY 2012 so that each qualifying hospital receives its appropriate share of the total $400 million.

We referred readers to the CMS Web site at: *http://www.cms.gov/AcuteInpatientPPS/TopOfPage* for the tables listed below. The tables were included collectively as the ''Section 1109 Files'' for the FY 2012 IPPS/LTCH proposed rule.

- The final list of eligible counties that was published in the FY 2011 IPPS/LTCH PPS final rule. We noted that we were not updating this table.
- The finalized list of qualifying hospitals, location, and payment weighting factors (based on the March 2010 update of the FY 2009 MedPAR file); based on the proposed clarifications described above for FY 2011.
- The distribution of the $400 million for FY 2011 and FY 2012 by State based on the proposed list of qualifying hospitals, location, and payment weighting factors.

We noted that the Web address for this Web site was effective as of April 19, 2011, and that, in the future, these tables may be archived to the Web site at: *http://www.cms.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage.*

Comment: Commenters supported CMS' continuation of its policy to distribute the remaining of the $400 million allocated under the provision of section 1109 of the Act in FY 2012. Commenters also supported CMS' proposal to make one-time annual payments through one Medicare contractor rather than individual Medicare contractors. Commenters asked CMS to provide the name and the contact information of the contractor who will be making the one-time annual payments to the qualifying hospitals. In addition, commenters urged CMS to notify the qualifying hospitals of the timing of their FY 2011 and FY 2012 payments.

Response: We appreciate the commenters' support of the implementation of the section 1109 provision. Qualifying hospitals received their share of the $150 million for their FY 2011 payments on July 14, 2011. The payments were made directly to the hospitals by one Medicare contractor. We will continue this payment process for FY 2012. If hospitals have questions with regard to this process, they can contact their Medicare contractor or CMS directly.

As we proposed, we are providing hospitals, in addition to the opportunity to submit comments on the proposed rule, the opportunity after the FY 2012 IPPS rulemaking cycle to notify CMS as to whether any qualifying hospitals removed from the list have been removed in error and to notify CMS if a hospital is on the list of qualifying hospitals and will not be a qualifying hospital (for example, a subsection (d) hospital) for any part of FY 2012. The public is allowed to submit input on these two topics via e-mail to Nisha Bhat, *nisha.bhat@cms.hhs.gov* by November 1, 2011. Given the November 1, 2011 deadline for hospitals to comment on the list of qualifying hospitals to receive section 1109 payments for FY 2012, we plan to distribute $250 million to the qualifying hospitals for FY 2012 in the end of 2011 or early 2012.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25947), we identified 11 providers that were not subsection(d) hospitals in FY 2011 and, therefore, do not qualify to receive section 1109 payments for FY 2011. In preparation of this final rule, we again reviewed our list of qualifying hospitals and have found that an additional hospital, Columbia Regional Hospital (CNN 260178), has not been a subsection(d) hospital for any part of FY 2011 and, therefore, does not meet the statutory criteria to receive payments under section 1109 for FY 2011 and FY 2012. We have revised the list of qualifying hospitals and their payment weighting factors for FY 2011 accordingly. In addition, we found that the following hospitals have converted to become CAHs during FY 2011 and will not be subsection (d) hospitals in FY 2012.

CMS Certification No.	Provider name
200032	Stephens Memorial Hospital.

CMS Certification No.	Provider name
320069	Miners' Colfax Medical Center.

Thus, these two hospitals will receive payments under section 1109 for FY 2011 but they will no longer qualify to receive payments for FY 2012. We have posted the list of qualifying hospitals and payment weighting factors for FY 2012 on the CMS Web site.

We refer readers to the CMS Web site at: *http://www.cms.gov/AcuteInpatientPPS/TopOfPage* for the tables listed below. The tables are included collectively as the ''Section 1109 Files'' for the FY 2012 IPPS/LTCH final rule.

- The final list of eligible counties that was published in the FY 2011 IPPS/LTCH PPS final rule. We note that we were not updating this table.
- The finalized list of qualifying hospitals, location, and payment weighting factors (based on the March 2010 update of the FY 2009 MedPAR file); based on the clarifications finalized above for FY 2011.
- The proposed list of qualifying hospitals, location, and payment weighting factors (based on the March 2010 update of the FY 2009 MedPAR file) based on the clarifications above for FY 2012. The final list of qualifying hospitals, location, and payment weighting factors for FY 2012 will be posted after comments on the accuracy of the list of qualifying hospitals are received and evaluated after November 1, 2011.
- The distribution of the $400 million for FY 2011 and FY 2012 by State based on the proposed list of qualifying hospitals, location, and payment weighting factors.

The Web address for this Web site is effective on the date of display of this final rule and, in the future, these tables may be archived to the Web site at: *http://www.cms.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage.*

K. Changes in the Inpatient Hospital Update

1. FY 2012 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for hospital inpatient operating costs by a factor called the ''applicable percentage increase.'' Prior to enactment of the Affordable Care Act, section 1886(b)(3)(B)(i)(XX) of the Act set the applicable percentage increase equal to the rate-of-increase in the hospital market basket for subsection (d) hospitals (hereafter referred to as ''IPPS hospitals'') in all areas, subject to the hospital submitting quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act. For hospitals that did not provide these data, the update was equal to the market basket percentage increase less an additional 2.0 percentage points. The update for the hospital-specific rates for SCHs and MDHs is set by section 1886(b)(3)(B)(iv) of the Act as discussed further below.

As discussed below in section IV.K.3. of this preamble, 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 2012 as equal to the rate-of increase in the hospital market basket for IPPS hospitals in all areas (which is currently based on the second quarter 2011 forecast of the FY 2006-based IPPS market basket), 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 0.1 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 2012 adjustment of 0.1 percentage point may result in the applicable percentage increase being less than zero.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25949), based on IHS Global Insight, Inc.'s (IGI's) first quarter 2011 forecast of multifactor productivity (MFP), we proposed an MFP adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.2 percent.

Consistent with current law, and based on IGI's first quarter 2011 forecast of the FY 2012 market basket increase, we proposed an applicable percentage increase to the FY 2012 operating standardized amount of 1.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for economy-wide productivity and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance with our rules. For hospitals that do not submit quality data, we proposed an applicable percentage increase to the operating standardized amount of −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent, less 2.0 percentage points for failure to submit quality data, less an adjustment of 1.2 percentage points for economy-wide productivity, and less an additional adjustment of 0.1 percentage point).

We did not receive any public comments on these proposals to implement the applicable percentage increase. However, we did receive public comments concerning our proposed MFP adjustment. We address these public comments in section IV.K.3. of this preamble. For this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are finalizing an applicable percentage increase to the FY 2012 operating standardized amount of 1.9 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 1.0 percentage point for economy-wide productivity and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance with our rules. For hospitals that do not submit quality data, we are finalizing an applicable percentage increase to the operating standardized amount of −0.1 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit quality data, less an adjustment of 1.0 percentage point for economy-wide productivity, and less an additional adjustment of 0.1 percentage point). We note that, for the proposed rule, we used the first quarter 2011 forecast of the FY 2006-based IPPS market basket rate-of-increase. For this final rule, we used the most recent data available, which was the second quarter 2011 forecast of the FY 2006-based IPPS market basket rate-of-increase. Similarly, for the proposed rule, we used IGI's first quarter 2011 forecast of MFP. For this final rule, we used the most recent data available, which was IGI's second quarter 2011 forecast of MFP. We also note that between the proposed and final rules, we also incorporated Bureau of Labor Statistics (BLS) revised historical data for MFP from 1987 to 2010, with 2010 being a preliminary value.

In the proposed rule, we proposed to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law. Specifically, in accordance with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we proposed to

add a new paragraph (iv) to § 412.64(d)(1) to set the applicable percentage increase to the FY 2012 operating standardized amount as the percentage increase in the market basket index, 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 a multifactor productivity adjustment and, lastly, subject to the additional reduction of 0.1 percentage point. We did not receive any public comments on this proposal. Therefore, in this final rule, we are adopting as final, without modification, the proposed changes to § 412.64(d) to reflect current law.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital specific rates for SCHs and MDHs 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, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25949), we proposed an update to the hospital-specific rates applicable to SCHs and MDHs of 1.5 percent for hospitals that submit quality data or −0.5 percent for hospitals that fail to submit quality data. We did not receive any public comments on this proposal. Therefore, for this final rule, we are finalizing an update to the hospital-specific rates applicable to SCHs and MDHs of 1.9 percent for hospitals that submit quality data or −0.1 percent for hospitals that fail to submit quality data. As we noted above, for the proposed rule, we used IGI's first quarter 2011 forecast of the FY 2006-based IPPS market basket rate-of-increase. For this final rule, we used the most recent data available, which was IGI's second quarter 2011 forecast of the FY 2006-based IPPS market basket rate-of-increase. Similarly, for the proposed rule, we used IGI's first quarter 2011 forecast of MFP. For this final rule, we used the most recent data available, which was IGI's second quarter 2011 forecast of MFP. We also note that between the proposed rule and the final rule, we also incorporated BLS revised historical data for MFP from 1987 to 2010, with 2010 being a preliminary value. For FY 2012, the regulations in §§ 412.73(c)(16), 412.75(d), 412.77(e), 412.78(e), and 412.79(d) already contain provisions that set the update factor for SCHs and MDHs equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, as we proposed, we are not making further changes to these five regulatory provisions to reflect the FY 2012 update factor for SCHs and MDHs.

2. FY 2012 Puerto Rico Hospital Update

Puerto Rico hospitals are paid a blended rate for their inpatient operating costs based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 1886(d)(9)(C)(i) of the Act is the basis for determining the applicable percentage increase applied to the Puerto Rico-specific standardized amount. Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act, which states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25949), we proposed an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 1.5 percent. We did not receive any public comments on this proposal. Therefore, for this final rule, we are finalizing an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 1.9 percent. As we noted above, for the proposed rule, we used IGI's first quarter 2011 forecast of the FY 2006-based IPPS market basket rate-of-increase. For this final rule, we used the most recent data available, which was IGI's second quarter 2011 forecast of the FY 2006-based IPPS market basket rate-of-increase. Similarly, for the proposed rule, we used IGI's first quarter 2011 forecast of MFP. For this final rule, we used the most recent data available, which was IGI's second quarter 2011 forecast of MFP. We also note that between the proposed rule and the final rule, we also incorporated BLS revised historical data for MFP from 1987 to 2010, with 2010 being a preliminary value.

For FY 2012, under the authority of section 1886(d)(9)(C)(i) of the Act, as amended by section 401(c) of Public Law 108–173, we proposed to revise the existing regulations at § 412.211(c) to 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 (76 FR 25949). We did not receive any public comments on this proposal. Therefore, in this final rule, we are adopting as final, without modification, the proposed changes to § 412.211(c) to reflect current law.

3. Productivity Adjustment

Section 3401(a) of the Affordable Care Act amended section 1886(b)(3)(B) of the Act to require certain adjustments to the ''applicable percentage increase'' to the operating IPPS. One such change is to require that, in FY 2012 (and in subsequent fiscal years), the applicable percentage increase be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period) (the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at: *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data.

The projection of MFP is currently produced by IHS Global Insight, Inc. (IGI), an economic forecasting firm. In order to generate a forecast of MFP, IGI replicated the MFP measure calculated by the BLS using a series of proxy variables derived from its U.S. macroeconomic models. These models take into account a broad range of factors that influence the total U.S. economy. IGI forecasts the underlying proxy components such as Gross Domestic Product (GDP), capital, and labor inputs required to estimate MFP and then combines those projections according to the BLS methodology. In Table IV.K.1 below, we identify each of the major MFP component series

employed by the BLS to measure MFP. We also provide the corresponding concepts forecasted by IGI and determined by IGI and CMS to be the best available proxies for the BLS series.

TABLE IV.K.1—MULTIFACTOR PRODUCTIVITY COMPONENT SERIES EMPLOYED BY THE BUREAU OF LABOR STATISTICS AND IHS GLOBAL INSIGHT

BLS series	IGI series
Real value-added output, constant 2005 dollars.	Non-housing, non-government, nonfarm real GDP, Billions of chained 2005 dollars—annual rate.
Private nonfarm business sector labor input; 2005 = 100.00.	Hours of all persons in private non-farm establishments, 2005 = 100.00, adjusted for labor composition effects.
Aggregate capital inputs; 2005 = 100.00.	Real effective capital stock used for full employment GDP, Billions of chained 2005 dollars.

IGI found that the historical growth rates of the BLS components used to calculate MFP and the IGI components identified are consistent across all series and, therefore, suitable proxies for calculating MFP. We have included below a more detailed description of the methodology used by IGI to construct a forecast of MFP, which is aligned closely with the methodology employed by the BLS. For more information regarding the BLS method for estimating productivity, we refer readers to the BLS Web site at: *http://www.bls.gov/mfp/mprtech.pdf.*

At the time of the development of this FY 2012 final rule, the BLS had published a historical time series of private nonfarm business MFP for 1987 through 2010, with 2010 being a preliminary value. Using this historical MFP series and the IGI forecasted series, the IGI had developed a forecast of MFP for 2011 through 2021, as described below.

To create a forecast of BLS' MFP index, the forecasted annual growth rates of the ''non-housing, non-government, nonfarm, real GDP,'' ''hours of all persons in private non-farm establishments adjusted for labor composition,'' and ''real effective capital stock'' series (ranging from 2011 to 2021) are used to ''grow'' the levels of the ''real value-added output,'' ''private nonfarm business sector labor input,'' and ''aggregate capital inputs'' series published by the BLS. Projections of the ''hours of all persons'' measure are calculated using the difference between projections of the BLS index of output per hour and real GDP. This difference is then adjusted to account for changes in labor composition in the forecast interval.

Using these three key concepts, MFP is derived by subtracting the contribution of labor and capital inputs from output growth. However, in order to estimate MFP, we need to understand the relative contributions of labor and capital to total output growth. Therefore, two additional measures are needed to operationalize the estimation of the IGI MFP projection: Labor compensation and capital income. The sum of labor compensation and capital income represents total income. The BLS calculates labor compensation and capital income (in current dollar terms) to derive the nominal values of labor and capital inputs. IGI uses the ''nongovernment total compensation'' and ''flow of capital services from the total private nonresidential capital stock'' series as proxies for the BLS' income measures. These two proxy measures for income are divided by total income to obtain the shares of labor compensation and capital income to total income. In order to estimate labor's contribution and capital's contribution to the growth in total output, the growth rates of the proxy variables for labor and capital inputs are multiplied by their respective shares of total income. These contributions of labor and capital to output growth are subtracted from total output growth to calculate the ''change in the growth rates of multifactor productivity'':

*MFP = Total output growth − ((labor input growth * labor compensation share) + (capital input growth * capital income share))*

The change in the growth rates (also referred to as the compound growth rates) of the IGI MFP are multiplied by 100 in order to calculate the percent change in growth rates (the percent change in growth rates are published by the BLS for its historical MFP measure). Finally, the growth rates of the IGI MFP are converted to index levels based to 2005 to be consistent with the BLS' methodology. For benchmarking purposes, the historical growth rates of IGI's proxy variables were used to estimate a historical measure of MFP, which was compared to the historical MFP estimate published by the BLS. The comparison revealed that the growth rates of the components were consistent across all series and, therefore, validated the use of the proxy variables in generating the IGI MFP projections. The resulting MFP index was then interpolated to a quarterly frequency using the Bassie method for temporal disaggregation. The Bassie technique utilizes an indicator (pattern) series for its calculations. IGI uses the index of output per hour (published by the BLS) as an indicator when interpolating the MFP index.

As described in section I. of the Addendum to this final rule, we proposed to determine the IPPS market basket percentage increase for FY 2012, which is used to determine the FY 2012 applicable percentage increase, based on the FY 2006-based IPPS market basket. The FY 2006-based IPPS market basket was finalized and adopted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43843). Section 3401(a) of the Affordable Care Act amended section 1886(b)(3)(B) of the Act in part by adding a new clause (xi) which requires that, after determining the applicable percentage increase for a fiscal year, ''such percentage increase shall be reduced by the productivity adjustment described in subclause (II)'' (which we refer to as the ''MFP adjustment''). Section 1886(b)(3)(B)(i)(XX) of the Act establishes the applicable percentage increase for FY 2007 and each subsequent fiscal year as equal to the rate-of-increase (that is, the percentage increase) in the hospital market basket for IPPS hospitals, 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 and to other statutory adjustments, including the productivity adjustment.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25951), we proposed that the MFP adjustment be subtracted from the FY 2012 operating applicable percentage increase. We proposed that the end of the 10-year moving average of changes in the MFP should coincide with the end of the

appropriate FY update period. Because the applicable percentage increase is reduced by the MFP adjustment, we believed it is appropriate for the numbers associated with both components of the calculation (the underlying market basket percentage increase used to determine the applicable percentage increase and the productivity adjustment) to line up so that changes in market conditions are aligned. Therefore, for the FY 2012 update, the MFP adjustment is calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2012. We proposed to round the final annual adjustment to the one-tenth of one percentage point level up or down as applicable according to conventional rounding rules (that is, if the number we are rounding is followed by 5, 6, 7, 8, or 9, we would round the number up; if the number we are rounding is followed by 0, 1, 2, 3, or 4, we would round the number down).

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we proposed to base the FY 2012 market basket update used to determine the applicable percentage increase for the IPPS on the first quarter 2011 forecast of the FY 2006-based IPPS market basket, which was estimated to be 2.8 percent. This percentage increase, 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, was then reduced by the proposed MFP adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.2 percent, which was calculated as described above and based on IGI's first quarter 2011 forecast. We also proposed that if more recent data were 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 2012 market basket update and MFP adjustment in the final rule. Following application of the productivity adjustment, the applicable percentage increase is then reduced by 0.1 percentage point, as required by section 1886(b)(3)(B)(xii) of the Act, as added and amended by sections 3401 and 10319(a) of the Affordable Care Act (as discussed in section I. of the Addendum to this final rule).

Comment: One commenter expressed concern about the impact of the proposed productivity adjustment, the Affordable Care Act mandated reduction, and the documentation and coding adjustment. The commenter specifically stated that further reductions cannot be sustained and will continue to deplete scarce resources, making hospitals' mission of providing high quality care to patients even more challenging.

Response: As the commenter acknowledged, the Affordable Care Act requires that a productivity adjustment and a 0.1 percentage point reduction be applied to IPPS provider payment updates for FY 2012. Therefore, CMS is mandated to apply these adjustments to the IPPS hospital payments for FY 2012. We refer readers to section II.D. of this preamble for our responses to public comments on the documentation and coding adjustment.

After consideration of the public comments we received and based on a more recent estimate of the market basket and MFP adjustment, we are finalizing our proposed method for calculating and applying the MFP adjustment. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we base the FY 2012 market basket update used to determine the applicable percentage increase for the IPPS on IGI's second quarter 2011 forecast of the FY 2006-based IPPS market basket rate-of-increase, which is estimated to be 3.0 percent. This percentage increase, 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 MFP adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.0 percent, which was calculated as described above and based on IGI's second quarter 2011 forecast. Following application of the productivity adjustment, the applicable percentage increase is then reduced by 0.1 percentage point, as required by section 1886(b)(3)(B)(xii) of the Act, as added and amended by sections 3401 and 10319(a) of the Affordable Care Act (as discussed in section I. of the Addendum to this final rule).

L. Additional Payments to Hospitals With High Percentage of End-Stage Renal Disease (ESRD) Discharges (§ 412.104)

Under existing regulations at § 412.104(a), we provide additional Medicare payments to a hospital for inpatient services provided to Medicare beneficiaries with end-stage renal disease (ESRD) who receive dialysis during a hospital stay if the hospital's ESRD Medicare beneficiary discharges, excluding certain MS–DRGs noted below, where the beneficiary receives dialysis during the inpatient stay, are 10 percent or more of its total Medicare discharges. These additional payments are intended to lessen the impact of the added costs for hospitals that deliver inpatient dialysis services to a high concentration of ESRD Medicare beneficiaries. The regulation provides that discharges classified into MS–DRG 652 (Renal Failure), MS–DRG 682 (Renal Failure with MCC), MS–DRG 683 (Renal Failure with CC), MS–DRG 684 (Renal Failure without CC/MCC), and MS–DRG 685 (Admit for Renal Dialysis) are excluded from the calculation of ESRD Medicare beneficiary discharges for purposes of determining a hospital's eligibility for these additional payments. We excluded these MS–DRGs because they include payment for the cost of inpatient dialysis treatments.

The current Medicare cost reporting instructions in the Provider Reimbursement Manual, Part II (PRM–II), at section 3630.1, require hospitals to enter as the denominator of the calculation on Line 5 ''total Medicare discharges as reported on Worksheet S–3, Part I,'' excluding discharges for the dialysis MS–DRGs. As drafted, this instruction includes only discharges for beneficiaries enrolled in original fee-for-service Medicare in the denominator of the calculation. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25951), we proposed to clarify that our policy is that the term ''Medicare discharges'' used in § 412.104(a) refers to discharges of all beneficiaries entitled to Medicare Part A. Discharges associated with individuals entitled to Medicare Part A include discharges of individuals receiving benefits under original Medicare, discharges of individuals whose inpatient benefits are exhausted or whose stay was not covered by Medicare, and discharges for individuals enrolled in Medicare Advantage Plans, cost contracts under section 1876 of the Act (health maintenance organizations (HMOs)) and competitive medical plans (CMPs). Consistent with this proposed clarification, these discharges would be included in the denominator of the calculation for the purpose of determining eligibility for the ESRD additional payment to hospitals. Similarly, for the numerator of this calculation, all discharges of ESRD beneficiaries who are entitled to Medicare Part A and who receive inpatient dialysis, subject to the exclusions of certain discharges classified into MS–DRGs 652, 682, 683, 684, and 685, would be included in the determination of eligibility for the additional payment to hospitals. We also stated that we intended to revise

section 3630.1 of the PRM–II to reflect this clarification.

Comment: One commenter disagreed with our proposed clarification to include Medicare Advantage discharges in the denominator of the calculation for the purpose of determining eligibility for the ESRD additional payment to hospitals. The commenter believed that CMS is inconsistent in its policies regarding the treatment of Medicare Advantage days and asserted that legally these discharges should not be treated the same as discharges of patients who are enrolled in original Medicare Part A.

Response: We do not agree with the assertion of the commenter. Beneficiaries who elect to receive their benefits through Medicare Advantage remain entitled to benefits under Medicare Part A while enrolled in Part C. For example, the hospice benefit is administered under Medicare Part A, regardless of whether an individual has elected to enroll in Part C. Thus, if a beneficiary enrolled in a Medicare Advantage plan elects to receive hospice care, that benefit is administered under the traditional fee-for-service model and not by the beneficiary's Medicare Advantage plan. If, while receiving hospice care, the beneficiary also needs hospital inpatient care unrelated to the condition that caused the beneficiary to elect hospice care, the cost of that care would still be administered by the beneficiary's Medicare Advantage plan. As a result, it is possible for a beneficiary enrolled in a Medicare Advantage plan to receive benefits administered under Part A and Part C simultaneously. Beneficiaries enrolled in Medicare Advantage plans are entitled to benefits under Part A, and we believe it is appropriate to include in the denominator all discharges of individuals entitled to Part A, regardless of whether their benefits are administered by a Medicare Advantage plan or by traditional fee-for-service Medicare.

Comment: One commenter indicated that including these days in both the numerator and denominator would limit a hospital's ability to qualify for the additional payment. The commenter disagreed with including the additional discharges in both the numerator and denominator and advocated that the additional discharges should be added to only the numerator.

Response: We acknowledge the commenter's concerns. However, there is no policy or legal rationale to treat these days differently for the purpose of the numerator and denominator of this calculation. We recognize that this may make it somewhat more difficult for some hospitals to qualify for this add-on payment, but note that it may allow some hospitals more opportunity to qualify if a large proportion of their Medicare Advantage patient discharges are for Medicare beneficiaries with ESRD.

Comment: Several commenters expressed concern that the instructions in section 3630.1 of the PRM–II currently do not include these days on the Medicare Cost Report Worksheet S–3. They also believed there are difficulties when identifying those discharges not associated with original Medicare Part A.

Response: We intend to revise these instructions to reflect the clarification in this final rule.

Comment: One commenter suggested that CMS define more clearly the effective date of the clarification.

Response: As explained above, beneficiaries who elect to receive their benefits through Medicare Advantage remain entitled to benefits under Part A and must be included in the computation of ''Medicare discharges'' for purposes of determining whether a hospital qualifies for additional payments under § 412.104(a). However, the PRM–II instructions currently do not provide for discharges associated with individuals enrolled in Medicare Advantage plans to be included in the calculation. Accordingly, this clarification is needed to ensure that hospitals understand that beneficiaries who have elected to receive their benefits through Medicare Advantage must be included in the ESRD add-on payment calculation. We intend to revise the PRM–II instructions to require that beneficiaries enrolled in MA plans be included in both the numerator and demoninator of this calculation. The revised instructions will be effective for cost reporting periods starting on or after October 1, 2011.

After consideration of the public comments we received, we are finalizing our clarification that the term ''Medicare discharges'' used in § 412.104(a) of the regulations refers to discharges of all beneficiaries entitled to Medicare Part A. Individuals entitled to Medicare Part A include individuals receiving benefits under original Medicare, individuals whose inpatient benefits are exhausted or whose stay was not covered by Medicare, and individuals enrolled in Medicare Advantage Plans, cost contracts under section 1876 of the Act (HMOs), and CMPs. Consistent with this clarification, these discharges, subject to the exclusions of certain discharges classified into MS–DRGs 652, 682, 683, 684, and 685, must be included in the denominator of the calculation for the purpose of determining eligibility for the ESRD additional payment to hospitals. Similarly, for the numerator of this calculation, all discharges of ESRD beneficiaries who are entitled to Medicare Part A and who receive inpatient dialysis, excluding discharges for the dialysis MS–DRGs, must be included in the determination of eligibility for the ESRD additional payment to hospitals. We intend to revise the instructions under section 3630.1 of the PRM–II to reflect this clarification. The revised instructions will apply to cost reporting periods beginning on or after October 1, 2011.

M. Changes to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

1. Background

Currently, certain pension costs may be allowable costs under Medicare to the extent such costs are related to the reasonable and necessary cost of providing patient care and represent costs actually incurred. Reasonable cost reimbursement is addressed in section 1861(v)(1)(A) of the Act. Section 1861(v)(1)(A) of the Act defines ''reasonable cost,'' in part, as the cost actually incurred, excluding costs found to be unnecessary in the efficient delivery of needed health services. Section 1861(v)(1)(A) of the Act does not specifically address the determination of reasonable costs, but authorizes the Secretary to promulgate regulations and principles to be applied in determining reasonable costs.

We have issued regulations implementing this provision of the Act, including 42 CFR 413.9(a), which provide that payments ''must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries.'' In addition, § 413.9(c)(2) states that ''The provision in Medicare for payment of reasonable cost of services is intended to meet the actual costs.'' Further, the regulations at 412.9(c)(3) state that ''Reasonable cost includes all necessary and proper expenses incurred in furnishing services * * *.'' Therefore, in accordance with the statute, the regulations include two principles that help guide the determination of which expenses may be considered allowable reasonable costs that can be paid under Medicare; that is, such costs must be ''related'' to the care of Medicare beneficiaries, and such costs must actually be ''incurred.''

Consistent with these provisions, we have issued instructions in section 2142 of the Provider Reimbursement Manual, Part I (PRM–I) for determining and reporting qualified defined benefit

pension costs on the cost report for Medicare cost-finding purposes. For Medicare wage index purposes, the cost reporting instructions in section 3605.2 of the Provider Reimbursement Manual, Part II (PRM–II) for Worksheet S–3, Part II, Lines 13 through 20, require hospitals to comply with the requirements in section 2142 of the PRM–I.

Specifically, section 2142.5 of the PRM–I defines the current period liability for pension cost (that is, the maximum allowable pension cost) based on the actuarial accrued liability, normal cost, and unfunded actuarial liability. Under section 2142.4(A) of PRM–I, these liability measurements are to be computed in accordance with the Employee Retirement Income Security Act of 1974 (ERISA), regardless of whether or not the pension plan is subject to ERISA. Also, section 2142.6(A) of the PRM–I requires the current period liability for pension cost to be funded in order to be allowable. In addition, section 2142.6(C) of the PRM–I allows for funding in excess of the current period liability to be carried forward and recognized in future periods. We note that, on March 28, 2008, CMS published Revision 436, a technical clarification to section 2142 of the PRM–I.

Under ERISA, the actuarial accrued liability and normal cost are typically determined on an ongoing plan basis using long-term, best-estimate assumptions. The interest assumption reflects the average rates of return expected over the period during which benefits were payable, taking into account the investment mix of plan assets. Pension costs for plans not subject to ERISA (such as church plans and plans sponsored by public sector employers) also are typically based on the actuarial accrued liability and normal cost using long-term, best estimate assumptions.

The Pension Protection Act (PPA) of 2006 (Pub. L. 109–280) amended ERISA. Under the PPA amendments to ERISA, the actuarial accrued liability and normal cost are no longer used as a basis for determining ERISA minimum required or maximum tax deductible contributions. ERISA contribution limits are now based on a ''funding target'' and ''target normal cost'' measured on a settlement basis using the current market interest rates for investment grade corporate bonds that match the duration of the benefit payouts. The Internal Revenue Service (IRS) publishes the applicable interest rate tables on a monthly basis. Because pension liabilities are very sensitive to changes in the interest rate used to discount future benefit payouts, pension costs based on the PPA ''funding target'' and ''target normal cost'' values are expected to be less stable than those based on the pre-PPA traditional long-term, best-estimate assumptions, which change infrequently. Furthermore, plans not subject to the ERISA requirements, as amended by the PPA, are not likely to use the new ''funding target'' and ''target normal cost'' basis for determining pension costs, and ERISA plans are not likely to continue to report costs developed using the actuarial accrued liability and normal cost based on long-term basis, best estimate assumptions. Accordingly, there is no longer a standard actuarial basis used by all plans.

In response to the PPA amendments to ERISA, we began a review of the rules for determining pension costs for Medicare cost-finding and wage index purposes. As an interim measure, we issued a Joint Signature Memorandum (JSM) in November 2009 that contained instructions and a spreadsheet to assist hospitals and Medicare contractors in determining the annual allowable defined benefit pension cost for the FY 2011 wage index (JSM/TDL–10061, 11–20–09, December 3, 2009). Although these instructions were released for purposes of the wage index, they also serve as interim guidance for Medicare cost-finding purposes.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25951 through 25953), we proposed to revise our policy for determining pension cost for Medicare purposes. As mentioned above, due to the ERISA rules, as amended by the PPA, there is no longer a standard actuarial cost basis used by all types of plans. Therefore, we proposed to no longer rely on actuarial computations to determine the maximum annual cost limitation for Medicare. Instead, the general parameters of our proposal would maintain the current requirement that pension costs must be funded to be reportable, and would require all hospitals to report the actual pension contributions funded during the reporting period, on a cash basis.

In addition, under this cash basis approach, we proposed separate methodologies for measuring pension costs for Medicare cost-finding purposes (discussed below under section IV.M.2. of this preamble) and for purposes of updating the wage index (discussed in section III.D.2. of this preamble). It was necessary to have two distinct proposals in order to address the different goals of determining a hospital's payments and updating the average hourly wage to establish the geographic area wage index. The function of the wage index is to measure relative hospital labor costs across areas. This function is distinct from Medicare payment determinations, where the goal is to measure the actual costs incurred by individual hospitals. These two distinct proposals would require separate updated instructions to section 2142 of the PRM–I for Medicare cost-finding purposes and section 3605.2 of the PRM–II for purposes of the wage index. Below is a detailed discussion of the new methodology for reporting pension costs for Medicare cost-finding purposes. A full discussion of our policy for reporting pension costs under the wage index is discussed in section III.D.2. of this preamble, along with a summary of the public comments we received, our responses, and statements of our final policy.

We note that we stated in the proposed rule that we ''would require all hospitals to report the actual pension contributions funded during the reporting period, on a cash basis.'' Our intent was for ''reporting period'' to refer to the hospital's Medicare ''cost reporting period'' rather than another defined reporting period since for cost-finding purposes pension costs are reported on a Medicare cost report basis. Similarly, below in the following discussions, the term ''reporting period'' refers to a Medicare cost reporting period.

The final policy below reflects our commitment to the general principles of the President's Executive Order released January 18, 2011, entitled ''Improving Regulation and Regulatory Review.''

2. Allowable Defined Benefit Pension Plan Cost for Medicare Cost-Finding Purposes

As mentioned above, the defined benefit pension plan costs (hereafter referred to as ''pension costs'') reported for Medicare payment purposes should reflect the actual costs incurred by an individual provider. In the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to retain the policy in the current manual requiring pension costs to be funded in order to be reportable. We believe funding is an appropriate basis because it measures the actual expenditure towards the current period liability for pensions. We also proposed to continue to limit the current period liability for pension costs (that is, maximum annual allowable pension costs). However, we proposed to change the methodology for calculating the limit on the current period liability. We proposed that this methodology would be effective for cost reporting periods beginning on or after October 1, 2011.

Specifically, we proposed a limit on the current period liability equal to 150 percent of the average contributions made during the three consecutive reporting periods out of the five most recent reporting periods which produce the highest average. We believe a threshold of 150 percent is appropriate for the following reasons: First, the proposed threshold should be adequate to allow for typical fluctuations in contributions and for inflation. Second, we believe a threshold is necessary to limit the current period liability in order to ensure that reported pension costs are reasonable and do not reflect excessive or advance funding in any particular year. In addition, the proposed limit would help ensure that pension costs in the current year are reasonable because we expect the limit to capture pension costs which relate exclusively to patient care services furnished in the current cost reporting period.

The proposed 150-percent limit was established based on an analysis of historical contribution data submitted by pension plans subject to ERISA and published by the U.S. Department of Labor (DOL). Based on our analysis of the DOL contribution data, we expect that pension costs in excess of the limit will only occur in a small number of cases. We believe the use of readily available historical contribution data to establish the limitation will avoid the complexity of a limitation based on technical actuarial measurements. A limit based on average contributions made during the three consecutive reporting periods out of the five most recent reporting periods which produce the highest average will help to ensure that periods when no contributions (or only minimal contributions) are made will not dramatically reduce the limit in subsequent periods.

We believe use of a 5-year look-back period will minimize the administrative burden on providers that would be associated with a longer period. We also believe using the three consecutive reporting periods which produce the highest average contributions will better reflect a typical average pension cost while use of contributions for any three periods, even nonconsecutive periods, could introduce atypical results. Specifically, using the three highest nonconsecutive years of contributions in the 5-year look-back period may overstate the average contribution. However, because excessive contributions tend to reduce future funding requirements, we believe it would be unusual for excessive contributions to occur in three consecutive periods.

While we proposed a limit, we recognized there may be situations when pension costs in excess of the 150-percent limit might be reasonable, such as a funding requirement imposed by a third party, that is, ERISA's minimum funding requirement, statute or collective bargaining agreement. Therefore, we proposed to allow hospitals with contributions in excess of the proposed limit to submit documentation demonstrating that all or a portion of the ''excess'' costs are reasonable and necessary for a particular cost reporting period. In addition, we believe that providers' pension costs in excess of the 150-percent limit that are not considered reasonable for the current cost reporting period are likely to be prefunded pension costs attributable to the patient care services for a future cost reporting period. Therefore, similar to the current instruction in section 2142.6(C) of the PRM–I, we proposed to continue to use a carry forward policy. Specifically, we proposed that current period contributions in excess of the 150-percent limit that are not considered reasonable for the current cost reporting period under the proposed review process be carried forward and reported in future period(s) as the applicable limit for the future period(s) will allow. In the proposed rule we inadvertently stated that ''Medicare contractors'' would be required to maintain historical data in order to determine the 150-percent limit and track any carry forward amounts. However, we intended to write that ''providers'' would be required to maintain historical data in order to determine the 150-percent limit and track any carry forward amounts. We also indicated that we anticipate making a worksheet available for this purpose.

We solicited public comments as to documentation or criteria that would be appropriate to make a determination as to whether excess costs are reasonable and necessary. We also invited public comments on the proposal and indicated special interest in receiving public comments related to our proposal to limit the reportable pension amount.

Comment: A number of commenters suggested CMS convene a Medicare Technical Advisory Group (MTAG) before establishing a policy on pension costs.

Response: An MTAG is not required by statute. Engaging in notice and comment rulemaking provides sufficient process for developing a policy on this issue. In addition, the actuarial terminology used in section 2142 of PRM–I is no longer used under ERISA as amended by the PPA. Accordingly, we believe it is important to address the pension cost issue as expeditiously as possible.

Comment: Many commenters supporting an MTAG also stated that an MTAG might recommend adoption of Generally Accepted Accounting Principles (GAAP) (with no funding limit) for the wage index, leading CMS to also adopt GAAP as the basis for cost-finding purposes, provided those costs are funded either during the cost reporting period or within 12 months after the end of the cost reporting period. Commenters also suggested that CMS consider any needed modifiers (to GAAP) for either underfunded or overfunded plans. One commenter noted that a proposal to base pension expense for both the wage index and for cost-finding purposes on a 3-year average of actual funding is inconsistent with the other principles of the cost report relying on GAAP and accrual versus cash-basis accounting. The commenters stated that pension funding should be treated the same as the liquidation of liabilities, to be paid within 1 year after the end of the cost reporting period, or with approval of an exception, within 3 years.

Response: Pension costs determined in accordance with GAAP (as promulgated by the Financial Accounting Standards Board) are somewhat unique compared to other types of costs under GAAP because pension costs under GAAP are not dependent on the amount funded. Therefore, in order to ensure that this policy is consistent with CMS policy that costs must be funded in order to be reportable, it was necessary to diverge from GAAP principles in this instance. Furthermore, since GAAP with a funding requirement for Medicare cost-finding purposes would require the GAAP pension expense to be modified to account for any prepaid costs (overfunding) or accrued costs (underfunding), we believe this would create unnecessary complexity.

Under the new policy, pension costs are based on the amount funded during the cost reporting period plus any carry forward amounts, subject to the 150-percent limitation. A provision to allow recognition of funding which occurs within 1 year after the end of the reporting period (or 3 years with approval) could result in confusion as to which period funding should be attributed. The period during which funding will be measured (and upon which costs determined) must be clearly and consistently defined.

We do not believe that pension costs determined under the new policy will be materially different from those that

would result under GAAP with a funding requirement because in either case, pension costs would be limited to the amount funded (including any carry forward contributions). Furthermore, we believe our policy offers more flexibility for providers to establish and follow a funding strategy that meets their organizational objectives.

Comment: A number of commenters supported the proposed limit on the current period liability equal to 150-percent of the average contributions made during the three consecutive cost reporting periods out of the five most recent cost reporting periods that produce the highest average. They particularly appreciated the additional provision allowing a hospital with pension contributions in excess of the proposed limit to submit documentation demonstrating that all or a portion of the ''excess'' costs are reasonable and necessary for a specific cost reporting period.

Response: We appreciate the commmenters' support of our proposal. We recognize there may be situations when pension costs in excess of the 150-percent limit are reasonable and necessary and should be reportable as a current period cost. Therefore, as proposed, this final policy will allow a provider to submit documentation to show that ''excess'' contributions are reasonable and necessary and should be recognized as current period costs.

Comment: One commenter asked CMS to clarify how the limit would be determined if there was a plan or corporate merger, if a provider adopted a new plan or increased benefits under an existing plan, or became a new Medicare provider. The commenter expressed concern that, although the limit would be easy to administer, it would ignore real costs in these situations.

Response: In a merger situation (either a plan merger or corporate merger), the contribution history should include all contributions made by a provider to a defined benefit plan (either a predecessor plan or the current plan) during the 5-year look-back period. Under a systemwide (multiple-employer) pension plan, the contribution history for each participating provider should reflect only the plan contributions attributed to that provider. For a provider who is new to the Medicare program, the contribution history used to determine the limit should include all pension contributions made during the 5-year look-back period (which is used to develop the 3 year average), including periods, before the provider was part of the Medicare program. In the case of a newly adopted plan, the 5-year look-back period and/or the 3-year averaging period will be limited to the number of cost reporting periods the provider sponsored a defined benefit pension plan. In the case of a benefit improvement, we believe the 150-percent limit (which includes a 50-percent margin for cost increases) will be adequate since the cost of benefit improvements is typically spread over a period of years. In any of these situations, a provider may submit documentation to show that contributions in excess of the 150 percent limit are reasonable and necessary and should be allowable as a current period cost.

Comment: One commenter asked for clarification as to which cost reporting periods will be used to determine the limit on allowable pension costs. Specifically, the commenter asked if CMS will base the limit on the hospital's five most recent settled cost reports or as-filed cost reports. Another commenter asked what timeframe constitutes ''recent'' cost reporting periods.

Response: The historical contribution data required to compute the limit are not currently reflected on the cost reports. Therefore, settled or as-filed cost reports are not used for the calculation. (We are exploring ways to modify the cost report to show the actual contributions made in each cost reporting period as well as the pension cost for the current period after application of the 150-percent limit.) Instead, the 150-percent limit will be based on the actual pension plan contributions made by a provider as shown on statements provided by the pension plan trustee or insurance carrier, or as reflected on Schedule B or SB of IRS Form 5500. In the case of a systemwide (multiple employer) pension plan, the home office will need to identify the contributions attributed to each participating provider. The limit will be based on the average contributions for the three highest consecutive cost reporting periods out of the five most recent cost reporting periods ending with the current cost reporting period.

Comment: One commenter asked whether the hospital would be required to submit documentation regarding its pension contributions in excess of the limit to the Medicare contractor or to CMS. The commenter also inquired as to how the reasonableness and necessity of the excess contribution will be determined and how the determination of reasonableness will be reported to the provider.

Response: We have not yet finalized the specific procedure to be used when requesting approval of excess contributions. Further details will be provided as soon as possible, after publication of this final rule. Each request will be reviewed on a facts and circumstances basis. We are not setting forth specific criteria for determining whether a pension cost is reasonable and necessary for the current reporting period because that may prevent us from responding to circumstances that we may not have anticipated and recognizing costs that are reasonable for the current period. However, examples of when approval will be likely be granted include excess contributions required to satisfy a funding requirement imposed by law or under a collective bargaining agreement, or to avoid ERISA funding restrictions.

Comment: There were a number of technical questions and requests for clarification on specific aspects of the proposed policy. One commenter requested that CMS clarify whether allowable pension costs for cost-finding will be based on cash contributions, subject to the 150 percent limit, regardless of whether the pension plan shows a current period liability under ERISA or another method. Another commenter observed ''the funding limit is based on 150 percent of three consecutive cost reporting periods out of recent reporting with the highest average and noted that this is similar in nature to the GME/IME three year rolling average in its complexities.'' This commenter asked if the data would be actual contributions from prior years, or would it be the contributions that were limited by a previous 150-percent limit.

Response: Under the revised policy, pension contributions up to the 150-percent limit will not be subject to actuarial requirements under ERISA, GAAP or otherwise. However, a provider with costs in excess of the limit will have the option to submit actuarial data to demonstrate that those costs are reasonable and necessary for the current cost reporting period and should therefore be included as current period pension costs.

The historical contributions used to determine the 150-percent limit would be the actual cash contributions made by the provider to the pension plan, without regard to the 150-percent limit applicable to any prior period.

The following example is provided to show the calculation of the FY 2012 pension cost for a provider with a September 30 fiscal year (FY) cost reporting end date:

• Contributions made in the five most recent cost reporting periods:

- October 1, 2011—September 30, 2012: $2,000,000
- October 1, 2010—September 30, 2011: 5,000,000
- October 1, 2009—September 30, 2010: 4,000,000
- October 1, 2008—September 30, 2009: 5,000,000
- October 1, 2007–September 30, 2008: 6,000,000
- October 1, 2011 Carry Forward Balance: $1,000,000

The 150-percent limit for FY 2012 will be based on contributions for FYs 2008 through 2010 because these represent the highest three consecutive years of contributions out of the 5 most recent years. The average contribution for those 3 highest consecutive years is ($4,000,000 + $5,000,000 + $6,000,000)/3 = $5,000,000. The limit equals $7,500,000 (150 percent of $5,000,000).

The provider's cash funding in the current cost reporting period (FY 2012) is $2,000,000 (none of which was reported as a pension cost in a prior period). The provider has also documented a carry forward balance of $1,000,000, which represents the cash basis contributions made prior to the effective date of the new policy which were not recognized as costs in a prior cost reporting period. For FY 2012, the provider may claim the full $3,000,000 ($2,000,000 in current period contributions plus $1,000,000 in carry forward contributions) because the amount does not exceed the $7,500,000 limit. If the provider's carry forward balance had been $8,000,000, only $7,500,000 would be reportable as a current period cost due to the 150 percent limit. In that case, the remaining $2,500,000 ($2,000,000 current period contributions + $8,000,000 carry forward balance − $7,500,000 current period 150 percent limit) should be reflected as a carry forward balance for the following year.

Comment: One commenter asked if current period pension expense would be calculated similar to previous years and would still be subject to the liquidation of liability requirements (that is, funded within 1 year of accrual). The same commenter speculated that there may be confusion on how to determine the allowable pension expense, given the various terms used between GAAP, PRM, IRS, and ERISA. The commenter asked for examples of how to compute allowable pension expense and to provide a crosswalk or revise the terms from the CMS manuals to GAAP and/or IRS terminology.

Response: Generally, Pension costs for cost-finding purposes will no longer be based on actuarially determined measurements. We are aware that there may be confusion due to differences in actuarial terminology and cost methodology applicable for various purposes. This is a key reason why we are no longer requiring actuarial cost measurements to determine pension costs. Accordingly, no crosswalk is needed to reconcile differences in terminology. Furthermore, under the new policy, pension costs will be determined on a cash basis rather than an accrual basis. Funding which occurs after the end of a cost reporting period will be considered as a pension funding for the subsequent cost reporting period, subject to the 150-percent limit in that year. Under the new policy, the liquidation of liability provision will no longer apply. However, the liquidation of liability provision would still be in effect for the cost reporting period immediately prior to the effective date of this new policy. An example of the calculation of the allowable pension cost under the new policy was included in our response to a previous comment.

Comment: One commenter recommended that there should be specific statements in the cost report that pension costs for cost-finding will be treated differently from pension costs for the wage index. The commenter also suggested separate PRM cost reporting instructions for the Medicare cost report versus the Medicare wage index, given that there will be separate methodologies for determining pension costs.

Response: We are implementing different pension cost policies for wage index and cost-finding purposes. Accordingly, the PRM will be revised to include separate and distinct pension cost provisions for wage index and cost finding purposes.

We would like to thank the provider community for their public comments regarding our proposed policy for reporting pension costs for Medicare cost-finding purposes. After considering their concerns and suggestions, we are finalizing our proposal for reporting pension costs for Medicare cost-finding purposes for the reasons set forth in the proposed rule (76 FR 25951 through 25953) and as explained in this final rule. This new policy is effective for cost reporting periods beginning on and after October 1, 2011.

Under this final policy, a provider's pension cost for cost-finding purposes will equal the cash basis contribution deposits (made within the current cost reporting period and not reflected as a pension cost for a prior cost reporting period) plus any carry forward contributions, subject to a limitation. The limitation is equal to 150 percent of the average pension contributions made by the provider during the highest 3 consecutive cost reporting periods out of the 5 most recent cost reporting periods (ending with the current cost reporting period). In the case of a newly adopted plan, the 5-year look-back period and/or the 3-year averaging period will be limited to the number of cost reporting periods the provider sponsored a qualified defined benefit pension plan.

This final policy allows a provider with current period contributions and carry forward contributions in excess of the 150-percent limit to submit documentation to show that all or a portion of the excess contributions are reasonable and necessary and should therefore be reportable as current period pension costs. Pension contributions in excess of the reportable amount can be carried forward and reported in a subsequent cost reporting period, subject to the 150-percent limitation. As of the effective date of this new policy, providers should establish a carry forward balance to account for any contributions made prior to the effective date of the new policy (on a cash basis) that were not reflected as pension costs in a prior period. The carry forward balance must then be updated annually to reflect any increases (current period contributions in excess of the reportable amount) or decreases (carry forward balances which are recognized as a current period pension cost). The provider must ensure that there is no duplication of recognized contributions in accounting for carry forward contributions. In addition, providers must document, and maintain for audit, the data used to establish the carry forward balance and any subsequent updates.

Under this revised policy, contributions are to be determined on a cash basis. Section 2305 of the PRM–I (liquidation of liabilities provision) will be amended, effective for cost reporting periods subject to this new policy, to exclude qualified defined benefit pension plan costs. The liquidation of liabilities provision will continue to apply to contributions made to liquidate pension costs for cost reporting periods prior to the effective date of this revised policy. We plan to make future amendments to conform existing regulations and PRM–I provisions with this final policy.

N. Rural Community Hospital Demonstration Program

1. Background

Section 410A(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), 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 program pays rural community hospitals for such services under a cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1) of MMA, 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, in conjunction with paragraphs (2) and (3) of section 410A(a), provided 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 program: 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.)

We originally solicited applicants for the demonstration program in May 2004; 13 hospitals began participation with cost reporting years beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the program and became CAHs. In a notice published in the **Federal Register** on February 6, 2008 (73 FR 6971), we announced a solicitation for up to 6 additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These four additional hospitals began under the demonstration program payment methodology with the hospital's first cost reporting period starting on or after July 1, 2008. At that time, there were 13 hospitals participating in the demonstration program.

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 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.) So far in CY 2011 one hospital has withdrawn from the demonstration, saying that a large number of managed care patients has made the demonstration methodology unfavorable. These actions left 7 of the pre-expansion 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.

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 seven 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 FY 2005, FY 2006, FY 2007, FY 2008, FY 2009, FY 2010, FY 2011 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, and 75 FR 50343 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, we are finalizing a methodology to calculate a budget neutrality adjustment factor to the FY 2012 national IPPS rates.

2. Changes to the Demonstration Program Made by the Affordable Care Act

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 under section 410A(a)(5) of Public Law 108–173, as amended (section 410A(g)(1) of Pub. L. 108–173, as added by section 3123(a) of the Affordable Care Act and further amended by section 10313 of that Act). Further, the

Affordable Care Act requires that, 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 shall 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 Pub. L. 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 Pub. L. 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 Pub. L. 108–173, as added by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of such Act). Additionally, we note that we indicated in the FY 2011 IPPS final rule (75 FR 50343) that section 410A(g)(4)(b) of Public Law 108–173 as added by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of that Act provides that the amount of payment under the demonstration program for covered inpatient hospital services furnished in a rural community hospital [other than services furnished in a psychiatric or rehabilitation unit of the hospital that is a distinct part] is the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period. We want to clarify that we believe that section 410A(g)(4)(B) 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, provides this with respect to a rural community hospital that is participating in the demonstration program under section 410A as of the last day of the initial 5-year period. Specifically, the Affordable Care Act requires that in the case of a rural community hospital that is participating in the demonstration as of the last day of the initial 5-year period, the Secretary in calculating payments under subsection (b) shall substitute under paragraph (1)(A) the phrase ''the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period'' for the phrase ''the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration.'' The phrase ''the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration'' does not precisely track the language in section 410A(b)(1)(A) of Public Law 108–173. Therefore, we cannot delete and replace it as described in the Affordable Care Act. However, we believe the language of section 410A(g)(4)(B)(i) of Public Law 108–173, as amended, is clear. Namely, a rural community hospital that is participating in the demonstration as of the last day of the initial 5-year period shall be paid for its covered inpatient hospital services ''the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period.'' (This methodology does not apply to services furnished in a psychiatric or rehabilitation unit of the hospital which is a distinct part.) For discharges occurring in a subsequent cost reporting period during the demonstration, the formula in section 410A(b)(1)(B) of Public Law 108–173, as amended, would apply to such hospitals. That is, the payment will be the lesser of reasonable cost or the target amount. We calculate the target amount in the second cost reporting period by taking the reasonable costs of providing covered inpatient hospital services in the first cost reporting period beginning on or after the first day of the 5-year extension and increasing it by the IPPS market basket percentage increase (as defined in section 1886(b)(3)(B)(iii) of the Act) for that particular cost reporting period. We calculate the target amount in subsequent cost reporting periods by taking the preceding cost reporting period's target amount and increasing it by the IPPS market basket percentage increase (as defined in section 1886(b)(3)(B)(iii) of the Act) for that particular cost reporting period. (We note that, in calculating target amounts, we utilize the IPPS market basket percentage increase as defined in section 1886(b)(3)(B)(iii) of the Act, as opposed to the applicable percentage increase as defined in section 1886(b)(3)(B)(i) of the Act. We note that section 410A(b)(2)(B) of Public Law 108–173, in pertinent part, provides that target amounts are ''increased by the applicable percentage increase (under clause (i) of section 1886(b)(3)(B) of the Social Security Act * * *) in the market basket percentage increase (as defined in clause (iii) of such section) for that particular cost reporting period.'' The phrase ''applicable percentage increase (under clause (i) of section 1886(b)(3)(B) of the Social Security Act * * *) in the market basket percentage increase * * *'' is ambiguous, as there is no applicable percentage increase in the market basket percentage increase. Because the focus of the provision is the amount of the IPPS market basket percentage increase, we believe the provision is addressing the IPPS market basket percentage increase, and not the applicable percentage increase, which includes other adjustments to the market basket percentage increase. Further, because section 410A(b)(2)(B) of Public Law 108–173 is addressing target amounts under the demonstration, we believed it was logical to read the statute as providing for an update structure mimicking the update structure for target amounts of reasonable cost-based providers like children's and cancer hospitals, as well as RNCHIs. This rationale applies any time we use the IPPS market basket percentage increase to update target amounts in the demonstration. With respect to hospitals that are newly joining the demonstration, they are paid the reasonable costs of providing covered inpatient hospital services, other than services furnished in a psychiatric or rehabilitation unit of the hospital which is a distinct part, for discharges occurring in the hospital's first cost reporting period beginning on or after the implementation of the demonstration program (section 410A(b)(1)(A) of Public Law 108–173). We have determined that each of these new hospitals will begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011. We chose this date because it follows immediately upon the notification of the hospitals of their acceptance to the demonstration and it will allow the hospitals to begin participation in the demonstration as soon as possible. With respect to rural community hospitals newly joining the demonstration, for discharges occurring

in a subsequent cost reporting period under the demonstration program, the formula in section 410A(b)(1)(B) of Public Law 108–173, as amended, would apply. That is, payments will be the lesser amount of reasonable costs or the target amount. We calculate the target amount in the second cost reporting period by taking the reasonable costs of providing covered inpatient hospital services in the first cost reporting period and increasing it by the IPPS market basket percentage increase for that particular cost reporting period. We calculate the target amount in subsequent cost reporting periods by taking the preceding cost reporting period's target amount and increasing it by the IPPS market basket percentage increase for that particular cost reporting period. In addition, various other technical and conforming changes were made to section 410A of Public Law 108–173 by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of that 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, which 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 reported in the proposed rule that we were waiting for these hospitals to respond as to whether they accept the terms and conditions stipulated for their participation in the demonstration; and, therefore, we based cost estimates for the demonstration for this new set of hospitals based on the assumption that all 19 hospitals would elect to participate. We proposed that if fewer were actually to make this election, we would accordingly adjust the demonstration cost estimates in this final rule. At the end of the response period, 18 of the 19 selected hospitals accepted the terms of conditions of the demonstration and agreed to participate; one hospital declined participation. Therefore, we are basing the cost estimates for this final rule on the assumption that 18 of these newly participating hospitals will participate in the demonstration during FY 2012.

3. FY 2012 Budget Neutrality Adjustment

In order to ensure that the demonstration is budget neutral as is required by the statute, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25955 through 25960), we proposed to adjust the national IPPS rates to account for any added costs attributable to the demonstration program. Specifically, we proposed that the budget neutrality adjustment would account for: (1) The estimated costs of the demonstration program in FY 2012 for the 8 currently participating hospitals (''pre-expansion participating hospitals''); (2) the estimated costs of the demonstration in FY 2012 for the 19 hospitals newly selected to begin participation in the demonstration program; and (3) the amount by which the costs of the demonstration program, as indicated by settled cost reports for cost reporting periods beginning in FYs 2007 and 2008 for hospitals participating in the demonstration program during FYs 2007 and 2008, exceeded the amount that was identified in the FY 2007 and FY 2008 IPPS final rules as the budget neutrality offsets for FYs 2007 and 2008.

We are finalizing our proposed methodology except where specified below. We note that we proposed that if updated data became available for the final rule, we would use them to estimate the costs of the demonstration program in FY 2012. For this final rule, we have updated data which resulted in various components of the methodology being updated. We explain in more detail below in sections IV.N.3. a. and b. the specific changes.

a. Component of the FY 2012 Budget Neutrality Adjustment That Accounts for Estimated FY 2012 Demonstration Program Costs of the ''Pre-Expansion Participating Hospitals''

In the proposed rule, we noted that eight hospitals that were selected for participation in either 2004 or 2008 are currently continuing to participate in the extension period mandated by the Affordable Care Act. (We refer to these hospitals as ''pre-expansion participating hospitals'' in this preamble discussion of the rural community hospital demonstration program.) (In the proposed rule, we said that hospitals were selected in 2005; this was a mistake. Hospitals were selected for the demonstration only in 2004 and in 2008.) In the proposed rule, the component of the FY 2012 budget neutrality adjustment to the national IPPS rates that accounts for the estimated demonstration program costs in FY 2012 for the eight ''pre-expansion participating hospitals'' was calculated by utilizing three separate methodologies: one methodology for the six hospitals that had participated in the demonstration program since its inception and that we indicated were continuing to participate in the demonstration program (''originally participating hospitals''); a second methodology for one hospital that is currently participating in the demonstration program and that was among the four hospitals that joined the demonstration program in 2008; and a third methodology for the other hospital that is currently participating in the demonstration program that was among the four hospitals that joined the demonstration program in 2008. Different methods were used for these three sets of hospitals because the data available to us to estimate the demonstration program costs for each was different. We are finalizing the above methodology, except as explained previously, certain aspects of the methodology have been updated in this final rule based on updated data. We also note that the number of hospitals that were selected for participation in either 2004 or 2008 and that are currently continuing to participate in the extension period decreased by one for this final rule since one of the ''originally participating'' hospitals left the demonstration. In order to account for this decrease, we adjusted the methodology described above and explained in detail below by reducing the number of pre-expansion participating hospitals used in the calculation from eight to seven and reducing the number of originally participating hospitals used in the calculation from six to five. We have updated cost report data available for this final rule, consistent with our proposal to use updated data in the final rule to the extent they are available. Specifically, in the following description, we are identifying for one of the pre-expansion participating hospitals that there is a more recently finalized cost report available (as compared to the ''as submitted cost report'' used in the proposed rule). We are updating various components of the payment methodology to reflect the newly available finalized cost report for this hospital. In the following description, we are identifying which cost reports are the same as those identified in the proposed rule, and we also identify the one that has changed.

(1) Consistent with the proposed rule, and for this final rule, for the five (six in the proposed rule) ''originally participating hospitals,'' that is,

hospitals that have participated in the project since its inception and that are continuing to participate, the estimate of the portion of the budget neutrality adjustment that accounts for the estimated FY 2012 demonstration program costs is based on data from their settled cost reports applicable to the second year of the demonstration—that is, for cost reporting periods ending in FY 2007. We are using these cost reports because they are the most recent finalized cost reports and, thus, we believe their accounting of costs is the most accurate indicator available to us at this time to estimate FY 2012 demonstration costs.

(2) For one of the two hospitals that joined the demonstration program in 2008, and that is still participating, we proposed to estimate the FY 2012 demonstration program costs under section 410A of Public Law 108–173 as amended based on data from its as submitted cost report beginning January 1, 2008. For this final rule, because we have received a finalized cost report for the cost report period beginning January 1, 2009, we are using updated cost report data for this hospital.

(3) The remaining hospital of the seven (eight in the proposed rule) ''pre-expansion participating hospitals'' which began participation in FY 2008 is an Indian Health Service provider. Historically, the hospital has not filed standard Medicare cost reports. Under the proposed rule, and for this final rule, we used its full ''as submitted'' cost report filed for the period beginning October 1, 2008 to estimate its FY 2012 costs. We used this ''as submitted'' cost report because as the most recent cost report we believe it allows us to estimate FY 2012 costs accurately.

As we proposed, for this final rule, we are using the same general methodology used for the FY 2011 IPPS/LTCH PPS final rule, but providing more detail. The methodology for calculating the estimated FY 2012 demonstration cost for the seven (eight in the proposed rule) ''pre-expansion participating hospitals'' is as follows:

Step 1: As proposed, in this final rule, in order to calculate demonstration costs for each of the five (six in the proposed rule) ''originally participating hospitals'' for the cost reporting period ending in FY 2007, we subtracted the amount it would have otherwise been paid under the applicable payment system(s) for covered inpatient hospital services without the demonstration during such period (as indicated on the settled cost report for this period) from the amount paid to it for such services under the reasonable cost methodology in section 410A(b) of Public Law 108–173 (as indicated on the settled cost report for this period). Steps 1(a) through (c) below are performed to calculate FY 2007 demonstration costs for these five hospitals. (As proposed, for this final rule, we are using final settled cost reports ending in FY 2007 to represent FY 2007 demonstration costs for each of these hospitals because a substantial portion of the months included within these cost report years (respective to each hospital) fall within FY 2007, and, therefore we believe that for purposes of this analysis it is appropriate to consider data from these cost reports to represent FY 2007 inpatient costs for the demonstration during that period.) In addition, we note that throughout the remainder of the preamble discussion on the budget neutrality adjustment for the rural community hospital demonstration we refer to ''covered inpatient hospital services'' as that term is defined in section 410A(f)(2) of Public Law 108–173 as amended as ''inpatient hospital services.'' We also note that the phrase ''the reasonable cost methodology'' means the reasonable cost methodology in section 410A(b) of Public Law 108–173 or the reasonable cost methodology in section 410A(b) of Public Law 108–173, as amended, as applicable in the particular situation.

- Step 1(a): As proposed, for this final rule, first, for each hospital, we subtracted the amount that would otherwise be paid under the IPPS for the hospital's inpatient hospital services (excluding those associated with swing beds) for the cost reporting period ending in FY 2007 (as indicated on the settled cost report for this period) from the amount paid for such services under the reasonable cost methodology (as indicated on the settled cost report for this period). The result of this difference is each hospital's demonstration costs for its inpatient hospital services (excluding those associated with swing beds) for the cost reporting period ending in FY 2007. (We used the amount the hospital would otherwise be paid under the IPPS as indicated above because this is the payment methodology under which the hospital's beds (excluding swing beds) would be paid in the absence of the demonstration. This rationale applies throughout the preamble discussion on the rural community hospital demonstration budget neutrality adjustment whenever this is a component of the methodology.)
- Step 1(b): As proposed, for this final rule, next, with respect to the hospitals that have swing beds, we subtracted the amount the hospital would otherwise be paid under section 1888(e)(7) of the Act for the inpatient hospital services associated with the swing beds for the cost reporting period ending in FY 2007 (as indicated in the settled cost report for this period) from the amount paid for such services under the reasonable cost methodology (as indicated in the settled cost report for such period). The result of this difference is each hospital's demonstration costs associated with its swing beds for the cost reporting period ending in FY 2007. (We used the amount the hospital would otherwise be paid under section 1888(e)(7) of the Act as indicated above because this is the payment methodology under which the hospital's swing beds would be paid in the absence of the demonstration. This rationale applies throughout the preamble discussion on the rural community hospital demonstration budget neutrality adjustment whenever this is a component of the proposed methodology.)
- Step 1(c): Next, under the proposed rule, in order to calculate total estimated FY 2010 demonstration costs for all six (five in this final rule) hospitals, we added together the differences calculated above in Step 1(a) and Step 1(b) as applicable for each of the six hospitals and then multiplied this sum by the IPPS market basket percentage increases for FYs 2008 through 2010, which were adopted in the respective IPPS final rules and a 2-percent annual volume adjustment for the years 2008 through 2010.

We note that, for this final rule, for purposes of Step 1(c), in order to calculate total estimated FY 2010 demonstration costs for all five hospitals, we added together the differences calculated above in Step 1(a) and Step 1(b) as applicable for each of the five hospitals and then multiplied this sum by the IPPS market basket percentage increases for FYs 2008 through 2010, which were adopted in the respective IPPS final rules and a 3-percent annual volume adjustment for the years 2008 through 2010. For this final rule, we are using a 3-percent volume adjustment. In the proposed rule, we proposed to include a volume adjustment in the methodology for calculating demonstration costs recognizing that the volume of services provided in small rural hospitals tend to fluctuate. In this final rule, we have revised the volume adjustment from the 2-percent amount stated in the proposed rule, which was based on an assessment at the inception of the demonstration as to the growth in volume of services, to 3 percent based on updated data. Three percent per year is the current estimate nationwide as to the rate of increase in

the number of Medicare fee-for-service discharges.

As we proposed, for this final rule, we are applying the applicable IPPS market basket percentage increases described above to model estimated FY 2010 demonstration costs because we believe that this update factor appropriately indicates the trend of increase in hospital operating costs. Further, this approach is consistent with the agency's use of the IPPS market basket percentage increase to update the rate-of-increase limits (which is a reasonable cost-based methodology) for children's and cancer hospitals as well as RNCHIs. Therefore, we believe it enables us to estimate appropriately demonstration costs that are tied to a reasonable cost-based methodology. Also, this approach is consistent with how we update target amounts under the demonstration under section 410A(b)(2)(B) of Public Law 108–173. We note that the rationale provided herein for utilizing an IPPS market basket percentage increase and a 3-percent annual volume adjustment to estimate demonstration costs is applicable throughout the preamble discussion on the rural community hospital budget neutrality adjustment whenever these factors are used to model the trend of increase and volume increases in the budget neutrality adjustment methodology finalized in this final rule.

As a side note, as a special feature of the demonstration, we added a supplemental worksheet to the standard hospital cost report which is completed by the fiscal intermediary in the final settlement for these five ''originally participating hospitals.'' This supplemental worksheet includes the calculation of the hospital's first year reasonable costs of inpatient hospital services (excluding those associated with swing beds) as set forth in section 410A of Public Law 108–173, and, in addition, for the hospital's second year cost reports (those cost reports ending in FY 2007), the target amount (that is, the previous year's Medicare reasonable cost amount for inpatient hospital services updated by the IPPS market basket percentage increase as provided in section 410A(b)(2)(B) of Pub. L. 108–173). (This supplemental worksheet also includes a calculation of the amount that would otherwise be paid for the hospital's inpatient hospital services under the IPPS, as is ordinarily presented on the standard hospital cost report. For hospitals that have swing beds, this supplemental worksheet also includes the following: the estimated amount the hospital would otherwise be paid under section 1888(e)(7) of the Act for the inpatient hospital services associated with the hospital's swing beds; the estimated amount the hospital would be paid under the reasonable cost methodology for the inpatient hospital services provided in its swing beds, and the hospital's target amount for its swing beds.

Step 2: In the proposed rule, in order to calculate estimated FY 2008 demonstration costs for the non-Indian Health Service hospital that began the demonstration program in 2008, we subtracted the estimated amount it would have otherwise been paid for inpatient hospital services without the demonstration under the applicable payment system(s) (as indicated on its ''as submitted'' cost report beginning January 1, 2008) from the estimated costs of such services under the reasonable cost methodology (as indicated on the ''as submitted'' cost report for this period). We proposed that Steps 2(a) through (c) below would be performed to calculate this amount.

Step 2(a): Specifically, we subtracted the estimated amount that would otherwise be paid under the IPPS for the hospital's inpatient hospital services (excluding swing beds) for the cost reporting period beginning January 1, 2008 (as indicated on the ''as submitted'' cost report) from the estimated amount to be paid for such services under the reasonable cost methodology (as indicated on the ''as submitted'' cost report for such period).

- Step 2(b): Next, we subtracted the estimated amount that would otherwise be paid under section 1888(e)(7) of the Act for the inpatient hospital services associated with the swing beds during the cost reporting period beginning January 1, 2008 (as indicated on the ''as submitted'' cost report) from the estimated amount to be paid for such services under the reasonable cost methodology as indicated on the ''as submitted'' cost report for such period.
- Step 2(c): We added together the differences calculated in Steps 2(a) and (b) above to obtain the hospital's total estimated FY 2008 demonstration cost.
- Step 2(d): Then, in order to calculate the hospital's estimated FY 2010 demonstration costs, we took the amount calculated in Step 2(c) above and multiplied it by the IPPS market basket percentage increases for FYs 2009 and 2010 as adopted in the respective IPPS final rules and a 2-percent annual volume adjustment for FY 2010.

For this final rule, we have updated data available for this non-Indian service hospital, which began the demonstration in 2008; specifically, we have a finalized cost report for the cost reporting period beginning January 1, 2009. This cost report has calculations for the reasonable cost of inpatient services, determined in accordance with the principles of section 410A of Pub. L 108–173, as well as what the cost amounts would be for the hospital absent the demonstration. Therefore, in this final rule, with respect to Step 2, in order to calculate estimated FY 2009 demonstration costs for the non-Indian Health Service hospital that began the demonstration program in 2008, we subtracted the estimated amount it would have otherwise been paid for inpatient hospital services without the demonstration under the applicable payment system(s) (as indicated on the final settled cost report beginning January 1, 2009) from the estimated costs of such services under the reasonable cost methodology (as indicated on the final settled cost report for this period). Steps 2(a) through (c) below are performed to calculate this estimated amount for the final rule. We note that we are using the cost report beginning January 1, 2009 to represent FY 2009 demonstration costs for this hospital because it corresponds most precisely to FY 2009 and, therefore, we believe correctly represents FY 2009 inpatient costs for the demonstration for that period.

- Step 2(a): Specifically, we subtracted the estimated amount that would otherwise be paid under the IPPS for the hospital's inpatient hospital services (excluding swing beds) for the cost reporting period beginning January 1, 2009 (as indicated on the finalized settled cost report) from the estimated amount to be paid for such services under the reasonable cost methodology (as indicated on the finalized settled cost report for such period).
- Step 2(b): Next, we subtracted the estimated amount that would otherwise be paid under section 1888(e)(7) of the Act for the inpatient hospital services associated with the swing beds during the cost reporting period beginning January 1, 2009 (as indicated on the finalized settled cost report) from the estimated amount to be paid for such services under the reasonable cost methodology as indicated on the finalized settled cost report for such period.
- Step 2(c): We added together the differences calculated in Steps 2(a) and (b) above to obtain the hospital's total estimated FY 2009 demonstration cost.
- Step 2(d): Then, in order to calculate the hospital's estimated FY 2010 demonstration costs, we took the amount calculated in Step 2(c) above and multiplied it by the IPPS market basket percentage increase for FY 2010 as adopted in the respective IPPS final

rule and a 3-percent annual volume adjustment for FY 2010 since the volume adjustment has been updated in this final rule. Whereas we proposed updates for FYs 2009 and 2010 in the proposed rule, we are only using an update for the latter year in this final rule because we are using more recent cost and payment data, which are obtained from the cost report for cost report period beginning January 1, 2009.

Step 3: Under the proposed rule, and for this final rule, in order to calculate the estimated FY 2009 demonstration costs for the Indian Health Service provider, we subtracted the estimated amount the hospital would have otherwise been paid for inpatient hospital services without the demonstration under the applicable payment system (as indicated on the ''as submitted'' cost report beginning October 1, 2008) from the estimated costs for such services under the reasonable cost methodology (as indicated in the ''as submitted'' cost report for such period). As proposed, for this final rule, Step 3(a) below is performed to calculate this amount. (As proposed, for this final rule, we are using the cost report beginning October 1, 2008 to represent FY 2009 demonstration costs for this hospital because it corresponds most precisely to FY 2009 and, therefore, we believe correctly represents FY 2009 inpatient costs for the demonstration for that period.)

- Step 3(a): Specifically, we subtracted the estimated amount the hospital would have otherwise been paid for inpatient hospital services under the IPPS in the cost reporting period beginning October 1, 2008 without the demonstration (as indicated on the ''as submitted'' cost report for this period) from the estimated amount to be paid under the reasonable cost methodology for such services (as indicated in the ''as submitted'' cost report for such period). We note that this provider had no swing beds, therefore, we did not estimate any portion of the costs under section 1888(e)(7) of the Act.
- Step 3(b): Next, under the proposed rule, in order to calculate the Indian Health Service provider's estimated FY 2010 demonstration costs, we multiplied the difference calculated in Step 3(a) above by the IPPS market basket percentage increase for FY 2010 adopted in the FY 2010 IPPS/LTCH PPS final rule and the 2-percent annual volume adjustment.

For this final rule, for purposes of step 3(b), in order to calculate the Indian Health Service provider's estimated FY 2010 demonstration costs, we multiplied the difference calculated in Step 3(a) above by the IPPS market basket percentage increase for FY 2010 adopted in the FY 2010 IPPS/LTCH PPS final rule and a 3-percent annual volume adjustment.

Step 4: In the proposed rule, in order to calculate total estimated FY 2010 demonstration costs for all eight ''pre-expansion participating hospitals'', we then added the estimated FY 2010 demonstration costs calculated with proposed rule data in Steps 1(c), 2(d), and 3(b) above.

For purposes of this final rule, with respect to Step 4, in order to calculate total estimated FY 2010 demonstration costs for all seven ''pre-expansion participating hospitals'', we then added the estimated FY 2010 demonstration costs calculated with the final rule data in Steps 1(c), 2(d), and 3(b) above.

Step 5: Next, under the proposed rule, in order to calculate total estimated FY 2012 demonstration costs for all eight (seven in this final rule) ''pre-expansion hospitals,'' we multiplied the amount calculated with proposed rule data in Step 4 above by the FY 2011 IPPS market basket percentage increase adopted in the FY 2011 IPPS/LTCH PPS final rule and the proposed FY 2012 IPPS market basket percentage increase contained elsewhere in the FY 2012 IPPS/LTCH PPS proposed rule and a 2-percent annual volume adjustment for FYs 2011 and 2012.

Under this final rule, for purposes of Step 5, in order to calculate total estimated FY 2012 demonstration costs for all seven ''pre-expansion hospitals,'' we multiplied the amount calculated in Step 4 above with the final rule data by the FY 2011 IPPS market basket percentage increase adopted in the FY 2011 IPPS/LTCH PPS final rule and the FY 2012 IPPS market basket percentage increase contained elsewhere in the final rule and a 3-percent annual volume adjustment for FYs 2011 and 2012. We used the FY 2012 IPPS market basket percentage increase adopted in this final rule because it is the most current estimate available at the time of this rule. (The FY 2012 IPPS market basket percentage increase adopted in this final rule is used when the FY 2012 IPPS market basket percentage is used to model the trend of increase which is used in the final budget neutrality adjustment methodology for the reason set forth previously.) Thus, for this final rule, we arrived at the total estimated FY 2012 demonstration costs for all seven currently participating hospitals which must be offset, which is $20,255,315.

b. Portion of the FY 2012 Budget Neutrality Adjustment That Accounts for Estimated FY 2012 Demonstration Program Costs for Hospitals Newly Selected to Participate in the Demonstration Program

Section 410A(g)(3) of Public Law 108–173, as added by section 3123 of the Affordable Care Act and as further amended by section 10313 of such Act, provides that ''[n]otwithstanding subsection (a)(4), during the 5-year extension period, not more than 30 rural community hospitals may participate in the demonstration program under this section.'' In the proposed rule, we indicated that 19 hospitals were newly selected to join the demonstration and, therefore, our proposed budget neutrality adjustment was based on data for Medicare inpatient costs and payments from recently submitted cost reports for these 19 hospitals. As indicated in section IV.N.2. of this preamble, 18 hospitals accepted the terms of conditions of the demonstration and agreed to participate. Based on this updated data, for this final rule, we had to adjust our budget neutrality adjustment to account for the estimated costs associated with the 18 hospitals, as opposed to 19 hospitals, that have agreed to participate. As proposed, in order to ensure budget neutrality for the newly selected hospitals, we are including a component in the budget neutrality adjustment factor to the FY 2012 national IPPS rates to account for the estimated FY 2012 costs of those new hospitals. As we proposed, for this final rule, we are generally using ''as submitted'' cost reports to estimate demonstration costs because they are the most recent cost reports and, therefore, we believe most accurately reflect the hospital's cost and payment for Medicare inpatient services in the respective year. We note that hospitals were required to submit pages from their most recent cost reports with their applications. For 13 of these hospitals, these cost reports had end dates in FY 2009; for the 5 remaining hospitals, they had end dates in FY 2010. Therefore, in various steps in the methodology below, we begin various estimates with FY 2009 if the hospital submitted a cost report ending in FY 2009, and FY 2010 if the hospital submitted a cost report ending in FY 2010.

As we proposed, for this final rule, we are using the following methodology in order to estimate FY 2012 demonstration program costs for the 18 newly selected hospitals. This methodology differs from that in the FY 2011 IPPS/LTCH PPS final rule,

because, at that time, hospitals had not been selected for participation, and thus we had no data specific to those hospitals that would enter the demonstration as a result of its expansion mandated by the Affordable Care Act.

Step 1(a): For each hospital that submitted a cost report ending in FY 2009, we subtracted the estimated amount that would be paid for its inpatient hospital services (excluding those associated with swing beds) under the IPPS for such period (as indicated on the ''as submitted'' cost report for such period) from the estimated amount for reasonable costs for such services (as indicated on the ''as submitted'' cost report for such period) in order to calculate the difference between the hospital's estimated cost and payment for its inpatient hospital services (excluding those associated with swing beds) during the cost reporting period ending in FY 2009.

Step 1 (b): For each hospital that submitted a cost report ending in FY 2010, we subtracted the estimated amount that would be paid for its inpatient hospital services (excluding those associated with swing beds) under the IPPS (as indicated on the ''as submitted'' cost report for such period) from the estimated amount for the reasonable cost for such services (as indicated on the ''as submitted'' cost report for such period) in order to calculate the difference between the hospital's estimated costs and payment for its inpatient hospital services (excluding those associated with swing beds) during such period.

Step 1(c): While a portion of the 18 newly selected hospitals that have swing beds reported estimated costs for those beds, some hospitals did not, namely a portion of the hospitals that submitted cost reports ending in FY 2009. Therefore, we needed to gap-fill in order to account for this issue. For each of the hospitals with swing beds that submitted cost reports ending in FY 2009, but that did not submit with its application estimated costs associated with those swing beds, we assigned an estimated cost for its swing beds based on an average of the estimated cost-payment difference associated with the swing beds of the newly participating hospitals that reported such data on their applications. We are assigning estimated costs based on the average of the cost-payment difference for those hospitals that submitted these data, because these hospitals represent a sample of hospitals chosen for the demonstration, which we believe can accurately reflect costs and payment. We believe that these amounts, derived from the applications of the hospitals that submitted these data, accurately reflect this sample because they are hospitals of similar size and circumstances. Furthermore, these hospitals, which submitted the data, were chosen from the same set of States as the overall set of the newly selected hospitals. As proposed, for this final rule, we utilized the methodology in Steps 1(c)(i) through (c)(iii) below to calculate this amount, except we note that, as explained previously, the annual volume adjustment and FY 2012 IPPS market basket percentage increase have changed from the proposed to this final rule based on updated data:

- Step 1(c)(i): For each of the hospitals with swing beds that submitted with its application both a cost report ending in FY 2009 and estimated costs of those swing beds during such period, we calculated its estimated cost-payment difference for those swing beds (that is, we subtracted the amount that the hospital estimates will be paid under section 1888(e)(7) of the Act for the inpatient hospital services associated with its swing beds for such period from the amount that the hospital estimates it would be paid for the reasonable costs for such services during such period as those amounts are reported on the hospital's application) by simply taking this amount from the hospital's application.
- Step 1(c)(ii): Then, for each of the hospitals with swing beds that submitted with its application both a cost report ending in FY 2010 and the estimated costs of those swing beds during such period, we calculated the difference between the estimated costs and payment for those swing beds for such period by simply taking this amount from the hospital's application. (We note that all hospitals that had swing beds and that submitted cost reports ending in FY 2010 with their application supplied data on the estimated cost and payment for swing bed services on these cost reports.)
- Step 1(c)(iii): Next, we totaled all of the individual amounts calculated under Steps 1(c)(i) and (c)(ii) above and then divided this amount by the total number of hospitals that provided data on estimated costs on swing beds in their applications. We used the result of this computation as the estimated cost for the swing beds for each of the hospitals that failed to submit estimated costs for those beds with their applications.
- Step 1(d): Then, in order to calculate the total costs during the cost reporting period ending in FY 2009 for each hospital that submitted a cost report ending in FY 2009, we did the following: (a) If the hospital had no swing beds, its total estimated costs for such period is the difference calculated under Step 1(a); (b) If the hospital had swing beds, we added the difference calculated under Step 1(a) with the difference calculated under Step 1(c)(i) or Step 1(c)(iii) as applicable.
- Step 1(e): Next, in order to calculate total estimated FY 2009 costs for all of the hospitals that submitted cost reports ending in FY 2009 with their applications, we added together all of the total estimated costs that were calculated for each such hospital under Step 1(d) above. We note that we believe that using cost reports ending in FYs 2009 and 2010 best reflect costs and payment in FYs 2009 and 2010 because these cost reports most closely respond to those fiscal years.
- Step 1(f): Then, in order to calculate the total estimated FY 2011 costs for the newly selected hospitals that submitted cost reports ending in FY 2009 with their applications, we multiplied the amount calculated in Step 1(e) above by the FYs 2010 and 2011 IPPS market basket percentage increases adopted in the respective IPPS/LTCH PPS final rules as well as a 3-percent (2-percent in the proposed rule) annual volume adjustment for each of FYs 2010 and 2011.
- Step 1(g): Then, in order to calculate the total estimated FY 2010 costs for each hospital that submitted a cost report ending in FY 2010, we did the following: (a) If the hospital had no swing beds, its total estimated costs is the difference calculated under Step 1(b); (b) If the hospital had swing beds, we added the difference calculated under Step 1(b) with the difference calculated under Step 1(c)(ii).
- Step 1(h): Next, in order to calculate the total FY 2010 costs for all of the hospitals that submitted FY 2010 cost reports with their applications, we added together all of the total estimated FY 2010 costs calculated for each such hospital under Step 1(g) above.
- Step (1)(i): Then, we calculated the total estimated FY 2011 costs for all of the newly selected hospitals that submitted cost reports ending in FY 2010 by multiplying the amount calculated in Step 1(h) above by the FY 2011 IPPS market basket percentage increase adopted in the respective IPPS/LTCH PPS final rule as well as a 3-percent (2-percent in the proposed rule) annual volume adjustment for FY 2011.
- Step (1)(j): Next, in order to calculate total estimated FY 2012 demonstration costs for all of the 18 newly selected hospitals, we added together the amounts calculated in Steps 1(f) and 1(i) above and then multiplied

this sum by the IPPS FY 2012 market basket percentage increase contained elsewhere in this final rule and a 3-percent annual volume adjustment for FY 2012. (We note that, for the proposed rule, we multiplied the amounts calculated in Steps 1(f) and 1(i) by the proposed FY 2012 IPPS market basket percentage increase contained elsewhere in the proposed FY 2012 IPPS\LTCH PPS proposed rule and a 2-percent annual volume adjustment. As explained previously, these factors have changed in this final rule based on updated data.) The amount of the estimated FY 2012 demonstration costs for the 18 newly selected hospitals, which must be offset, is $32,196,745.

c. Portion of the FY 2012 Budget Neutrality Adjustment to Offset the Amount by Which the Costs of the Demonstration Program in FYs 2007 and 2008 Exceeded the Amount That was Identified in the FYs 2007 and 2008 IPPS Final Rules as the Budget Neutrality Offset for FYs 2007 and 2008

In addition, we proposed that, in order to ensure that the demonstration program in FYs 2007 and 2008 was budget neutral, we would incorporate a component into the budget neutrality adjustment factor to the FY 2012 national IPPS rates, which would offset the amount by which the demonstration program costs as indicated by settled cost reports beginning in FYs 2007 and 2008 for hospitals participating in the demonstration program during FYs 2007 and 2008 exceeded the amount that was identified in the FYs 2007 and 2008 IPPS final rules as the budget neutrality offset for FYs 2007 and 2008. Specifically, we proposed the following methodology (this is the same methodology as used in the FY 2011 IPPS/LTCH PPS final rule, but we added detail):

- Step One: Calculate the costs of the demonstration program for each of FYs 2007 and 2008 according to the settled cost reports that began in FYs 2007 or 2008 for the then participating hospitals (which represent the third and fourth years of the demonstration program for each of the then participating hospitals) and then add these two sums together. The costs of the demonstration program for each of FYs 2007 and 2008 is the difference resulting from subtracting the total amount that would otherwise be paid to the then participating hospitals under the applicable payment system(s) (that is, under the IPPS and under section 1888(e)(7) of the Act to the extent the participating hospital had swing beds) without the demonstration from the amount paid to those hospitals under the demonstration payment methodology in section 410A(b) of Public Law 108–173. (We proposed to use these settled cost reports, which represent the third and fourth years of the demonstration program for each of the then participating hospitals, because we believed they correctly represent inpatient costs for the demonstration program during each of those 2 years. These settled cost reports represent the third and fourth years of the demonstration, because the demonstration started with cost report start dates on or after October 1, 2004. Therefore, the first year of the demonstration program would be represented by cost reports with a start date between October 1, 2004 and September 30, 2005 (that is, FY 2005; the second year of the demonstration program is represented by cost reports with start date between October 1, 2005 and September 30, 2006 (FY 2006); the third year of the demonstration program is represented by cost reports with start date between October 1, 2006 and September 30, 2007 (FY 2007); the fourth year of the demonstration program is represented by cost reports with start date between October 1, 2007 and September 30, 2008 (FY 2008).
- Step Two: Subtract the amount that was offset by the budget neutrality adjustment for FYs 2007 and 2008 ($9,197,870 for FY 2007 and $9,681,893 for FY 2008) from the combined costs of the demonstration program in FYs 2007 and 2008 as calculated in Step one.
- Step Three: The result of Step two is a dollar amount, for which we would calculate a factor that would offset such amounts and would be incorporated into the overall proposed budget neutrality adjustment to the proposed national IPPS rates for FY 2012. This specific component to the overall budget neutrality adjustment for FY 2012 would account for the difference between the combined costs of the demonstration program in FYs 2007 and 2008 and the amount of the budget neutrality adjustment published in the FYs 2007 and 2008 IPPS final rules and, therefore, would ensure that the demonstration program is budget neutral for FYs 2007 and 2008.

Because of delays in the settlement process for the demonstration hospitals' third and fourth year cost reports, that is, for cost reporting periods starting in each FYs 2007 and 2008 respectively, we were unable in the proposed rule to state the costs of the demonstration program corresponding to FYs 2007 and 2008 for purposes of determining the amount by which the costs corresponding to FYs 2007 and 2008 exceeded the amount offset by the budget neutrality adjustment for FYs 2007 and 2008. Similarly, for this final rule, we are unable to identify the specific numeric amount representing this offsetting process that can be incorporated into the budget neutrality adjustment applied to the national IPPS rates due to delays in the settlement process for the demonstration hospitals' third and fourth year cost reports. We note that we anticipate that they may be available for the FY 2013 IPPS/LTCH PPS proposed and final rules. Therefore, the estimated adjustment to the national IPPS rates in this final rule cannot include a component to account for these costs.

For this FY 2012 IPPS/LTCH PPS final rule, the estimated amount for which an adjustment to the national IPPS rates is being calculated is the sum of the amounts specified in sections IV.N.3.a. and IV N.3.b. of this final rule, which is $52,452,060 (this estimate does not account for the numeric result of the method in IV.N.3.c.). Sections IV.N.3.a. and IV.N.3.b. of this final rule state dollar amounts, which represent estimated costs attributable to the demonstration program for the respective component of the overall estimated calculation of the final budget neutrality factor for FY 2012. This estimated amount is based on the specific assumptions identified, as well as from data sources that are used because they represent either the most recently finalized, (that is, settled) or, if ''as submitted,'' recently available cost reports.

Comment: One commenter pointed out that if the newly participating hospitals' cost reports for the preceding year are not settled, or the hospital is appealing certain determinations made by the fiscal intermediary or MAC, the target amount for any year under the demonstration program may be subject to change. The commenter asked whether cost reports would have to be reopened to reflect the final settlement of the years in which the respective target amount is developed.

Response: We will approach this issue consistent with standard cost report review.

O. Bundling of Payments for Services Provided to Outpatients Who Later Are Admitted as Inpatients: 3-Day Payment Window

1. Background

Section 1886(a)(4) of the Act includes in the definition of ''operating costs of inpatient hospital services'' the cost of diagnostic services (including clinical diagnostic laboratory tests) ''or other services related to the admission'' (as defined by the Secretary) furnished by

the hospital (or by an entity that is wholly owned or operated by the hospital) to the patient during the 3 days preceding the date of the patient's admission to a subsection (d) hospital subject to the IPPS. For a non-subsection (d) hospital (psychiatric hospitals and units, inpatient rehabilitation hospitals and units, long-term care hospitals, children's hospitals, and cancer hospitals), the statutory payment window is 1 day preceding the date of the patient's admission.

Section 102(a)(1) of the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (Pub. L. 111–192, enacted on June 25, 2010) specifies that the term in section 1886(a)(4) of the Act, ''other services related to the admission'', includes ''all services that are not diagnostic services (other than ambulance and maintenance renal dialysis services) for which payment may be made under this title [Title XVIII] that are provided by a hospital (or an entity wholly owned or wholly operated by the hospital) to a patient—(A) on the date of the patient's inpatient admission; or (B) during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of admission unless the hospital demonstrates (in a form and manner, and at a time, specified by the Secretary) that such services are not related (as determined by the Secretary) to such admission.'' Public Law 111–192 makes no changes to the existing policy regarding billing for diagnostic services.

Under the 3-day (or 1-day) payment window policy, all outpatient diagnostic services furnished to a Medicare beneficiary by a hospital (or an entity wholly owned or operated by the hospital), on the date of a beneficiary's admission or during the 3 days (1 day for a non-subsection (d) hospital) immediately preceding the date of a beneficiary's inpatient hospital admission, must be included on the Part A bill for the beneficiary's inpatient stay at the hospital. All outpatient nondiagnostic services provided by the hospital (or an entity wholly owned or wholly operated) on the date of the inpatient admission or during the 3 days (1 day for a non-subsection (d) hospital) immediately preceding the date of a beneficiary's inpatient hospital admission are deemed related to the admission and must be billed with the inpatient stay unless the hospital attests that specific nondiagnostic services are unrelated to the hospital claim.

Further, section 102(c) of Public Law 111–192 prohibits the reopening of a claim, adjusting a claim, or making payments pursuant to any request for payment under Title XVIII, submitted by an entity (including a hospital or an entity wholly owned or operated by the hospital), for services (as described in section 102(c)(2) of Pub. L. 111–192), for purposes of treating, as unrelated to a patient's inpatient admission, services provided during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of the patient's inpatient admission. Services described in section 102(c)(2) of Public Law 111–192 are other services related to the admission which were previously included on a claim or request for payment submitted under Part A of Title XVIII for which a reopening, adjustment, or request for payment under Part B of Title XVIII, was not submitted prior to June 25, 2010 for purposes of treating, as unrelated to a patient's inpatient admission.

In an interim final rule with comment period issued in the **Federal Register** on August 16, 2010 (75 FR 50346 through 50349), we discussed and made changes to the Medicare regulations pertaining to the 3-day payment (or, if applicable, 1-day) window policy in order to comport with the requirements of section 102 of Pub. L. 111–192. We refer readers to that interim final rule with comment period for further information about the 3-day (or, if applicable, 1-day) payment window policy. We had received public comments on the August 16, 2010 interim final rule with comment period, and we indicated in the FY 2012 IPPS/LTCH PPS proposed rule that we planned to address these public comments as well as any public comments we may receive on the proposals in the proposed rule in this FY 2012 IPPS/LTCH PPS final rule.

Comment: One commenter supported the statutory and regulatory changes made to the 3-day payment window provision. One commenter asked for clarification of the timeframe for submitting claims based on the requirements of section 102(c) of Public Law 111–192. The commenter's understanding is that a hospital must have identified any unrelated nondiagnostic services for which it wished to bill separately on an outpatient claim for services provided prior to June 25, 2010, and cannot file an adjustment claim now to unbundle any such services from the inpatient admission if it did not originally do so prior to June 25, 2010. The commenter's assumption is that providers can file an adjustment claim for services that have been billed since June 25, 2010. The commenter suggested that CMS make a simple statement to that effect so it is unambiguous to providers that this statutory provision only applies to services provided prior to June 25, 2010.

Response: Section 102(c) of Public Law 111–192 prohibits us from reopening a claim, adjusting a claim, or making payment pursuant to any request for payment, submitted for other services related to the admission, which were previously included on a claim or request for payment for which a reopening, adjustment, or request for payment under Part B was not submitted prior to June 25, 2010. Hospitals may bill Medicare separately for outpatient nondiagnostic services furnished prior to June 25, 2010, provided that: (1) The services are not related to an inpatient stay (the determination of ''related'' for services furnished prior to June 25, 2010 is based on guidance published in the **Federal Register** on February 11, 1998 (63 FR 6866)); (2) such services were not previously included on a Medicare claim; and (3) the claim meets all applicable filing deadlines.

Section 102(c) of Public Law 111–192 does not preclude a provider from submitting a new Medicare Part B claim and a Part A adjustment claim for the purpose of unbundling outpatient services that the provider believes were improperly bundled with an inpatient claim, in circumstances where all of the following conditions are met: (a) The outpatient services were furnished to a beneficiary on or after June 25, 2010; (b) the outpatient services were not provided on the same calendar day as a beneficiary's inpatient admission; (c) the outpatient services were nondiagnostic; (d) the provider attests that the outpatient services were clinically unrelated to the beneficiary's inpatient admission and such claim is supported by documentation in the patient's medical record; and (e) the claim meets all applicable filing deadlines.

Comment: Some commenters urged CMS to consider providing guidance as to how providers may establish policies and procedures for identifying nondiagnostic services that are unrelated to the admission, and what those policies and procedures should consider in making this determination. One of the commenters recognized that CMS looks to hospitals to make this determination, but given the volume of questions about the payment window policy for Medicare both prior to and since the statutory change, the commenter stated that it seems many hospitals remain confused about how to make that determination.

Some commenters requested that CMS clearly define ''clinically

associated'' outpatient nondiagnostic services in the Medicare Claims Processing Manual to avoid further confusion in the hospital community regarding what constitutes unrelated outpatient nondiagnostic services. According to one of the commenters, lack of a clear definition of clinically associated services could cause confusion and more complications under post-review audits.

One commenter supported the continued use of an exact match (for all digits) between the ICD–9–CM principal diagnosis code assigned for both the preadmission services and the inpatient stay to identify services that are clinically associated with the admission. Another commenter did not support using ICD–9–CM codes to define what is related and what is not related and suggested that all continuous services are by definition related services.

According to one of the commenters, it will be substantially difficult for billing systems to present an opportunity for the hospital to determine when to unbundle such services in any reasonable way short of holding claims from being generated and submitted for what may amount to a very large number of inpatient claims, and this may serve to slow down the billing process for those claims. The commenter contended that most billing systems for hospital services have capabilities to define bundling rules for diagnostic services that should always be bundled into the inpatient admission for billing purposes. However, for bundling of nondiagnostic services (or for unbundling), the commenter believed that a manual process was necessary so that hospitals would not make perfunctory decisions regarding when to bundle or not bundle. The commenter was concerned that this could lead to hospitals always making the determination to bundle to save the administrative time, effort, and cost to unbundle or to define rules to always unbundle particular nondiagnostic services without assuring that they should truly be unbundled.

Response: In accordance with section 1886(a)(4) of the Act, outpatient nondiagnostic services furnished within the 3-day (or, if applicable, 1-day) window that are related to an inpatient admission must be bundled with the billing of the inpatient stay. An outpatient nondiagnostic service is related to the admission if it is clinically associated with the reason for a patient's inpatient admission. As we discussed above and in the interim final rule with comment period issued in the **Federal Register** on August 16, 2010 (75 FR 50346 through 50349), section 102 of Public Law 111–192 broadened the definition of related outpatient nondiagnostic services. Adopting the definition that CMS had prior to June 25, 2010, for related nondiagnostic services, as suggested by one of the commenters (that is, there would need to be an exact match (all 5 digits) between the principal diagnosis code assigned for both the preadmission services and the inpatient stay) would be too narrow and would impermissibly limit the number and scope of outpatient nondiagnostic services that are clinically related to the admission and should be bundled with the inpatient stay payment.

In response to the commenter who requested that all continuous services (for example, inpatient admission through the emergency department, hospitalization for complications after outpatient surgery, among others) be considered related services and be included in the inpatient stay, we believe that may result in services being bundled in the inpatient stay that are not related to the admission. However, we will take these comments into consideration as we develop updates to the Medicare instructions in the future.

Comment: One commenter urged CMS to delay the effective date of this policy to April 1, 2011, because—

(1) Hospitals did not have a policy in place on June 25, 2010, and have not programmed their billing systems to accommodate this policy retroactively. According to the commenter, to ask hospitals to retroactively implement this policy presents a major burden with regard to system changes, as well as claims rebilling and/or adjusting; and

(2) The creation of the condition code or modifier is administered through the National Uniform Billing Committee and should follow that body's guidelines that state approved changes are usually effective April 1, October 1, or about 90 days after approval, as appropriate.

Response: Section 102(a) of Public Law 111–192 pertains to the 3-day (or 1-day) payment window and was effective for services furnished on or after the date of enactment, June 25, 2010. CMS does not have the authority to delay the enactment of this law.

Comment: Some commenters were concerned that hospitals have not historically included the diagnosis and procedures codes from the outpatient services on the inpatient claim, only the charges. The commenters were concerned that inclusion of the diagnosis codes from the outpatient claim could impact the MS–DRG assignment as well as have health statistic and quality reporting implications.

The commenters also were concerned with the administrative burden of having to recode the outpatient procedures from CPT–4 codes, which are reported in the outpatient setting, to ICD–9–CM codes, which are reported in the inpatient setting. The commenters also raised questions regarding the type of documentation that will be required to support adding the code to an inpatient claim.

Response: As we specified in a memorandum to hospitals explaining the policy changes pertaining to nondiagnostic services subject to the payment window (dated August 9, 2010 and distributed to hospitals through the fiscal intermediaries/MACs), hospitals must include on a Medicare claim for a beneficiary's inpatient stay the diagnoses, procedures, and charges for all preadmission outpatient diagnostic services and all admission-related preadmission outpatient nondiagnostic services. We note that, in combining on the inpatient bill the diagnoses, procedures, and charges for the outpatient services, a hospital must convert CPT–4 codes to ICD–9–CM codes and include outpatient diagnostic and admission-related nondiagnostic services that span the period of the payment window. We are aware that the inclusion of some diagnosis codes reported on the outpatient claim that are bundled into the inpatient stay may affect the MS–DRG assignment. Also, the inclusion of an outpatient surgical procedure that is converted from CPT–4 coding to ICD–9–CM coding for inpatient reporting may affect the MS–DRG assignment of the inpatient claim. The law requires that preadmission diagnostic services and related nondiagnostic services be included on the claim for the inpatient admission. Therefore, in some cases, including such services on the inpatient claim may affect the MS–DRG assignment and, when appropriately included, is permissible.

The process of bundling claims has remained unchanged. That is, the bundling of claims incorporates transferring all the information reported in the outpatient encounter, such as the diagnosis and procedure codes as well as the charges, to the inpatient setting. We are aware that there are separate ICD–9–CM Coding Guidelines for the inpatient setting and the outpatient setting. Appropriate guidelines should be followed at the time of coding based on the setting of the encounter. We note that the bundling rules for the 3-day (1-day) payment window policy do not affect the Coding Guidelines for

inpatient and outpatient settings. In response to the commenter's request for guidance on the type of documentation that would be required to support adding the code to an inpatient claim, the guidance would be the same for reporting any diagnosis on a claim. If there is documentation in the patient's medical record that confirms that the condition or diagnosis is present, that diagnosis should be reported.

2. Condition Code 51 (Attestation of Unrelated Outpatient Nondiagnostic Services)

As we stated in the August 16, 2010 interim final rule with comment period (75 FR 50348), we intend to establish a process for hospitals to attest to nondiagnostic services as being unrelated to the hospital claim when a hospital submits an outpatient claim. As part of the process, hospitals would be required to maintain documentation in the beneficiary's medical record to support their claim that the outpatient nondiagnostic services are unrelated to the beneficiary's inpatient admission.

The National Uniform Billing Committee (NUBC) is a committee established by the American Hospital Association and includes the participation of all the major national provider and payer organizations. The NUBC was formed to develop a single billing form and standard data set that could be used nationwide by institutional providers and payers for handling health care claims. The NUBC has provided a mechanism through the establishment of a condition code for a hospital to attest directly on the outpatient claim to specific nondiagnostic services as being clinically unrelated to an inpatient hospital claim (that is, the preadmission diagnostic services are clinically distinct or independent from the reason for the beneficiary's inpatient admission). As of April 1, 2011, a hospital must add condition code 51 on claims for separately billed outpatient nondiagnostic services furnished on or after June 25, 2010 (the date of enactment of Public Law 111–192) if the hospital wishes to attest to nondiagnostic services as being unrelated to the inpatient hospital claim. We issued a manual system revision through Change Request #7142, Transmittal 796, on October 29, 2010, instructing CMS contractors to accept condition code 51 on outpatient claims.

Comment: One commenter supported the use of a condition code but believed that the use of a condition code alone should be sufficient to signify that unrelated outpatient services billed on a separate outpatient claim are distinct from the inpatient services. The commenter discouraged CMS from requiring hospitals to maintain documentation in the beneficiary's medical record to support their claim that the outpatient services are related.

Another commenter disagreed with the proposal to implement an attestation process. The commenters stated that it would require additional administrative effort by hospital staff that does not seem necessary, as claims are required to be filed correctly under the law. According to the commenter, if an attestation is required, the attestation process should be easy to follow and clearly defined.

One commenter was concerned about the ease with which hospitals could apply a condition code and that unwarranted unbundling could still occur, depending on how the standard is defined for nondiagnostic related services.

Response: The implementation of condition code 51, effective April 1, 2011, provides a process for hospitals to attest to nondiagnostic services as being unrelated to the inpatient hospital claim when a hospital submits an outpatient claim. However, upon review, the hospital must be able to document that the services are unrelated based on information in the patient's medical record. As we stated in the interim final rule with comment period issued in the **Federal Register** on August 16, 2010 (75 FR 50348), hospitals have experience with making similar attestations on the outpatient or inpatient claim.

3. Applicability of the Payment Window Policy to Services Furnished at Physicians' Practices

We have received several inquiries regarding the applicability of the payment window to preadmission services furnished at hospital-owned or hospital-operated physicians' clinics or practices. The statutory language under section 1886(a)(4) of the Act is clear that the 3-day (or, where applicable, 1-day) payment window policy applies not only to diagnostic and related nondiagnostic services furnished to patients at hospitals, but also to those services furnished at entities that are wholly owned or operated by the admitting hospital. In a 1998 final rule on payment for preadmission services (63 FR 6866), we stated, ''A hospital-owned or hospital-operated physician clinic or practice is subject to the payment window provision. The technical portion of preadmission diagnostic services performed by the physician clinic or practice must be included on the inpatient bill and may not be billed separately. A physician's professional service is not subject to the window.'' Thus, we made clear that the term ''entities'' under this section of the statute includes physicians' clinics or practices. Although the 1998 rule provides specific guidance regarding billing for preadmission diagnostic services furnished at hospital-owned or hospital-operated physician's practices, we had issued no guidelines regarding billing for preadmission nondiagnostic services provided by a hospital-owned or hospital-operated physician's practice.

Prior to the June 25, 2010 enactment of section 102(a)(1) of Public Law 111–192, the payment window policy for preadmission nondiagnostic services was rarely applicable because the policy required an exact match between the principal ICD–9 CM diagnosis codes for the outpatient services and the inpatient admission. Because of the exact match policy, very few services furnished in a physician's office or clinic that is wholly owned or operated by the hospital would have been be subject to the policy. However, the change to the payment window policy made by Public Law 111–192 broadened the definition of nondiagnostic services that are subject to the payment window to include any nondiagnostic service that is clinically related to the inpatient admission, regardless of whether the inpatient and outpatient diagnoses are the same. As a result, this statutory change broadens the applicability of the payment window policy in hospital-owned or hospital-operated physician offices or clinics (that is, clinics that are not provider-based but are wholly owned or operated by the hospital). We note that, under the amended statute, in order to be able to bill separately for nondiagnostic preadmission services that fall within the payment window, hospitals and hospital-owned or hospital-operated entities must now attest that the services are not related to an admission by using condition code 51 (Attestation of Unrelated Outpatient Nondiagnostic Services) when billing for the services.

In response to ongoing requests to clarify the applicability of the payment window policy to preadmission nondiagnostic services provided in hospital-owned or hospital-operated physicians' offices or clinics, as we did in the proposed rule, we are clarifying that the 3-day (or, where applicable, 1-day) payment window policy applies to both preadmission diagnostic and nondiagnostic services furnished to a patient at physician's practices that are wholly owned or wholly operated by the admitting hospital. For purposes of the payment window, ''wholly owned

or operated'' means that the admitting hospital must be the sole owner or the sole operator of the entity providing the preadmission services. A hospital is considered the sole operator of an entity if the hospital has exclusive responsibility for conducting or overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity (we refer readers to the regulations at 42 CFR 412.2(c)(5)(i) and to discussions and examples of wholly owned or operated scenarios in rules issued in the **Federal Register** on January 12, 1994 (59 FR 1656) and February 11, 1998 (63 FR 6865 through 6867)).

In the circumstance in which a clinic or a physician office that is not provider-based meets the definition of being wholly owned or wholly operated by the hospital and the 3-day (or, if applicable, 1-day) payment window applies to related nondiagnostic preadmission services, the overhead costs associated with those services would be considered operating costs of inpatient hospital services and, as such, included in the hospital's bill for the inpatient service. As explained more fully in the CY 2012 Medicare Physician Fee Schedule proposed rule (76 FR 42915), we have proposed that Medicare's payment to the physician for the physician fee schedule service would be at the lower facility rate, which does not include overhead, staff, equipment, and supplies required to perform the service in the physician's office (rather than the higher nonfacility rate that does include those overhead costs) in order to avoid duplicate payment for the services under both the IPPS and the Medicare Physician Fee Schedule.

Under 42 CFR 414.22(b)(5)(i), Medicare pays physicians using the nonfacility relative value units when services are provided in a physician's office and bases physician payment on the facility relative value units when the physician provides services in a facility, including hospitals, skilled nursing facilities, community mental health centers, and ambulatory surgical centers. Because a hospital-owned or hospital-operated physician practice or clinic that is not provider-based is a nonfacility setting, we have proposed in the CY 2012 Medicare Physician Fee Schedule proposed rule (76 FR 42915) to change the regulation to reflect the proposal to pay for a service provided in a nonfacility setting at the facility rate in order to comply with section 102(a) of Public Law 111–192. We indicated in the IPPS proposed rule that we intended to discuss such a proposal in more detail in a future physician fee schedule proposed rule and address how this statutory provision will be implemented in physicians' offices that are wholly owned or wholly operated by the hospital. In all circumstances, we would expect that, in the case of a physician practice that is wholly owned or wholly operated by the hospital, the hospital would inform the physician offices and clinics when an inpatient admission occurs.

Comment: One commenter stated that it may be difficult to track activity between hospital-owned practices and the hospital that owns the practices.

Response: Due to the fact that the hospital owns the facility, it is our expectation that the hospital will be able to coordinate and track the patient activity of the facilities it owns. The full adoption of electronic medical record should help facilitate coordination and tracking of patients within and among hospital systems.

We received a few public comments regarding the applicability of the payment window policy to services furnished at physicians' practices that are wholly owned or wholly operated by the hospital. We stated in the FY 2012 IPPS/LTCH PPS proposed rule that CMS would address the payment window policy as it impacts physician billing in the CY 2012 Medicare Physician Fee Schedule proposed rule. Therefore, those comments are not within the scope of this IPPS/LTCH final rule. The CY 2012 Medicare Physician Fee Schedule proposed rule (CMS–1524–P) appeared in the **Federal Register** on July 19, 2011. The deadline for submitting public comments on that proposed rule is August 30, 2011. Instructions for submitting public comments on that proposed rule are included in the proposed rule (76 FR 42772).

P. Changes to MS–DRGs Subject to the Postacute Care Transfer Policy

1. Background

Existing regulations at § 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy, set forth in § 412.4(f), provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is double the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases are also eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to the fixed-loss outlier threshold for nontransfer cases (adjusted for geographic variations in costs), divided by the geometric mean length of stay for the MS–DRG, and multiplied by the length of stay for the case, plus one day.

We established the criteria set forth in § 412.4 for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the DRG's total number of discharges and proportion of short-stay discharges to postacute care exceed the 55th percentile for all DRGs, CMS will apply the postacute care transfer policy to that DRG and to any other MS–DRG that shares the same base DRG. In the preamble to the FY 2006 final rule (70 FR 47419), we stated that ''we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific DRG.''

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a reduced per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6)). For an MS–DRG to qualify for the special payment methodology, the geometric mean

length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. DRGs that are part of an MS–DRG group must meet DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

2. Changes to the Postacute Care Transfer MS–DRGs

Based on our annual review of MS–DRGs, we have identified a number of MS–DRGs that should be included on the list of MS–DRGs subject to the postacute care transfer policy. As we discussed in section III.G. of the proposed rule, in response to public comments and based on our analysis of FY 2010 MedPAR claims data, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to make several changes to MS–DRGs to better capture certain severity of illness levels, to be effective for FY 2012. Specifically, we proposed to modify the assignment of the autologous bone marrow transplants now assigned to MS–DRG 015 (Autologous Bone Marrow Transplant) to capture the severity levels of ''with CC/MCC'' and ''without CC/MCC.'' We proposed to establish two new MS–DRGs (proposed MS–DRGs 016 and 017 (Autologous Bone Marrow Transplant with MCC/CC and without MCC/CC, respectively) to replace MS–DRG 015. We also proposed to establish three new MS–DRGs to capture three severity of illness levels for skin debridement—proposed MS–DRG 570 (Skin Debridement with MCC); proposed MS–DRG 571 (Skin Debridement with CC); and proposed MS–DRG 572 (Skin Debridement without CC/MCC). In addition, we proposed to move the codes for rechargeable dual array deep brain stimulation (codes 02.93 and 86.98) to MS–DRGs 023 and 024 (Craniotomy with Major Device Implant/Acute Complex CNS PDX, with MCC and without MCC, respectively) where similar devices are currently assigned. We proposed to move two procedure codes that either repair a thoracic aneurysm or place a stent graft (codes 38.45 and 39.73) out of MS–DRG 237 and 238 (Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm Repair, and Major Cardiovascular Procedures with MCC and without MCC, respectively). We proposed to assign these two codes to MS–DRGs 219, 220, and 221 (Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC, with CC, and without CC, respectively). We proposed to add a procedure code for partial gastrectomy (43.89) to MS–DRGs 619, 620, and 621 (O.R. Procedure for Obesity with MCC, with CC, and without CC/MCC, respectively). A discussion of these proposed changes and our final changes can be found in section II.G. of the preamble of the final rule.

In light of the proposed changes to the MS–DRGs, according to the regulations under § 412.4(c), we evaluated these proposed FY 2012 MS–DRGs against the general postacute care transfer policy criteria using the FY 2010 MedPAR data. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). As a result of our review, we proposed to update the list of MS–DRGs that are subject to the postacute care transfer policy to include the proposed new MS–DRGs 570, 571, and 572 for FY 2012. (These MS–DRGs were reflected in Table 5, which was listed in section VI. of the Addendum to the proposed rule and available via the Internet, and were also listed in the tables at the end of this section.)

In addition, based on our evaluation of the proposed FY 2012 MS–DRGs using the FY 2010 Med PAR data, we identified the following two existing MS–DRGs that meet the criteria to be subject to the postacute care transfer policy for FY 2012: MS–DRGs 023 (Craniotomy with Major Device Implant or Acute Complex CNS PDX with MCC) and MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS PDX without MCC). We proposed to add these two MS–DRGs to the list of MS–DRGs that are subject to the postacute care transfer policy for FY 2012. The following table lists the respective criteria for each MS–DRG that we proposed to add to the postacute care transfer policy list.

Further, based on our evaluation of the proposed FY 2012 MS–DRGs using the FY 2010 Med PAR data, we determined that MS–DRGs 228 (Other Cardiothoracic Procedures with MCC), 229 (Other Cardiothoracic Procedures with CC), 230 (Other Cardiothoracic Procedures without CC/MCC), 640 (Miscellaneous Disorders of Nutrition, Metabolism, Fluids/Electrolytes with MCC), and 641 (Miscellaneous Disorders of Nutrition, Metabolism, Fluids/Electrolytes without MCC) no longer meet the postacute care transfer criteria. Therefore, we proposed that they be removed from the list of DRGs subjected to the postacute care transfer policy, effective FY 2012.

Finally, we determined that MS–DRGs 216 (Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC), 217 (Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC), and 218 (Cardiac Valve & Other Major Cardiothoracic Procedure without CC/MCC) meet the criteria for the special payment methodology. Therefore, we proposed that they would be subject to the DRG special payment methodology, effective FY 2012.

Comment: Several commenters supported the proposed changes to the lists of MS–DRGs subject to the postacute care transfer and special payment policy. Commenters also requested that CMS expand its analysis to remove additional MS–DRGs that no longer meet the postacute care transfer policy criteria and to add MS–DRGs that currently meet special payment policy criteria.

Response: As stated in the FY 2006 final rule (70 FR 47419), CMS determined that an annual review of all DRGs ''would likely lead to great volatility in the payment methodology of certain DRGs''. Therefore, it is our policy to not conduct an annual review of MS–DRGs unless we have proposed to make changes to specific MS–DRGs. We note that, during this rulemaking process, we reviewed additional MS–DRGs for which we were proposing changes to determine whether they meet the postacute care transfer or special payment policy criteria (MS–DRGs (16, 17, 219, 220, 221, 237, 238, 250, 251, 573, 574, 575, 576, 577, 578, 619, 620, and 621). However, in the proposed rule, we only discussed the MS–DRGs that were proposed to be newly added to, or removed from, the postacute care transfer or special payment policy, as listed on Table 5. Following issuance of the proposed rule, we conducted an additional review of MS–DRGs for purposes of finalizing the postacute care transfer and special payment status policy modifications, and that review confirmed that these previously reviewed MS–DRGs do not require any further changes in postacute care transfer or special payment status.

During this review, we determined that MS–DRGs 640 (Miscellaneous Disorders of Nutrition, Metabolism, Fluids/Electrolytes with MCC) and 641 (Miscellaneous Disorders of Nutrition, Metabolism, Fluids/Electrolytes without MCC) were inadvertently listed as MS–DRGs for which significant GROUPER logic changes were being proposed. The changes to these MS–DRGs were determined to be descriptive title changes only and not material logic changes. Therefore, considering whether

to change the postacute care transfer and special payment policy status for these MS–DRGs was a technical error. Therefore, we are not finalizing our proposed changes for these two MS–DRGs. The remaining proposed changes to the postacute care transfer and special payment policy lists are being finalized as proposed and are summarized in the following tables. We refer readers to the bolded text in the first table to see which criteria were not met in our analysis for each MS–DRG removed from the postacute care transfer policy list. Table 5, which is listed in section VI. of the Addendum to this final rule and available through the Internet on the CMS Web site, lists all MS–DRGs for FY 2012 and specifies whether or not they are subject to the postacute care transfer policy and the special payment policy. For FY 2012, there are a total of 275 MS–DRGs subject to the postacute care transfer policy, and 30 MS–DRGs meet the special payment policy criterion.

LIST OF MS–DRGS CHANGING POSTACUTE CARE TRANSFER POLICY STATUS IN FY 2012

MS–DRG	MS–DRG Title	Total cases	Postacute care transfers (55th percentile: 1,596)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 8.0037%)	Postacute care transfer policy status
023	CRANIO W MAJOR DEV IMPL/ACUTE COMPLEX CNS PDX W MCC OR CHEMO IMPLANT.	4,631	2,225	373	8.05	YES
024	CRANIO W MAJOR DEV IMPL/ACUTE COMPLEX CNS PDX W/O MCC.	1,745	*1,000	161	9.23	YES**
228	OTHER CARDIOTHORACIC PROCEDURES W MCC.	1,936	*1,223	456	23.55	NO
229	OTHER CARDIOTHORACIC PROCEDURES W CC.	2,395	*1,322	421	17.58	NO
230	OTHER CARDIOTHORACIC PROCEDURES W/O CC/MCC.	640	*228	11	*1.72	NO
570	SKIN DEBRIDEMENT W MCC	5,189	3,968	1,558	30.03	YES
571	SKIN DEBRIDEMENT W CC	5,538	3,832	1,087	19.63	YES
572	SKIN DEBRIDEMENT W/O CC/MCC	2,539	*1,378	226	8.90	YES**

* Indicates a current postacute care transfer policy criterion that the MS–DRG did not meet.
** As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS–DRGs that share the same base MS–DRG shall all meet postacute care transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

LIST OF MS–DRGS CHANGING DRG SPECIAL PAYMENT POLICY STATUS IN FY 2012

MS–DRG	MS–DRG Title	Geometric mean length of stay	Average charges of 1-day discharges	50% of average charges for all cases within MS–DRG	Special payment policy status
216	CARDIAC VALVE & OTH MAJ CARDIOTHORACIC PROC W CARD CATH W MCC.	14.2497327	$164,838	125,398	YES
217	CARDIAC VALVE & OTH MAJ CARDIOTHORACIC PROC W CARD CATH W CC.	9.518336312	126,655	84,669	YES
218	CARDIAC VALVE & OTH MAJ CARDIOTHORACIC PROC W CARD CATH W/O CC/MCC.	7.102572558	0	0	YES

Q. Hospital Services Furnished Under Arrangements

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25964 and 25965), we stated that, for purposes of Medicare payment, section 1861(b) of the Act defines ''inpatient hospital services'' in part as ''* * * the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital: (1) Bed and board; (2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients * * *; and (3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements.''

We noted that the statute specifies that ''routine services,'' for example, bed, board, nursing and other related services, except those specified at paragraph (3) of section 1861(b) of the Act are to be provided by ''the hospital,'' and not just ''a hospital.'' Similarly, we noted that our implementing regulations at 42 CFR 409.12 indicate that Medicare pays for ''nursing and related services, use of hospital * * * facilities, and medical social services as * * * inpatient hospital services or inpatient CAH services . . . only if those services are ordinarily furnished by the hospital or CAH.'' We pointed out that, consistent with the statute, only with regard to other diagnostic or therapeutic services do the regulations at 42 CFR 409.16 state that Medicare will also pay for these services if furnished ''by others under arrangements made by the hospital or CAH.''.

Instructions at section 2118 (Cost of Services Furnished under Arrangement) of the Provider Reimbursement Manual, Part I (PRM–I), relating to payment for routine services, allow additional

services to be provided under arrangements. It had come to our attention that some providers in the hospital community have interpreted the provision relating to services provided ''under arrangement'' under section 2118 of the PRM–I to mean that even routine services described in sections 1861(b)(1) and (b)(2) of the Act, which are normally provided to hospital inpatients by the hospital, can be provided outside the hospital by an outside entity under arrangement.

To the extent that our manual provisions could be read to allow hospitals to furnish such ''routine services'' ''under arrangement,'' we proposed a change to limit the services a hospital may provide under arrangement to reflect the statutory definition of ''inpatient hospital services'' and the implementing regulations. Under our proposed policy, if routine services, that is, services described in sections 1861(b)(1) and (b)(2) of the Act, are provided in the hospital, they are considered as being provided ''by the hospital .'' We stated that we believe that this proposal is consistent with the statute because the statutory language specifying that the routine services described in sections 1861(b)(1) and (b)(2) of the Act be provided ''by the hospital'' suggests that the hospital is required to exercise professional responsibility over the services, including quality controls. In situations in which certain routine services are provided through arrangement ''in the hospital,'' for example, contracted nursing services, we believe the arrangement generally results in the hospital exercising the same level of control over those services as the hospital does in situations in which the services are provided by the hospital's salaried employees.

Therefore, if routine services are provided in the hospital to its inpatients, we consider the service as being provided by the hospital. However, if these services are provided to its patients outside the hospital, the services are considered as being provided under arrangement, and not by the hospital. Therefore, consistent with the statute, only therapeutic and diagnostic services can be provided under arrangement outside the hospital. We indicated that if we finalized this policy, we would change the provisions of section 2118 of the PRM–I accordingly.

We received numerous comments from the hospital provider community as well as several provider organizations. A few commenters had singular, limited comments; the majority of commenters presented arguments, similar in content, against adopting our proposed change to limit the services a hospital could provide under arrangement.

Comment: Commenters argued that our proposal to limit the services a hospital may provide under arrangements is not required by the statute or regulations. Commenters also believed that CMS' proposed reading of the statutory definition of inpatient hospital services is only one possible interpretation of the statute. Furthermore, commenters stated that CMS' ''use of the definition of inpatient hospital services as the basis for its proposal may not be appropriate'' and concluded that, under our proposal, ''routine services, including ICU services, would not be considered to be inpatient hospital services,'' but that we did not state ''what such services would be if not inpatient hospital services * * *.''

Response: In the proposed rule, we focused our discussion on section 1861(b) of the Act because it provides the statutory basis for our policy to limit the services that may be furnished under arrangement. As we noted in the proposed rule, the reference to diagnostic or therapeutic items or services in section 1861(b)(3) of the Act includes the language, ''[furnished by] * * * or by others under arrangements.'' Therefore, we believe it is consistent with the statutory language to limit the services that may be furnished outside of a hospital under arrangement to only diagnostic and therapeutic services.

Our policy does not alter the definition of inpatient hospital services, but instead limits the services a hospital may provide under arrangements outside the hospital. Under our proposal, if a patient of Hospital A is in Hospital B receiving routine services, the patient will still be an ''inpatient,'' but the services will not be considered ''inpatient hospital services'' furnished by the hospital for purposes of payment for services defined under section 1861(b) of the Act. If the patient is admitted to Hospital B, then the patient would be an ''inpatient'' of Hospital B and the routine services furnished to that individual would meet the definition of ''inpatient routine services'' under section 1861(b) of the Act.

Comment: Commenters wrote that there are ''specific statutory provisions * * * that would allow hospitals to use the type of arrangements CMS is proposing to prohibit,'' and argued that, ''CMS's reliance on the tangentially-related hospital inpatient services definition as the basis for its proposal seems to be an end-run around them.'' Section 1862(a)(14) of the Act was cited as specific statutory authority that allows hospitals to furnish all categories of inpatient hospital services under arrangement. Commenters noted that this provision does not limit the type of entity that may furnish services under arrangement nor specify what services may be provided under arrangement.

Response: We disagree with this position. Section 1862(a)(14) of the Act states, in part, that payment under Part A or Part B may not be made for certain services ''furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements * * * with the entity made by the hospital or CAH.'' Although we agree with the commenters that the language of section 1862(a)(14) of the Act does not place restrictions on what services may be provided under arrangement, it does not specifically authorize the furnishing of routine services to be provided under arrangement, nor does it conflict with the interpretation of section 1861(b) of the Act set forth in the proposed rule. Instead, when read in conjunction with section 1861(b) of the Act, as interpreted in our proposal, the language ''furnished under arrangements'' in section 1862(a)(14) of the Act is limited to only those services that may be furnished under arrangement consistent with our proposed policy.

Comment: Commenters discussed a decision of the Provider Reimbursement Review Board (PRRB) in which pulmonary intensive care services were furnished under arrangements to patients of one hospital by another hospital located across the street (*University of Missouri Med. Ctr.* v. *BCBSA,* PRRB Dec. No. 79–D82, Medicare & Medicaid Guide (CCH) 30, 317 (Nov. 28, 1979)). The PRRB found that ''routine inpatient services provided under arrangement * * * are allowable costs and are incorporated in the provider's costs of routine services.'' The PRRB also found that the services were properly furnished under arrangements. Commenters noted that the CMS Administrator did not modify or reverse this decision, and thereby, it was the final decision of the Secretary.

Response: We recognize that certain routine services have previously been provided under arrangements, and we are now changing this policy to preclude a hospital from furnishing routine services under arrangements with another entity unless the services are provided in the hospital in which the patient has been admitted as an

inpatient. We note that the date of this PRRB decision was November 28, 1979. This was 3 years prior to the statutory payment provisions included in the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, which sets Medicare payment based on reasonable costs subject to a ceiling, and 4 years prior to implementation of the IPPS. We point out that both hospitals involved in the PRRB case were paid under the same Medicare payment provisions at that time, that is, routine cost limits.

As discussed in greater detail below, we have decided to change this policy because we are concerned that similar arrangements between entities that are not paid under the same Medicare payment provisions—for example, arrangements between IPPS hospitals and hospitals excluded from the IPPS—have resulted in hospitals receiving payments for services based on payment provisions that do not ordinarily apply to that facility.

Comment: One commenter cautioned that CMS should recognize that there are regulations that allow hospitals-within-hospitals (HwHs) to obtain other services through contract or other agreements. The commenter specifically cites the requirement that a HwH ''performs the basic functions of [a hospital] through the use of employees or under contracts or other agreements with entities other than the hospital occupying space in the same building or on the same campus * * *'' This requirement further states that food and dietetic services, housekeeping, maintenance, among others, could be obtained under contracts or agreements with the co-located hospital. The commenter urged CMS to clarify that the proposed change will not impact a HwH's ability to obtain the necessary services that are allowed under the HwH requirements at 42 CFR 412.22.

Response: We developed the HwH regulations to ensure, to the extent possible, that co-located hospitals (two hospitals occupying space in the same building or in one or more separate buildings located on the same campus) function as two separate entities, each having its own governing body, medical staff, chief medical officer, and chief executive officer. In addition, the HwH has to meet other criteria, including at least one of the criteria specified in § 412.22(e)(1)(v), regarding performance of basic hospital functions. Under the changes to our policy governing services furnished under arrangements that we are finalizing in this final rule, the services that can be furnished to the HwH under § 412.22(e)(1)(v)(A) (food and dietetic services, housekeeping and maintenance, and other services necessary to maintain a clean and safe physical environment) by the host hospital or an entity that controls both hospitals could still be furnished at the hospital (the HwH) to that hospital's patients. Likewise, the provision at § 412.22(e)(1)(v)(A) allowing specified basic functions to be performed at a HwH through the use of employees or under contracts or other arrangements with entities other than the co-located hospital, or through a third entity that controls both hospitals, would only apply where those routine services are furnished at the HwH. If, however, the HwH was moving its patients to another hospital to receive routine services under arrangements with that hospital, and maintaining that patient in hospital records as its own inpatient, it would not be allowed under the changes to the ''hospital services provided under arrangement'' that we are finalizing in this final rule.

Comment: One commenter was concerned with what it characterized as CMS' lack of clarity about why it proposed this change. The commenter recommended that CMS not finalize the proposal until it provides a sufficient policy rationale for the proposal, or explains the circumstances that are causing CMS to be concerned.

Response: As noted above, we became aware that some hospitals were furnishing certain routine services, including ICU services, under arrangement. For example, under certain arrangements, if an inpatient of an IPPS-excluded hospital (''hospital A'') required ICU services, and the IPPS-excluded hospital could not provide these services, the patient was moved to an IPPS hospital (''hospital B'') that could furnish the ICU services. In these situations, the patient was not transferred to hospital B but was moved from an inpatient bed of hospital A to an inpatient bed of hospital B. However, the IPPS-excluded hospital treated these services as being provided under arrangement and included the cost of those services on its cost report. We find it problematic that the patient was, at all times, considered an inpatient of hospital A even though the patient occupied an inpatient bed at hospital B.

Because the two hospitals in the example above are under two different payment systems, we believe this arrangement can result in inappropriate and potentially excessive Medicare payments. The IPPS-excluded hospital, hospital A, is paid on a reasonable cost basis, subject to a ceiling. In most cases, this payment is greater than if the hospital were paid under the IPPS for the same patient. Furthermore, although there is a ceiling on the amount of Medicare payment for hospital A, there are also provisions that allow hospital A to receive adjustments to its ceiling in certain circumstances, which could allow payment to hospital A above those allowed by its ceiling. Therefore, these current arrangements could allow hospital A to request an adjustment to its ceiling because its ICU costs have increased beyond what is allowed. In that case, hospital A would receive additional payments beyond its ceiling. We believe that by limiting the furnishing of routine services under arrangements to situations in which the services are furnished in hospital A, we will reduce the opportunity for gaming. In these more limited situations, hospital A will exercise sufficient control over the use of hospital resources when furnishing these services such that the services are appropriately included in hospital A's cost report.

Under our proposal, if hospital A did not have the resources to treat a patient, it would transfer the patient to hospital B for ICU services, and hospital B would bill Medicare consistent with the IPPS provisions. Hospital A would be paid for an inpatient discharge.

Comment: Numerous commenters believed that CMS' primary goal in proposing to limit the kinds of services that can be provided under arrangement was to ensure that the hospital will exercise professional responsibility over the ''arranged for'' services. Commenters claimed that CMS had provided no evidence that the hospital furnishing the routine or ICU services cannot exercise the same responsibility. Therefore, the commenters claimed that CMS had not provided a sufficient policy rationale in support of the proposal.

Response: Section 207 of the Hospital Manual (Pub. No. 10) states with respect to furnishing services under arrangements, that such arrangements were ''not intended that [the hospital] merely serve as a billing mechanism for the other party * * *.The hospital's professional supervision * * * requires many of the same quality controls as are applied to the services furnished by salaried employees.'' As discussed in more detail above, the current policy may also result in inappropriate and excessive Medicare payments, as well as present an opportunity for gaming, and we believe it is appropriate to limit the inclusion of costs on a cost report to those situations in which the hospital has exercised sufficient control and responsibility over the use of hospital resources in treating patients.

Comment: One commenter cited two recent Medicare initiatives that involve ACOs, the Pioneer ACO Program under

the Innovation Center and the Medicare Shared Savings Program under section 1899 of the Affordable Care Act, as evidence of the Secretary's commitment to high-level efficiency, provider collaboration, and innovative service models which will preserve or enhance quality of care for beneficiaries while promoting greater efficiencies throughout the Medicare program. The commenter noted that the present policy that CMS has proposed to disallow, where a hospital furnishing ICU services ''under arrangements'' to inpatients of another hospital is an existing example of efficient use of medical resources as well as successful provider collaboration that also enhances the level of beneficiary care and therefore, allowing such an arrangement to continue is fully consistent with CMS' stated objectives.

Response: We understand that inter-facility cooperation and collaboration can indeed result in savings for the Medicare program, and we are committed to the specific goals of the CMMI and the Shared Savings Program. However, we do not agree that such positive objectives are applicable to the existing arrangements under which inpatients at one hospital effectively become inpatients at another hospital for as long a time as necessary, without having been discharged from the first hospital and admitted to the second.

Comment: Most commenters requested that CMS, if it finalizes the proposed policy, adopt a grandfathering provision to allow hospitals that have been furnishing routine services under arrangements outside of the hospital to continue furnishing these services in this manner. Commenters stated that this policy would place significant administrative burdens on these hospitals, would be more expensive to the Medicare program, would be inconvenient and disruptive to patients, and would inappropriately inflate readmission rates under the Hospital Readmissions Reduction Program.

Response: We do not believe it is appropriate to adopt a grandfathering provision. As noted above, we are concerned that, without this policy change, Medicare will continue to pay inappropriately for these services. That is, payment to IPPS hospitals should be based on the DRG payment amount, and payment to excluded hospitals should not be based in part on the costs of routine services that the hospital has not furnished directly to its patients.

We do not believe that our proposal would be disruptive or inconvenient to patients; it does not prevent hospitals from transferring patients to another facility to receive necessary services that the transferring hospital cannot provide.

We recognize that, for a few providers, this policy will require the hospital to discharge its patients to the other hospital that will provide the routine/ICU services. However, this is necessary in order to be consistent with our current reading of section 1861(b) of the Act.

We do not believe that a hospital's readmission rates under the Hospital Readmissions Reduction Program would be affected by this policy because transfers to other providers are not included in the calculations of excess readmissions. Each of the measures of readmissions used in the Hospital Readmissions Reduction Program has exclusions for transfers to other hospitals. We discuss these exclusions in section IV.C. of this preamble.

After consideration of the public comments and for the reasons set forth above, we are finalizing our proposal. Therefore, effective for services provided on or after October 1, 2011, if routine services are provided in the hospital to its inpatients, these services are considered as being provided by the hospital. However, if services are provided outside the hospital, the services are considered as being provided under arrangement. Only therapeutic and diagnostic items and services may be furnished under arrangement outside of the hospital.

R. Finalization of Interim Final Rule With Comment Period on Revisions to the Reduction and Increases to Hospitals FTE Resident Caps for Graduate Medical Education Payment Purposes

On March 14, 2011, we issued in the **Federal Register** (76 FR 13515) an interim final rule with comment period that implemented section 203 of the Medicare and Medicaid Extenders Act of 2010 relating to the treatment of teaching hospitals that are members of the same Medicare graduate medical education affiliated groups for the purpose of determining possible full-time equivalent (FTE) resident cap reductions. In this final rule, we are restating a majority of the provisions of the interim final rule with comment period, responding to the public comments we received, and stating our final policy.

1. Background and Provisions of the Interim Final Rule With Comment Period

a. Statutory Authority

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 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 full-time equivalent (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 an additional payment amount 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, known as the indirect medical education (IME) adjustment, 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 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 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 on the FTE resident count for IME purposes is effective for

discharges occurring on or after October 1, 1997.

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. Section 5503 of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals, and to authorize the ''redistribution'' of the estimated number of FTE resident slots to other qualified hospitals. In addition, section 5503 amended section 1886(d)(5)(B)(v) of the Act to require the application of section 1886(h)(8) of the Act provisions ''in the same manner'' as the FTE resident caps for IME. The regulations implementing section 5503 of the Affordable Care Act were included in the Hospital Outpatient Prospective Payment System final rule with comment period, published on November 24, 2010 in the **Federal Register** (75 FR 72147). Section IV.R.1.b. of this final rule summarizes the provisions of section 5503 of the Affordable Care Act as implemented in the November 24, 2010 **Federal Register**.

b. Reductions and Increases to Hospitals' FTE Resident Caps for GME Payment Purposes Under Section 5503 of the Affordable Care Act

As previously discussed, 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 instituted a cap on the number of allopathic and osteopathic residents a hospital is allowed to count for direct GME and IME purposes. Dental and podiatric residents are not included in this statutorily mandated cap. Some hospitals have trained a number of allopathic and osteopathic residents in excess of their FTE resident caps, while other hospitals have reduced their FTE resident counts to some level below their FTE resident caps. Section 5503 of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for reductions in the statutory FTE resident caps for direct GME under Medicare for certain hospitals, and authorizes a ''redistribution'' to hospitals of the estimated number of FTE resident slots resulting from the reductions. Section 5503 of the Affordable Care Act also amended section 1886(d)(5)(B)(v) of the Act to require application of the provisions of section 1886(h)(8) of the Act ''in the same manner'' to the FTE resident caps for IME.

Section 1886(h)(8)(A) of the Act provides that, effective for portions of cost reporting periods occurring on or after July 1, 2011, a hospital's FTE resident cap will be reduced if its ''reference resident level'' is less than its ''otherwise applicable resident limit,'' as these terms are described below. Section 1886(h)(8)(A)(ii) of the Act and the November 24, 2010 **Federal Register** (75 FR 72147) describes which hospitals are exempt from a cap reduction under section 5503 of the Affordable Care Act. Included in that group are rural hospitals with fewer than 250 acute care inpatient beds. For other hospitals, any such reduction will be equal to 65 percent of the difference between the hospital's ''otherwise applicable resident limit'' and its ''reference resident level.''

Under section 1886(h)(8)(B) of the Act, the Secretary is authorized to increase the FTE resident caps for certain categories of hospitals for portions of cost reporting periods occurring on or after July 1, 2011, by an aggregate number that does not exceed the estimated overall reduction in FTE resident caps for all hospitals under section 1886(h)(8)(A) of the Act. A single hospital may receive an increase in its FTE resident cap of no more than 75 additional FTEs. That is, a hospital is allowed to receive up to 75 additional slots for direct GME and up to 75 additional slots for IME. In determining which hospitals will receive an increase in their FTE resident caps, sections 1886(h)(8)(C) through 1886(h)(8)(E) of the Act directs us to do all of the following:

- Take into account the demonstrated likelihood of the hospital filling the additional positions within the first three cost reporting periods beginning on or after July 1, 2011.
- Take into account whether the hospital has an accredited rural training track program.
- Distribute 70 percent of the resident slots to hospitals located in States with resident-to-population ratios in the lowest quartile.
- Distribute 30 percent of the resident slots to hospitals located in a State, a territory of the United States, or the District of Columbia that are among the top 10 States, territories, or the District in terms of the ratio of the total population living in an area designated as a health professional shortage area (HSPA), as of March 23, 2010, to the total population, and/or to hospitals located in rural areas.

A comprehensive description of the rules implementing the cap slot redistribution under section 1886(h)(8) of the Act can be found in the November 24, 2010 **Federal Register** (75 FR 72168).

c. Treatment of Affiliated Groups Under Section 5503 of the Affordable Care Act

A previous redistribution of ''unused'' FTE resident slots was performed in 2005 under section 422 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 422 of the MMA provided for the redistribution of unused residency positions effective for portions of cost reporting periods beginning on or after July 1, 2005. While the redistribution under section 5503 of the Affordable Care Act as initially enacted is similar to the previous redistribution under section 422 of MMA, there are substantive differences between the two provisions. One of those differences involves the treatment of hospitals that were members of the same Medicare GME affiliated groups for purposes of determining whether a hospital should receive a cap reduction. The regulations governing Medicare GME affiliated groups and Medicare GME affiliation agreements are at 42 CFR 413.75(b) and 413.79(f), respectively. Medicare GME affiliation agreements allow teaching hospitals to temporarily transfer cap slots to other hospitals in order to facilitate the cross-training of residents. The duration of the temporary cap slots transfer is a minimum of 1 year beginning on July 1 of a year, per the Medicare GME affiliation agreement.

Under section 422 of MMA, the statute explicitly directed the Secretary to apply the provisions to hospitals that were members of the same Medicare GME affiliated group as of July 1, 2003. Specifically, section 1886(h)(7)(A)(iii) of the Act states ''The provisions of clause (i) shall be applied to hospitals which are members of the same Medicare GME affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) as of July 1, 2003.'' Therefore, in implementing section 422 of MMA, we based the FTE resident cap reductions for hospitals that were participating in a Medicare GME affiliated group on the aggregate cap and count data from all hospitals participating in the same Medicare GME affiliated group(s). If a hospital was training a number of

residents below its FTE resident cap for the reference cost reporting period but the hospital was part of a Medicare GME affiliated group for some or all of that reference cost reporting period, the Medicare contractor determined if the aggregate affiliated count for all hospitals in the Medicare GME affiliated group was greater than the aggregate affiliated cap. If the aggregate affiliated count was greater than the aggregate cap, then there was no reduction made to the FTE caps of any hospital in the Medicare GME affiliated group (even for the hospital that was part of the Medicare GME affiliated group, but was training below its cap).

However, as we noted in the November 24, 2010 **Federal Register** (75 FR 72161), in contrast to section 422 of MMA, section 5503 of the Affordable Care Act as initially enacted did not include language specific to Medicare GME affiliated groups as was included in section 422 of MMA under section 1886(h)(7)(A)(iii) of the Act. Thus, section 5503 of the Affordable Care Act as initially enacted did not provide for determinations based on the aggregate experience of a Medicare GME affiliated group. Therefore, we stated in the November 24, 2010 **Federal Register** (75 FR 72161), that the determination of whether a hospital would receive a cap reduction based on that individual hospital's experience and not the aggregate experience of the Medicare GME affiliated group.

d. Section 203 of the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309)

Section 203 of the Medicare and Medicaid Extenders Act of 2010 (MMEA) further amended section 1886(h)(8) of the Act by adding a new subparagraph (I) which reads: ''(I) Affiliation.—The provisions of this paragraph shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) and the reference resident level for each such hospital shall be the reference resident level with respect to the cost reporting period that results in the smallest difference between the reference resident level and the otherwise applicable resident limit.'' This subparagraph refers to the treatment of hospitals that are members of the same Medicare GME affiliated groups, as described in section IV.R.1.c. of this final rule for purposes of determining a hospital's possible cap reductions under section 1886(h)(8)(A) of the Act. Similar to section 422 of MMA, this amendment to the language at section 1886(h)(8) of the Act allows us to consider hospitals that are members of the same Medicare GME affiliated group in the aggregate, rather than only on an individual basis, for the purposes of determining a GME FTE cap reduction.

Although this amendment allows us to implement section 5503 of the Affordable Care Act in a manner similar to section 422 of MMA, a key difference in implementation remains. One point of note is that section 422 of MMA (section 1886(h)(7)(A)(ii)(I) of the Act) refers to the most recent cost reporting period ending on or before September 30, 2002, as the reference cost reporting period. However, as stated in the August 11, 2004 **Federal Register** (69 FR 49125), if a hospital was a member of a Medicare GME affiliated group for the academic year beginning July 1, 2003, its reference cost reporting period was the cost reporting period that included July 1, 2003. This differs from section 5503 of the Affordable Care Act, which instructs the Secretary to choose the reference cost reporting period out of the hospital's three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been settled or has been submitted to the Medicare contractor by March 23, 2010, that has the *highest* FTE resident count (section 1886(h)(8)(H)(i) of the Act).

For hospitals that were members of the same Medicare GME affiliated groups, the MMEA now allows us to determine the reference cost reporting period as the cost reporting period out of the hospitals three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been settled or has been submitted to the Medicare contractor by March 23, 2010, with the smallest difference between the reference resident level and the otherwise applicable resident limit (section 1886)(h)(8)(I) of the Act). Therefore, based on the amendment made to section 1886(h)(8) of the Act by section 203 of the MMEA of adding subparagraph (I), in the interim final rule with comment period, we established a methodology to determine whether a hospital is subject to a cap reduction under section 5503 of the Affordable Care Act based on that hospital's participation in a Medicare GME affiliated group(s) or an emergency Medicare GME affiliated group under 42 CFR 413.79(f). Although the MMEA provision applies to both regular Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements, for ease of reference, we refer in this discussion to both with the phrase ''Medicare GME affiliation agreements.'' We believe that the purpose of section 203 of MMEA is to amend section 1886(h)(8) of the Act in order to implement section 5503 of the Affordable Care Act in a manner that is similar to section 422 of MMA with regard to treatment of hospitals that are members of the same Medicare GME affiliated group. Accordingly, we are implementing section 203 of the MMEA in a manner similar to the way in which section 422 of MMA was implemented. The methodology used to determine a cap reduction for hospitals that are members of the same affiliated group is as follows:

Part 1: Determine the ''Reference Cost Reporting Period''

The Medicare contractor will assess each hospital on an individual basis. First, the Medicare contractor will determine whether a hospital was a member of a Medicare GME affiliated group at any point during any of the hospital's three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been settled or has been submitted to the Medicare contractor by March 23, 2010. That is, the Medicare contractor will determine whether the caps during any of those three cost reporting periods were revised because the hospital was a member of a Medicare affiliation agreement. If a hospital was not a member of a Medicare GME affiliated group during any of those three cost reporting periods, the Medicare contractor will determine if and by how much that hospital's FTE resident caps should be reduced in accordance with the policy established in the November 24, 2010 final rule (75 FR 72155 through 72168).

If the Medicare contractor determines that a hospital was a member of a Medicare GME affiliated group at any point during *any* of the three most recent cost reporting periods ending before March 23, 2010 for which a cost report has been settled or has been submitted to the Medicare contractor by March 23, 2010, subparagraph (I) of section 1886(h)(8) of the Act applies, and the Medicare contractor will determine a hospital's reference cost reporting period by determining the cost reporting period from the three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been settled or has been submitted to the Medicare contractor by March 23, 2010, that results in the *smallest* difference between the reference resident level and the otherwise applicable resident limit. For example, a hospital with a FYE of December 31 may not be a member of a Medicare GME affiliated group for the

academic years beginning July 1, 2006, 2007, or 2008, but it may be a member of a Medicare GME affiliated group for the academic year beginning July 1, 2005. In the cost reporting period ending December 31, 2006, the months of January through June 2006 would be affected by the July 1, 2005 Medicare GME affiliation agreement. Therefore, in this example, the hospital is indeed a member of a Medicare GME affiliated group at some point, albeit for only a portion of a cost reporting period, during its three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been settled or has been submitted to the Medicare contractor by March 23, 2010 (in this case, these cost reporting periods would include FYE December 31, 2008, FYE December 31, 2007, and FYE December 31, 2006), and as such its reference cost reporting period would be determined as the cost reporting period that results in the *smallest* difference between the reference resident level and the otherwise applicable resident limit. As previously discussed, section 422 of the MMA specified a single time period that would be used for all hospitals that were members of a Medicare GME affiliated group; that is as of July 1, 2003. However, section 5503 of the Affordable Care Act does not specify one cost reporting period, but rather it specifies that the reference cost reporting period is one out of three possible cost reporting periods. For a hospital that was a member of a Medicare GME affiliated group at any point during any of the three applicable cost reporting periods, after determining the cost report that is a hospital's reference cost reporting period based on the cost report that results in the *smallest* difference between the reference resident level and the otherwise applicable resident limit, to determine whether there are any excess slots we believe it is appropriate to consider whether a hospital was a member of a Medicare GME affiliated group as of July 1 of that reference cost reporting period. The hospital may or may not have been a member of a Medicare GME affiliated group during that reference cost reporting period. We do not believe that section 1886(h)(8)(I) of the Act, as added by section 203 of the MMEA, requires that a hospital must be a member of a Medicare GME affiliated group during all 3 cost reporting periods, nor during the year determined to be the reference cost reporting period. Rather, being a member of a Medicare GME affiliated group at some point in only one of the three cost reporting periods warrants that a hospital's reference cost reporting period be determined based on which cost report has the smallest difference between the reference resident level and the otherwise applicable resident limit. To determine if an FTE resident cap reduction is appropriate, if the hospital was a member of a Medicare GME affiliated group as of July 1 in the reference cost reporting period, we will look at the Medicare GME affiliated group in the aggregate, when we determine if the subject hospital has excess capacity for purposes of a reduction under sections 5503 and 203. If the hospital was not a member of a Medicare GME affiliated group as of July 1 in the reference cost reporting period, excess FTEs training at other members of the affiliated group will not be considered for the purposes of a reduction under sections 5503 and 203 and that hospital's FTE resident caps should be reduced in accordance with the policy established for hospitals that are not members of Medicare GME affiliated groups in the November 24, 2010 final rule (75 FR 72155 through 72168). The nature of this determination underscores the fact that reductions to the FTE resident caps of hospitals that are members of Medicare GME affiliated groups must still be made on an individual hospital basis. The following is an example of a reference cost reporting period determination. (For ease of illustration, this example focuses on reductions to the IME FTE resident caps only, but the methodology is the same for reductions to the direct GME FTE resident caps):

Hospital A has a FTE resident cap of 10 FTE residents. Hospital A's three most recent cost reports that have been settled or submitted to the Medicare contractor by March 23, 2010 include cost reporting periods with FYE 12/31/2006, 12/31/2007, and 12/31/2008. During these three cost reporting periods, Hospital A trained 8, 9, and 9 FTE residents, respectively. For the academic years beginning July 1, 2006 and July 1, 2007, Hospital A was not a member of a Medicare GME affiliated group. However, for the academic year beginning July 1, 2008, Hospital A is affiliated with Hospital B and Hospital C. As a result of its Medicare GME affiliation agreement with Hospitals B and C, Hospital A's adjusted cap or otherwise applicable resident limit is 12 for the academic year beginning July 1, 2008. Thus, when determining the reference cost reporting period for Hospital A, the Medicare contractor would compare the resident level for Hospital A with its otherwise applicable resident limit for each of the cost reporting period as indicated below:

- Cost Reporting Period 1 (01/01/2006–12/31/2006): 10 (FTE Resident Cap)—8 (FTE Resident Count) = 2
- Cost Reporting Period 2 (01/01/2007–12/31/2007): 10 (FTE Resident Cap)—9 (FTE Resident Count) = 1
- Cost Reporting Period 3 (01/01/2008–12/31/2008): 11 (Adjusted FTE Resident Cap)—9 (FTE Resident Count) = 2

(Note that although Hospital A received an increase of 2 FTEs, from 10 to 12, under the Medicare GME affiliation agreement for the academic year beginning July 1, 2008, since Hospital A has a 12/31 fiscal year end, the actual cap adjustment is prorated to half of 2, for an increase to its FTE resident cap of 1, equaling 11). In this example, the smallest difference between the reference resident level and the otherwise applicable resident limit for Hospital A is 1, which occurs in the cost reporting period with FYE 12/31/2007. Thus, Hospital A's reference cost reporting period is 01/01/2007–12/31/2007. Note that Hospital A is not a member of a Medicare GME affiliated group during FYE 12/31/07. The implications of this are discussed below.

Part 2: Determine the Applicable Reductions

For a hospital that was a member of a Medicare GME affiliated group at any point during any of its three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been settled or has been submitted to the Medicare contractor by March 23, 2010, once the Medicare contractor determines that hospital's reference cost reporting period (that is, the cost report with the smallest difference between the hospital's FTE resident cap and FTE resident count), the Medicare contractor must then determine if the hospital was a member of a Medicare GME affiliated group *as of the July 1 that occurs during that reference cost reporting period.* If not, and the hospital's FTE resident count was *equal to or exceeded* its FTE resident cap in that reference cost report, no reduction to its FTE resident cap is made and no further steps are necessary. If that hospital's FTE resident count was *less* than its FTE resident cap during that reference cost report, then the Medicare contractor would reduce the FTE resident cap by 65 percent of the difference between the FTE resident cap and the FTE resident count.

If the hospital was a member of a Medicare GME affiliated group *as of the July 1 that occurs during that reference*

cost reporting period, the Medicare contractor will look at the members of the Medicare GME affiliated group for that period in the aggregate, for the purpose of determining a reduction *to the particular hospital's FTE resident cap.* In other words, assuming the Medicare contractor is assessing Hospital X, once it is determined that Hospital X was training residents below its adjusted FTE resident cap as part of a Medicare GME affiliation agreement occurring during Hospital X's reference cost reporting period, the Medicare contractor will treat the hospitals in the Medicare GME affiliated group in the aggregate, *but only for the purpose of determining the reduction to Hospital X's FTE resident cap.* The Medicare contractor will not actually reduce the FTE resident caps of the other hospitals that were affiliated with Hospital X in that year because each hospital is evaluated separately, and it may be that the reference cost reporting periods for the other hospitals may not be the same as Hospital X's reference cost reporting period. (It may be that the reference cost reporting period for another hospital is one in which that hospital was *not* part of a Medicare GME affiliated group, in which case, treatment as a group is not warranted when determining that hospital's FTE cap reduction).

For the hospital that was a member of a Medicare GME affiliated group *as of the July 1 that occurs during that reference cost report,* the Medicare contractor will determine for each hospital in the Medicare GME affiliated group respectively its FTE resident cap and FTE resident count (IME and direct GME separately). The Medicare contractor will add each hospital's FTE resident caps (IME and direct GME separately) to determine the aggregate affiliated FTE resident cap. The contractor will then add each hospital's FTE resident count (IME and direct GME separately) to determine the aggregate affiliated FTE resident count. If the aggregate FTE resident counts are equal to or exceed the aggregate FTE resident caps, no reductions would be made to that particular hospital's FTE resident cap under section 5503 of Affordable Care Act, and no further steps are necessary for that hospital. We emphasize that at this point, the contractor has only determined that *the particular hospital* will not be subject to an FTE resident cap reduction—as the FTE resident cap reduction determination is ultimately one that is done on an individual hospital basis, *at this point the contractor has not made any determinations regarding the status of the other hospitals that are in the same Medicare GME affiliated group as the particular hospital under review.*

However, where the aggregate FTE resident count is below the aggregate FTE resident cap (IME and direct GME separately), a reduction to the particular hospital's FTE resident cap would be necessary. In these cases, for each hospital that is a member of the same Medicare GME affiliated group, the Medicare contractor will determine the following FTE information from the cost report that includes July 1 of the particular hospital's reference cost reporting period:

(1) The ''1996'' FTE resident cap (as adjusted by new programs, if applicable) for the hospital under review—For IME, from Worksheet E, Part A of the Medicare cost report, the sum of lines 3.04 and 3.05. If the hospital's IME FTE resident cap was reduced under section 422 of the MMA, subtract from this sum the amount reported on Worksheet E–3, Part VI, line 13. For direct GME from Worksheet E–3, Part IV of the Medicare cost report, the sum of lines 3.01 and 3.02. If the hospital's direct GME FTE resident cap was reduced under section 422 of the MMA, subtract from this sum the amount reported on Worksheet E–3, Part VI, line 2.

(2) The ''affiliated'' FTE resident cap for the hospital under review assessed—For IME, line 3.07; and for direct GME, line 3.04.

(3) The total number of allopathic and osteopathic FTE residents for the hospital under review—For IME, line 3.08; for direct GME, line 3.05.

(4) The difference between the aggregate ''affiliated'' FTE resident cap and the total FTE resident counts for all of the affiliated hospitals—For IME, **Σ** line 3.08 minus **Σ** (lines 3.04 + 3.05—applicable section 422 reduction amount); and for direct GME, **Σ** line 3.05 minus **Σ** (lines 3.01 + 3.02— applicable section 422 reduction amount).

(5) For IME, for those hospitals whose FTE resident count from line 3.08 is greater than the ''affiliated'' FTE resident cap on line 3.07, indicate ''zero.'' For direct GME, for those hospitals whose FTE resident count from line 3.05 is greater than the ''affiliated'' FTE resident cap on line 3.04, indicate ''zero.'' For IME, for those hospitals whose FTE resident count from line 3.08 is less than the ''affiliated'' FTE resident cap on line 3.07, determine the difference between the hospital's ''affiliated'' FTE resident cap and the hospital's FTE resident count, line 3.08 minus line 3.07. For direct GME, for those hospitals whose FTE resident count from line 3.05 is less than the ''affiliated'' FTE resident cap on line 3.04, determine the difference between the hospital's ''affiliated'' FTE resident cap and the hospital's FTE resident count, line 3.05 minus line 3.04.

(6) For IME and direct GME separately, to determine the total amount by which the FTE resident counts are below the ''affiliated'' FTE resident caps, add the amounts determined under step 5 for all hospitals that trained fewer residents than its ''affiliated'' FTE resident caps.

(7) For IME and direct GME separately, determine a pro rata cap reduction *for the hospital under review* by dividing the hospital's specific amount in step 5 by the total amount for all of those hospitals in step 6, and multiply by the amount in step 4 (that is, (step 5/step 6) × step 4).

(8) For IME and direct GME separately, determine the actual cap reduction *for the hospital under review* by multiplying the pro rata cap reduction from step 7 by 0.65.

(9) For IME and direct GME separately, determine the reduced FTE resident cap *for the hospital under review* by subtracting the actual cap reduction from step 8 from the ''1996'' FTE resident cap from step 1. This is the hospital's FTE resident cap effective July 1, 2011.

The following is an example of how the reductions to the FTE resident caps will be determined where the FTE resident counts in the aggregate for hospitals that were affiliated as of July 1 of the reference cost reporting period for a particular hospital are below the hospitals' FTE resident caps in the aggregate. For ease of illustration, this example focuses on reductions to the IME caps only, but the methodology is the same for reductions to the direct GME caps.

In this example, the Medicare contractor has determined, using the methodology from Step 1, that the reference cost reporting period (the period with smallest difference between the reference resident level and the otherwise applicable resident limit) for Hospital D is January 1, 2007 to December 31, 2007. The academic year that occurs in this reference cost reporting period begins July 1, 2007. Hospitals D, E, and F are members of a Medicare GME affiliated group for the academic year that begins July 1, 2007. Hospital D is also separately affiliated with Hospitals G and H for the academic year that begins July 1, 2007. Thus, the affiliated group for GME payment purposes, and for purposes of determining possible FTE cap reductions for Hospital D under subparagraph (I) consists of Hospitals D, E, F, G, and H. Hospital E's cost report

that includes July 1, 2007 is FYE June 30, 2008. Hospital D's, F's, and G's cost report that includes July 1, 2007 is their FYE December 31, 2007, and Hospital H's cost report that includes July 1, 2007 is its FYE September 30, 2007. Using steps 1 through 9 above, the reduction to the FTE resident caps for Hospital D is determined in the table below.

Hospital	1996 FTE Caps (Step 1)	"Affiliated" FTE Cap (Step 2)	FTE Count (Step 3)	Number of FTEs Below the "Affiliated" Cap (Step 5)	Pro Rata Reduction (Step 7)	Actual Cap Reduction (Step 8)	Final FTE Cap (Step 9)
D	115	90	75	-15	-8	-5.2	109.8
E	80	100	125	0	N/A	N/A	N/A
F	120	10	10	0	N/A	N/A	N/A
G	95	115	125	0	N/A	N/A	N/A
H	30	125	65	-60	N/A	N/A	N/A
Totals	**440**	**440**	**400**	**-75**	**N/A**	**N/A**	**N/A**
		Step 4 →	**-40**	**Step 6** ↑			

In this example, Hospital D's FTE resident count of 75 was 15 less than its ''affiliated'' FTE resident cap of 90, and Hospital H's FTE resident count of 65 was 60 less than its ''affiliated'' FTE resident cap of 125 (as determined under step 5). Hospital F's ''affiliated'' FTE resident cap equaled its FTE resident count. Under this methodology, the fact that Hospitals E and G exceeded their respective ''affiliated'' FTE resident caps minimizes the reductions to Hospital D's ''1996'' FTE resident caps through the calculation of a pro rata reduction under step 7.

We note that although Hospital H is also under its cap; its cap is not reduced in this exercise. Under section 5503, the cap reduction determination is calculated individually for each hospital based on its individual reference cost reporting period, so each hospital would be evaluated for a possible reduction separately. Hospital H will be evaluated separately, and it may be that Hospital H's reference cost report may not be its FYE September 30, 2007 cost report, and ultimately, Hospital H may or may not be subject to an FTE resident cap reduction. Thus, under step 8, the actual cap reduction of 5.2 FTEs for Hospital D is determined by taking 65 percent of 8 (rather than 65 percent of 15). As a result, under step 9, Hospital D's final FTE resident cap effective on July 1, 2011 is determined to be 109.8 FTEs.

We also note that the reduction to Hospital D's ''1996'' FTE resident caps was minimized only because Hospitals E and G exceeded their ''affiliated'' FTE resident caps. If all hospitals in the Medicare GME affiliated group had trained residents below their ''affiliated'' FTE resident caps, a pro rata reduction would not benefit Hospital D. In that case, the ''1996'' FTE resident caps of Hospital D in the Medicare GME affiliated group would be reduced by 65 percent of the difference between its ''affiliated'' FTE resident cap and FTE resident count.

We believe this final policy is similar to the method used to implement section 422 of the MMA with regard to hospitals that were members of the same Medicare GME affiliated group in that, as under section 422 of the MMA, we are only treating a hospital as part of a group if the hospital was a member of a Medicare GME affiliation agreement during its reference cost reporting period under section 1886(h)(8) of the Act. In implementing section 203 of the MMEA in this manner, we believe we have addressed the concerns raised by commenters in response to the August 3, 2010 proposed rule (75 FR 46395) in that this policy could protect hospitals from a loss of slots if the aggregate counts equal to or exceed the ''affiliated''' FTE resident caps, and could limit the loss of slots in the instance where a hospital is a member of a Medicare GME affiliated group and the aggregate counts are below the ''affiliated'' FTE resident caps.

2. Summary of the Provisions of the Interim Final Rule With Comment Period

As stated earlier, in the final rule published in the November 24, 2010 **Federal Register** (75 FR 71800), we implemented section 5503 of the Affordable Care Act, which added a new section 1886(h)(8) to the Act. Section 5503 of the Affordable Care Act provides for reductions in the statutory FTE resident caps for direct GME under Medicare for certain hospitals, and authorizes a ''redistribution'' to hospitals of the estimated number of FTE resident slots resulting from the reductions. Section 5503 of the Affordable Care Act also amended section 1886(d)(5)(B)(v) of the Act to require application of the provisions of section 1886(h)(8) of the Act ''in the same manner'' to the FTE resident caps for IME. Section 1886(h)(8) of the Act requires that any such reduction to the FTE resident caps will be equal to 65 percent of the difference between the hospital's ''otherwise applicable resident limit'' and its ''reference resident level.'' Section 5503 of the Affordable Care Act as initially enacted did not include language specific to Medicare GME affiliated groups and did not provide for FTE resident cap reduction determinations based on the aggregate experience of a Medicare GME affiliated group. Accordingly, section 203 of the MMEA further amended section 1886(h)(8) of the Act to specify that the provisions of section 1886(h)(8) of the Act shall be applied to hospitals which are members of the same Medicare GME affiliated group, and the ''reference resident level'' for each such hospital is the FTE resident count from the cost reporting period that results in the smallest difference between the FTE resident count and the FTE resident cap. In the March 14, 2011 interim final rule with comment period, we implemented section 203 of the MMEA relating to the treatment of teaching hospitals that are members of the same Medicare graduate medical education affiliated groups for the purpose of determining possible full-time equivalent resident cap reductions. We also revised § 413.79(m)(7) of our regulations to

reflect the changes made by section 203 of the MMEA.

3. Summary of Public Comments, Departmental Responses, and Statements of Final Policies

a. Summary of Public Comments and Departmental Responses

Comment: Several commenters supported CMS' interpretation and implementation of section 203 of the MMEA. One commenter believed that CMS has ''very reasonably'' addressed a complex issue, considering that the Affordable Care Act requires that multiple cost reporting periods be referenced to determine possible cap reductions, and the MMEA's intent that CMS consider affiliated group participation in deciding the appropriate level of cap reductions. Commenters stated that they recognized the challenges and complexities of the implementation of section 203 of the MMEA, but that CMS' methodology is reasonable. Given the complexities of implementation, commenters urged CMS to review public comments received on the interim final rule with comment period very carefully and make modifications if necessary.

Response: We appreciate the commenters' support and recognition of our efforts to develop a process that is as fair, reasonable, and intuitive as possible within the statutory guidelines for determining if and by how much the FTE resident caps of hospitals that were members of Medicare GME affiliated groups will be reduced. Likewise, we have made sure that we applied deliberate, thoughtful, and equitable treatment in reviewing and responding to public comments we received on the interim final rule with comment period.

Comment: Commenters suggested that CMS test its methodology for validity because it is difficult to assess such a national policy on hospital-specific reductions. Commenters asked CMS to compare the sum of the cap reductions that result from the methodology in the interim final rule with comment period to the result that would have occurred in the absence of the interim final rule with comment period in order to avoid inappropriate results. Moreover, commenters stated that these checks should be performed for each affiliated group, and for each individual hospital, to ensure that all reductions are not counterintuitive, or that a hospital would not be getting a greater reduction under application of the MMEA methodology, than in the absence of being treated as part of an affiliated group.

One commenter stated that it did not believe it was the expectation of Congress that the inclusion of section 203 within the MMEA would result in only minor changes in the overall results of the reduction determinations made under section 5503 of the Affordable Care Act. Thus, this commenter believed that CMS should implement a ''global check'' to ensure that the resulting reductions applied to all affiliated groups sum to significantly less than would have been the case absent the application of this methodology.

Response: As the commenters have already acknowledged, it was difficult to devise a methodology for applying a pro rata reduction to the FTE resident caps of hospitals that were in Medicare GME affiliated groups during their reference cost reporting period. This is because we had to examine FTE resident caps and counts over a 3-year period, not under a single one as under section 422 of the MMA, and account for the fact that, for hospitals in Medicare GME affiliated groups, FTE resident caps and counts could vary over those 3-year periods. Determining if and when to apply section 203 of the MMEA at the individual hospital level or at the affiliated group level was somewhat challenging. Nevertheless, given the fluid dynamics of Medicare GME Affiliated groups that result from sharing FTE resident caps and resident rotations, we understood that under any mathematical formula that could be applied, there could be the potential for unexpected results and unintended consequences. In recognition of this challenge, we, in conjunction with the Medicare contractors, made sure that in each instance that the pro rata reduction was applied, the FTE resident cap reduction to an affiliated hospital was *less than* the reduction that it would have received in the absence of the section 203 of the MMEA and being treated as part of a Medicare GME affiliated group. In other words, in all cases, we made sure that each affiliated group and each hospital only benefited from treatment as a group. Furthermore, we also ensured that if an FTE resident cap reduction was warranted at the individual hospital level, no other hospital in the affiliated group was negatively impacted by the pro rata reduction that occurred to an individual hospital. That is, because, as we explained in the interim final rule with comment period (76 FR 13518 and 13519), the Medicare contractor was to assess each hospital and ultimately make an FTE resident cap reduction on an individual basis, other hospitals in the Medicare GME affiliated group whose FTE resident counts exceeded their applicable FTE resident caps during their reference cost reporting periods would not be receiving FTE cap reductions, and would not be impacted.

Comment: One commenter asked CMS to clarify the impact on the redistribution of ''unused'' IME cap slots when a Medicare GME affiliated group includes a hospital that reports and receives only direct GME reimbursement (for example, a children's or cancer hospital). The commenter stated that because the residents would likely qualify for IME payments at an IPPS hospital, it would seem inappropriate to reduce the aggregate IME cap of the affiliated group simply because IME slots were being used by a non-IME hospital. (The commenter also noted that, with regard to HRSA's Children's GME Payment Program (CHGME), HRSA advised children's hospitals receiving cap slots under a Medicare GME Affiliation Agreement with an IPPS hospital to share only the direct GME cap and not the IME cap.)

Response: Because children's hospitals are excluded from payment under the IPPS under section 1886(d) of the Act, they do not receive IME payment and they do not have IME FTE caps for Medicare purposes. ''IME caps'' that have been assigned to children's hospitals under HRSA's CHGME program have no bearing on Medicare payment. Children's hospitals with approved medical residency training programs only receive direct GME payments from Medicare and, therefore, only have direct GME FTE resident caps. Therefore, when a children's hospital is part of a Medicare GME affiliation agreement with an IPPS hospital, while direct GME FTE resident cap slots may be transferred between the two facilities, the amount entered for the IME FTE resident cap slots should be ''zero'' or ''not applicable.'' (We note that the same is true for teaching IRFs or IPFs that affiliate with IPPS hospitals. The IME teaching adjustment under the IRF PPS and the IPF PPS has no bearing on the IPPS, and should not be reflected in Medicare GME affiliation agreements).

We disagree with the commenter who believed that we are reducing the aggregate IME cap of the affiliated group simply because IME slots are being used by a hospital that does not receive payment under the IPPS. Rather, we believe that under section 5503 of the Affordable Care Act, the FTE resident caps of hospitals, affiliated or not, are being reduced in the instance where there is *excess capacity* between the

hospital's FTE resident cap and FTE resident count. If, under the Medicare GME affiliation agreement, an IPPS hospital sends FTE slots and residents to a children's hospital, only direct GME FTE slots are being transferred. IME slots remain with the IPPS hospital, and if they are not actually being used by the IPPS hospital, there is excess IME capacity. Thus, if, in the Medicare GME affiliated group as a whole, the aggregate IME FTE resident cap exceeds the aggregate IME FTE resident count (that is, there is excess capacity), whether or not a children's hospital is one of the hospitals in the affiliated group, one or more of the hospitals in that affiliated group will ultimately be subject to a reduction to its FTE resident cap. (Because a children's hospital has no IME cap, it will obviously not be the hospital subject to the IME FTE resident cap reduction.)

Comment: One commenter asked CMS to confirm that the ''actual cap reduction'' cannot exceed the ''1996'' FTE cap for a hospital that was a member of a Medicare GME affiliated group during their reference cost reporting period. Specially, the commenter asked for confirmation that a hospital with a ''1996'' FTE cap of zero would never have an FTE cap reduction. The commenter stated that they assumed no hospital would be assigned a negative ''final FTE cap'' effective July 1, 2011.

Response: The commenter is correct that an FTE resident cap reduction under section 5503 of the Affordable Care Act, consistent with section 422 of the MMA, cannot exceed the amount in a hospital's 1996 FTE resident cap (including applicable add-ons for new programs under § 413.79(e) of the regulations). Further, an FTE resident cap cannot be reduced below zero, nor would an FTE resident cap that is already zero be further reduced.

Comment: Commenters reiterated that it is Congress' position that only unused slots be removed from hospitals subject to section 5503 of the Affordable Care Act and, therefore, asked CMS to consider the most recent cost reporting data available, specifically from the academic year 2010, in the implementation of section 5503. These commenters asserted that section 203 of the MMEA applies to ''hospitals which are members of the same affiliated group (emphasis added),'' and that it is effective ''as if included in the enactment of section 5503(a)'' of the Affordable Care Act. The commenters stressed that the statute did not state that the provision pertains to ''hospitals that *were* members of the same affiliated group.'' The commenters argued that ''without explanation,'' the interim final rule with comment period applies the protections of the MMEA only to those hospitals that were affiliated *prior* to the 2010 academic year, which is contrary to the plain reading of the statute. Rather, the commenters believed that a hospital that was in an affiliated group on the date the ACA was enacted is entitled to protection under the MMEA.

Response: We disagree with the commenters that the plain reading of the statute requires that the protections of the MMEA regarding being a member of a Medicare GME affiliated group be applied to hospitals that ''are'' members of the same affiliated group ''as of the date of enactment'' (that is, March 23, 2010) because the MMEA is effective ''as if included in the enactment of section 5503(a)'' of the Affordable Care Act. Rather, we believe that the plain reading of the language that section 203 of the MMEA is effective ''as if included in the enactment of section 5503(a)'' of the Affordable Care Act means that (1) the provisions of section 5503 should be applied to affiliated hospitals (that is, consideration as a group should be given, not only at the individual hospital level), and (2) for these affiliated hospitals, the reference resident level for each such hospital shall be the reference resident level with respect to the cost reporting period that results in the smallest difference between the reference resident level and the otherwise applicable resident limit. Section 203 of the MMEA did not in any way make any changes to the Affordable Care Act timeframe of the reference cost reporting periods. Rather, section 203 of the MMEA only stated that, for a hospital that is part of a Medicare GME affiliated group, that reference period should be the one that results in the smallest difference between the FTE resident cap and the FTE resident count. As a result, even for hospitals that are affiliated, their reference cost reporting period would be chosen from the very same reference cost reporting periods as nonaffiliated hospitals; that is, any of the three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been settled or has been submitted to the Medicare contractor by March 23, 2010. Therefore, the fact that a hospital was affiliated as of March 23, 2010, has no bearing on the choice of the reference cost reporting period. Because the MMEA did not revise the rule regarding the timeframe for the reference cost reporting periods, the hospital's cost report for its academic year 2010 cannot be used as the hospital's reference cost reporting period.

Comment: Commenters made the following suggestions on how CMS should properly implement section 203 of the MMEA:

(1) Consistent with the method that CMS initially proposed for implementing the provision for affiliated hospitals under section 422 of the MMA, use the adjusted FTE cap from the Medicare GME affiliation agreement in effect for academic year 2010, while determining the FTE count from whichever cost reporting period CMS would otherwise use.

(2) Use the adjusted FTE cap and the FTE count from a cost reporting period that at least partially overlaps academic year 2010. For a hospital with a December 31 fiscal year end, this period would be its fiscal year 2009 cost reporting period. The commenter also stated that where the adjusted FTE caps for those earlier periods is favorable to hospitals; it had no objection to CMS' exercise of its discretion to use those earlier period adjusted FTE caps in its FTE cap reduction calculation. However, for hospitals that were in an affiliated group only in academic year 2010, the commenter asserted that the legislation requires that CMS take the corresponding agreement into account in its calculations.

(3) Allow the hospital to show that it has slots approved within the past 3 years that remained unfilled, accounting for at least 5 percent of the hospital's unadjusted 1996 FTE caps;

(4) Consider whether the hospital has evidence of cross-training activities in years prior to academic year 2010. In the commenter's case, the commenter alleged that two hospitals had been ''training partners since 2006,'' but as a result of a ''mere oversight,'' they had not entered into a Medicare GME affiliation agreement until July 1, 2009. The commenter asserted that ''nothing about the joint training, however, could be characterized as a 'rushed attempt to avoid a cap reduction.' ''

Response: In response to the commenters' first recommendation, the portion of section 422 of the MMA that is relevant to hospitals that were part of a Medicare GME affiliated group is implemented at section 1886(h)(7)(A)(iii) of the Act, which states, ''the provisions of clause (i) shall be applied to hospitals which are members of the same affiliated group * * * as of July 1, 2003.'' As we explained in the August 11, 2004 final rule (69 FR 49126), ''we proposed to interpret clause (i) to mean that the Secretary is to use a hospital's July 1, 2003 'affiliated' FTE resident cap as the otherwise applicable FTE resident cap when determining a possible reduction

to the FTE resident cap. In other words, if a hospital is affiliated as of July 1, 2003, we proposed to superimpose the 'affiliated' FTE resident cap onto the hospital's reference cost reporting period * * * If a hospital is part of a Medicare affiliated group for the program year beginning July 1, 2003, we are proposing to compare the hospital's July 1, 2003 'affiliated' FTE resident cap to its resident level on the most recent cost report ending on or before September 30, 2002.''

We did not finalize this approach under the MMA because we received public comments that opposed this approach and ''expressed great concern regarding the proposed methodology whereby a hospital's 'affiliated' FTE resident cap for the period July 1, 2003 to June 30, 2004 would be compared to the hospital resident FTE counts corresponding to a different (in some cases, not even overlapping) period for purposes of section 422'' (69 FR 49128). Those commenters stated that CMS should provide the most straightforward option and that ''it would not 'make sense' to reduce the FTE resident cap of a hospital based on a comparison of its cap in an affiliation agreement that was from a period different than its reference cost reporting period. Therefore, most commenters generally recommended that each hospital's specific July 1, 2003 'affiliated' FTE resident cap should be compared to its FTE resident count for the July 1, 2003 through June 30, 2004 academic year, while one commenter recommended that CMS allow each hospital to elect whether to have its specific July 1, 2003 'affiliated' FTE resident cap compared to its FTE resident count for the [cost reporting] period July 1, 2003 to June 30, 2004, for purposes of determining if and by how much the hospital's FTE resident caps would be reduced'' (69 FR 49128).

As we acknowledged when we implemented section 422 of the MMA, hospitals either benefit or are disadvantaged somewhat in each instance that Congress chooses a base year or years for purposes of determining future payments (69 FR 49129). Similarly, for section 5503 of the Affordable Care Act, Congress clearly specified the base years, and the public has been given notice since November 24, 2010, that they consist of the three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been settled or submitted to the Medicare contractor by March 23, 2010. We strove to implement section 422 of the MMA in the fairest and most reasonable manner, and we are making every effort to implement section 5503 of the Affordable Care Act consistently with section 422 whenever feasible. We believe it is certainly reasonable to conclude that just as many commenters opposed our original proposal under section 422 to superimpose the adjusted affiliated FTE resident cap from the affiliation agreement ''as of July 1, 2003'' onto an earlier reference cost report, many commenters would again oppose and reject a final similar policy under section 5503. Therefore, in the case of section 203 of the MMEA, we believe it would be inappropriate to adopt the position of a small number of commenters suggesting that we compare an FTE resident cap that applies to a later Medicare GME affiliation agreement to an FTE resident count from an earlier cost reporting period.

While the commenters' suggested method in the instant case would help a particular hospital, because under the July 1, 2009 affiliation agreement the commenters mentioned, this hospital happened to have *given away* slots, thereby reducing its adjusted FTE resident caps, this method could adversely affect other hospitals that were *receiving* slots under the July 1, 2009 affiliation agreement. Therefore, we are not adopting the commenters' suggestion regarding use of the adjusted FTE cap from the Medicare GME affiliation agreement in effect for academic year 2010, while determining the FTE count from whichever cost reporting period CMS would otherwise use.

We do not agree with the commenters' second suggestion to use the adjusted FTE resident cap and the FTE resident count from a cost reporting period that at least partially overlaps the July 1, 2009–June 30, 2010 academic year because this could result in use of a reference cost report that does not comport with the statutory requirement to use one of the three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been settled or has been submitted to the Medicare contractor by March 23, 2010. As the commenters even noted, for a hospital with a December 31 fiscal year end, this period would be its fiscal year 2009 cost reporting period. However, that cost report would not likely have been submitted to the Medicare contractor by March 23, 2010. The commenters stated that they have no objection to the use of an earlier cost reporting period where the adjusted FTE caps for those earlier periods are favorable to a hospital. However, we do not believe it is appropriate to institute a policy where hospitals may pick and choose which cost reporting period would be most favorable to them to use as the reference cost reporting period. As we stated in response to a comment in the November 24, 2010 final rule (75 FR 72160), ''* * * we do not believe it would be appropriate to include in the determination of which cost reports are used to establish a hospital's reference resident level, those cost reporting periods that occurred at the time the Affordable Care Act was in development. Rather the cost reporting period used to determine the reference resident level should be a cost reporting period that reflects a number of FTE residents that a hospital is accustomed to training, not a number of FTE residents that is based on a hospital's rushed attempt to avoid a cap reduction.''

Regarding the commenters' third recommendation, there is no skirting the issue that there are still unfilled slots. We do not have the authority to waive cap reductions for any excess capacity, even for hospitals that may demonstrate that they have been or are consistently filling almost all of their FTE slots. Regarding the fourth recommendation, we do not believe there is any validity to considering whether a hospital had evidence of cross-training activities in years prior to the July 1, 2009–June 30, 2010 academic year. Evidence of cross-training does not equate to an actual, formal Medicare GME affiliation agreement in which responsible representatives of each hospital agree to exchange FTE resident cap slots. Rather, in accordance with the long-standing regulations regarding Medicare GME affiliation agreements at section 413.79(f)(1), a formal agreement must be submitted to CMS and the Medicare contractor by July 1 of an academic year in order to effectuate the transfer of FTE slots. We cannot deem hospitals to be affiliated simply because cross-training occurred. Accordingly, we are not adopting the commenters' third and fourth suggestions either.

Comment: Commenters stated that CMS should not be resistant to changing its policy as expressed in the interim final rule with comment period out of a concern that doing so would violate the ''logical outgrowth'' doctrine. The commenters asserted that their comments addressed the ''exact same'' subject-matter as that addressed in the interim final rule with comment period, namely implementing section 203 of the MMEA for hospitals that are members of an affiliated group. Although CMS did not make any proposals pertaining to the use of academic year 2010 Medicare GME affiliation agreements in the interim final rule with comment period, the commenter stated that CMS should have done so as part of ''proper

rulemaking.'' Further, the commenters asserted that CMS should have recognized that members of an affiliated group in academic year 2010 are entitled to the protections of the statute; therefore, CMS cannot use its flawed, incomplete analysis as a basis for rendering its final implementation decisions deficient as well. In addition, the commenters argued that CMS has taken latitude in prior rules and in implementing a similar provision in the MMA, where CMS made major changes between its proposed rule and final rule concerning cap reductions for affiliated providers. Lastly, the commenters understood that CMS is unlikely to apply changes made at this juncture to its calculation of the pool of slots to be reallocated and as such, there are no affected parties meriting protection under the logical outgrowth doctrine. Therefore, based on these arguments, commenters expect CMS to furnish a legal memorandum that addresses why it is legally impossible for CMS to revise its interim final rule with comment period.

Response: Contrary to the commenters' assumption, we are not concerned about logical outgrowth as we do believe that the commenters' comments are within the scope of the interim final rule with comment period on determination of possible FTE cap reductions for hospitals that are members of a Medicare GME affiliated group. Rather, we disagree with the commenters' arguments both on statutory and policy grounds, as explained in response to the same commenters' comments above. (For example, we disagree with the commenters on what the plain reading of the language at section 203 of the MMEA is, and we disagree with the commenters that it would be appropriate to include in the determination of which cost reports are used to establish a hospital's reference resident level, those cost reporting periods that occurred at the time the Affordable Care Act was in development). Therefore, we are not accepting the commenters' recommendations and are finalizing the methodology for determining if and by how much the FTE resident caps of hospitals in Medicare GME affiliated groups are to be reduced, as expressed in the interim final rule with comment period (76 FR 13515).

Comment: Commenters urged CMS to allow hospitals to provide updated FTE count data to CMS, given the severity of the consequences of the reductions. Commenters stated that CMS has given its contractors until December 31, 2011, to finalize their FTE cap reduction audits so there is sufficient time to review any data that hospitals may furnish them regarding their actual FTE counts for the cost reporting periods at issue.

Response: If, by allowing hospitals to provide ''updated'' FTE count data, the commenters mean that hospitals should be allowed to provide FTE count data from cost reporting periods *after* the three applicable reference cost reporting periods, as we stated above, we do not believe it would be appropriate to include in the determination of which cost reports are used to establish a hospital's reference resident level, those cost reporting periods that occurred at the time the Affordable Care Act was in development. In response to the commenters' assertion that because CMS has given its contractors until December 31, 2011, to finalize FTE cap reduction audits, there is sufficient time for the contractors to review data regarding actual FTE counts, as we explained in the November 24, 2010 final rule (75 FR 72154), this provision regarding audits continuing until December 31, 2011, was intended to be used only under certain limited circumstances. Specifically, we explained that ''there may be instances where the *audits of the reference resident levels* may not be completed by July 1, 2011, and that, within *the scope of their normal audit work,* the Medicare contractors will complete as many of these audits as possible, and some of the audits may not be completed until December 31, 2011'' (emphasis added) (75 FR 72154). Thus, the intent was not to require the Medicare contractors to perform lengthy and protracted reviews specifically for the purpose of implementing section 5503, nor to allow hospitals to present additional FTE resident count data in all instances. Rather, only if additional FTE resident count data was required by and presented to the contractor *within the scope of the contractor's normal audit work,* and that normal audit work would not be completed by July 1, 2011, it would be permissible for the audit work to proceed until December 31, 2011. Therefore, as implemented, the estimate of slots available for redistribution that CMS determined prior to July 1, 2011, would be relatively close to the number of available slots that would be determined based on the final audited data. If we were to allow all hospitals to revise their cost report data and delay all decisions until December 31, 2011, the estimated number of slots available for redistribution would be rendered completely meaningless.

Comment: Commenters expressed general dissatisfaction with caps on resident FTEs because they believed the caps are outdated. One commenter expressed dissatisfaction that urban teaching hospitals in several states were unjustly excluded from receiving resident slots under section 5503 of the Affordable Care Act.

Response: We thank the commenters for these comments, but note that they are not within the scope of the interim final rule with comment period.

b. Final Policies

After consideration of the public comments we received, we are finalizing all of the provisions set forth in the March 14, 2011 interim final rule with comment period, including the revision of § 413.79(m)(7) of the regulations, without modification.

4. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

(44 U.S.C. Chapter 35)

5. Regulatory Impact Statement

a. Statement of Need

We need to issue a document that will finalize the provisions of the March 14, 2011 interim final rule with comment period, including the regulatory provisions under 42 CFR 413.79(m)(7).

b. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (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 Order 12866 directs 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more

in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

In the November 24, 2010 final rule which implemented section 5503 of the Affordable Care Act (75 FR 72239), we mentioned that we were unable to project how many FTE resident slots will be available for redistribution under section 5503 of the Affordable Care Act. Unlike section 422 of the MMA, which also provided for a redistribution of FTE resident slots but provided that the redistributed slots will be paid using the national average per resident amount (PRA) for direct GME payment purposes, section 5503 of the Affordable Care Act requires that hospitals be paid for their additional FTE resident slots using the hospitals' specific PRAs. Because we had not yet determined the number of FTE resident slots that will be redistributed under section 5503 of the Affordable Care Act or which hospitals will be receiving additional FTE resident slots, we could not calculate a direct GME impact for section 5503 of the Affordable Care Act. Similarly, we cannot calculate a direct GME dollar impact for section 203 of the MMEA.

Because the general effect of section 203 of the MMEA is to protect from loss or mitigate the loss of slots of hospitals that are members of a Medicare GME affiliated group, there are fewer direct GME and IME slots available for redistribution to other hospitals. However, we are unable to compute a dollar impact on the redistribution of those slots to other hospitals. First, although there are currently 307 hospitals that are members of a Medicare GME affiliated group, these hospitals were not necessarily members of Medicare GME affiliated groups during the reference cost reporting periods specified by section 5503 of the Affordable Care Act. Second, since, as of this date, final determinations have not been made with regard to the number of slots that all affected hospitals will be losing or receiving, we cannot determine a financial impact for purposes of direct GME and IME for this provision.

In the interim final rule with comment period, we solicited public comment on our analysis. We did not receive any public comments specific to this impact.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most physician practices, hospitals and other providers are small entities, either by nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of less than $7.0 to $34.5 million in any 1 year). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's Web site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13.*

Individuals and States are not included in the definition of a small entity.

The RFA requires an agency to prepare an initial regulatory flexibility analysis when they issue a general notice of proposed rulemaking. However, HHS has maintained a longstanding policy of voluntarily preparing initial regulatory flexibility analyses for all rulemaking. The Secretary has determined that this final rule will not have 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

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 2011, that threshold is approximately $136 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because this rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

c. Anticipated Effects

We believe the general effect of section 203 of the MMEA is that it could protect from loss or mitigate the loss of slots for hospitals that are members of a Medicare GME affiliated group, and therefore, there could be fewer direct GME and IME slots available for redistribution to other hospitals.

d. Alternatives Considered

Although there may be alternatives, the method we are finalizing in this final rule is the most consistent with that of a similar provision for hospitals that are members of Medicare GME affiliated groups implemented as part of section 422 of the MMA.

e. Conclusion

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis as well as a regulatory impact analysis. For the reasons outlined in the RIA, we are not preparing an analysis for either the RFA or section 1102(b) of the Act because we have determined that this final rule will not have a direct significant economic impact on a substantial number of small entities or a direct significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

6. Comment on Issues Outside of the Scope of the Interim Final Rule With Comment Period

We received one comment regarding nuyrsing and allied health pass-through payments. This comment is outside of the scope of the interim final rule with comment period. Therefore, we are not responding to is in this final rule.

V. Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services ''in accordance with a prospective payment system established by the Secretary.'' Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs 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 xpayment 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, currently 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).

B. Exception Payments

The regulations at § 412.348(f) provide that 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. This policy was originally established for hospitals during the 10-year transition period, but as we discussed in the FY 2003 IPPS final rule (67 FR 50102), we revised the regulations at § 412.312 to specify that payments for extraordinary circumstances are also made for cost reporting periods after the transition period (that is, cost reporting periods beginning on or after October 1, 2001). 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).

During the transition period, under §§ 412.348(b) through (e), eligible hospitals could receive regular exception payments. These exception payments guaranteed a hospital a minimum payment percentage of its Medicare allowable capital-related costs depending on the class of the hospital (§ 412.348(c)), but were available only during the 10-year transition period. After the end of the transition period, eligible hospitals can no longer receive this exception payment. However, for a certain period after the transition period, eligible hospitals may receive additional payments under the special exceptions provisions at § 412.348(g), which guarantees all eligible hospitals a minimum payment of 70 percent of its Medicare allowable capital-related costs provided that special exceptions payments do not exceed 10 percent of total capital IPPS payments. Hospitals eligible for special exceptions payments are required to submit documentation to the fiscal intermediary or MAC indicating the completion date of their project. Special exceptions payments may be made only for the 10 years from the cost reporting year in which the hospital completes its qualifying project, and the hospital must have completed the project no later than the hospital's cost reporting period beginning before October 1, 2001. Thus, an eligible hospital may receive special exceptions payments for up to 10 years beyond the end of the capital IPPS transition period. Under this limitation on the period for special exceptions payments at § 412.348(g)(7) of the regulations, FY 2012 is the final year hospitals can receive special exceptions payments. (For more detailed information regarding the special exceptions policy under § 412.348(g), we refer readers to the FY 2002 IPPS final rule (66 FR 39911 through 39914) and the FY 2003 IPPS final rule (67 FR 50102).)

C. New Hospitals

Under the IPPS for capital-related costs, § 412.300(b) of the regulations defines a new hospital as a hospital that has operated (under current or previous ownership) for less than 2 years. For example, the following hospitals are not considered new hospitals: (1) A hospital that builds new or replacement facilities at the same or another location, even if coincidental with a change of ownership, a change in management, or a lease arrangement; (2) a hospital that closes and subsequently reopens; (3) a hospital that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years; and (4) a hospital that changes its status from a hospital that is excluded from the IPPS to a hospital that is subject to the capital IPPS. For more detailed information, we refer readers to the FY 1992 IPPS final rule (56 FR 43418). During the 10-year transition period, a new hospital was exempt from the capital IPPS for its first 2 years of operation and was paid 85 percent of its reasonable costs during that period. Originally, this provision was effective only through the transition period and, therefore, ended with cost reporting periods beginning in FY 2002. Because, as discussed in the FY 2003 IPPS final rule (67 FR 50101), we believe that special protection to new hospitals is also appropriate even after the transition period, we revised the regulations at § 412.304(c)(2) to provide that, for cost reporting periods beginning on or after October 1, 2002, a new hospital (defined under § 412.300(b)) is paid 85 percent of its Medicare allowable 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 2003 IPPS final rule (67 FR 50101 through 50102) for a detailed discussion of the special payment provisions for new hospitals under the capital IPPS after the 10-year transition period.)

D. 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.

Prior to FY 1998, hospitals in Puerto Rico were paid a blended capital IPPS rate that consisted of 75 percent of the capital IPPS Puerto Rico specific rate and 25 percent of the capital IPPS Federal rate. However, effective October 1, 1997 (FY 1998), in conjunction with the change to the operating IPPS blend percentage for hospitals located in Puerto Rico required by section 4406 of Public Law 105–33, we revised the methodology for computing capital IPPS payments to hospitals in Puerto Rico to be based on a blend of 50 percent of the capital IPPS Puerto Rico rate and 50 percent of the capital IPPS Federal rate. Similarly, in conjunction with the change in operating IPPS payments to hospitals located in Puerto Rico for FY 2005 required by section 504 of Public Law 108–173, we again revised the methodology for computing capital IPPS payments to hospitals located in Puerto Rico to be based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS

Federal rate effective for discharges occurring on or after October 1, 2004.

E. Changes for FY 2012: MS–DRG Documentation and Coding Adjustment

1. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize patient severity of illness in Medicare payment rates. Adoption of the MS–DRGs resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, there are 747 MS–DRGs, and for FY 2012, we are adopting 4 additional MS–DRGs (for a total of 751 MS–DRG). By increasing the number of DRGs and more fully taking into account patient severity of illness in Medicare payment rates, the MS–DRGs encourage hospitals to change their documentation and coding of patient diagnoses. In that same final rule with comment period (72 FR 47183), we indicated that we believe 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 changes in documentation and coding. Accordingly, we established adjustments to both the national operating standardized amount and the national capital Federal rate to eliminate the estimated effect of changes in documentation and coding resulting from the adoption of the MS–DRGs that do not reflect real changes in case-mix. 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. However, to comply with section 7(a) of Public Law 110–90, enacted on September 29, 2007, in a final rule published in the **Federal Register** on November 27, 2007 (72 FR 66886 through 66888), we modified the documentation and coding adjustment for FY 2008 to −0.6 percent, and consequently revised the FY 2008 IPPS operating and capital payment rates, factors, and thresholds accordingly, with these revisions effective October 1, 2007.

For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent instead of the −1.8 percent adjustment established in the FY 2008 IPPS final rule with comment period. As discussed in the FY 2008 IPPS final rule with comment period (72 FR 48447 and 48733 through 48774), we applied an additional documentation and coding adjustment of −0.9 percent to the FY 2009 IPPS national standardized amounts and the national capital Federal rate. The documentation and coding adjustments established in the FY 2009 IPPS final rule, as amended by Public Law 110–90, are cumulative. As a result, the −0.9 percent documentation and coding adjustment in FY 2009 was in addition to the −0.6 percent adjustment in FY 2008, yielding a combined effect of −1.5 percent. (For additional details on the development and implementation of the documentation and coding adjustments for FY 2008 and FY 2009, we refer readers to section II.D. of this preamble and the following rules published in the **Federal Register**: August 22, 2007 (72 FR 47175 through 47186 and 47431 through 47432); November 27, 2007 (72 FR 66886 through 66888); and August 19, 2008 (73 FR 48447 through 48450 and 48773 through 48775).)

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24092 through 24101), we presented the results of a retrospective evaluation of the FY 2008 data for claims paid through December 2008. We sought public comment on our methodology and analysis and our proposal to apply a prospective adjustment to address the effect of documentation and coding changes unrelated to changes in real case-mix in FY 2008. In addition, we sought public comment on addressing in the FY 2011 rulemaking cycle any effect of documentation and coding changes that do not reflect real changes in case-mix for discharges occurring during FY 2009. However, after consideration of the public comments received on the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, consistent with the application of the documentation and coding adjustment to the operating IPPS standardized amounts, we determined that it would be appropriate to postpone the adoption of any additional documentation and coding adjustments to the capital IPPS rates until a full analysis of FY 2009 case-mix changes could be completed (74 FR 43926 through 43928).

For the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24014), we performed a thorough retrospective evaluation of the most recent available claims data, and the results of this evaluation were used by our actuaries to determine any necessary payment adjustments beyond the cumulative −1.5 percent adjustment that has already been applied to the national capital Federal rate to ensure budget neutrality for the implementation of MS–DRGs. Specifically, we performed a retrospective evaluation of the FY 2009 claims data updated through December 2009 using the same analysis methodology as we did for FY 2008 claims in the FY 2010 IPPS/RY 2010 LTCH PPS proposed and final rules. Based on this evaluation, our actuaries determined that the implementation of the MS–DRG system resulted in a 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. We also noted our intent to update our analysis with FY 2009 data on claims paid through March 2009 (sic) for the FY 2011 IPPS/LTCH PPS final rule. (We note that the March 2009 update date for claims paid data in the proposed rule should have stated March 2010.)

As intended, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50355), we updated our analysis with FY 2009 data on claims paid through March 2010 in that final rule. For the FY 2011 IPPS/LTCH PPS final rule, applying the same analysis methodology as we did for the proposed rule to an FY 2009 claims data updated through March 2010 verified the 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. The 5.4 percent estimate of the cumulative effect of changes in documentation and coding under the MS–DRG system that did not reflect real changes in case-mix for FYs 2008 and 2009 exceeded the cumulative −1.5 percent prospective documentation and coding adjustment that had already been applied to the national capital Federal rate by 3.9 percentage points (5.4 percent minus 1.5 percent). Therefore, in FY 2011, an additional cumulative adjustment of −3.9 percent to the national capital Federal rate would be necessary to eliminate the full effect of the documentation and coding changes due to the adoption of the MS–DRGs on future payments.

Therefore, in that same final rule, under the Secretary's broad authority under section 1886(g) of the Act, consistent with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, we implemented an adjustment to the FY 2011 national capital Federal rate of −2.9 percent to account for part of the effect of the estimated changes in documentation and coding changes under the MS–DRG system that occurred in FYs 2008 and 2009 that did not reflect real changes in case-mix. We also established that we will leave the −2.9 percent adjustment in place for subsequent fiscal years to account for the effect of that documentation and coding change in

subsequent years. Furthermore, we stated our intention to address the remaining estimated adjustment to the national capital Federal rate of −1.0 percent (that is, the estimated effect of documentation and coding changes under the MS–DRG system of −5.4 percent minus the existing −0.6 percent and −0.9 percent adjustments and the −2.9 percent adjustment for FY 2011) in future rulemaking cycles.

2. Prospective MS–DRG Documentation and Coding Adjustment to the National Capital Federal Rate for FY 2012 and Subsequent Years

As we stated in the FY 2012 IPPS/LTCH PPS proposed rule, we continue to believe that it is appropriate to make adjustments to the capital IPPS rates to eliminate the effect of any documentation and coding changes as a result of the implementation of the MS–DRGs. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 accurately reflected the changes due to documentation and coding that occurred in those years. As noted in section V.A. of the preamble of the proposed rule and this preamble, under section 1886(g) of the Act, the Secretary has broad authority in establishing and implementing the IPPS for acute-care hospital inpatient capital-related costs (that is, the capital IPPS). 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. Accordingly, we believe that it is appropriate under the Secretary's broad authority under section 1886(g) of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, to make adjustments to the national capital Federal rate to eliminate the full effect of the documentation and coding changes resulting from the adoption of the MS–DRGs. We believe that this is appropriate because, in absence of such adjustments, the effect of the documentation and coding changes resulting from the adoption of the MS–DRGs results in inappropriately high capital IPPS payments because that portion of the increase in aggregate payments is not due to an increase in patient severity of illness (and costs).

As discussed above, based on our retrospective evaluation of the FY 2009 claims, our actuaries determined that implementation of the MS–DRG system resulted in a 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. To date, we have made adjustments to the national capital Federal rate to account for 4.4 percent (that is, −0.6 percent in FY 2008, −0.9 percent in FY 2009, and −2.9 percent in FY 2011) of the estimated 5.4 percent documentation and coding effect. Thus, our current estimate of the remaining adjustment to the national capital Federal rate is −1.0 percent to account for the effect of documentation and coding changes under the MS–DRG system for FYs 2008 and 2009.

In the proposed rule, under the Secretary's broad authority under section 1886(g) of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, consistent with the intention we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50357), we proposed to reduce the national capital Federal rate in FY 2012 by −1.0 percent to account for the remainder of the cumulative effect of the estimated changes in documentation and coding under the MS–DRG system in FYs 2008 and 2009 that did not reflect real changes in case-mix. Furthermore, consistent with the documentation and coding adjustments we have made in the past, we proposed to leave this proposed −1.0 percent adjustment in place for subsequent fiscal years to account for the effect in FY 2012 and subsequent years. As explained above, this proposed −1.0 percent adjustment accounts for the remainder of our current estimate of the cumulative effect of documentation and coding changes under the MS–DRG system for FYs 2008 and 2009 of −5.4 percent minus the existing −0.6 percent, −0.9 percent, and −2.9 percent adjustments.

We did not receive any public comments on our proposal to permanently reduce the national capital Federal rate in FY 2012 by −1.0 percent to account for the remainder of the cumulative effect of the estimated changes in documentation and coding under the MS–DRG system that occurred during FYs 2008 and 2009 that did not reflect real changes in case-mix. (The public comments we received on our methodology and the magnitude of our estimate of cumulative effect of the estimated changes in documentation and coding under the MS–DRG system that occurred during FYs 2008 and 2009 that did not reflect real changes in case-mix are discussed in section II.D. of this preamble.)

In this final rule, under the Secretary's broad authority under section 1886(g) of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Pub. L. 110–90, consistent with the intention we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50357), as we proposed, we are reducing the national capital Federal rate in FY 2012 by −1.0 percent to account for the remainder of the cumulative effect of the estimated changes in documentation and coding under the MS–DRG system that occurred during FYs 2008 and 2009 that did not reflect real changes in case-mix. Furthermore, consistent with the documentation and coding adjustments we have made in the past, and as we proposed, we will leave this −1.0 percent adjustment in place for subsequent fiscal years to account for the effect in FY 2012 and subsequent years. As explained above, this −1.0 percent adjustment accounts for the remainder of our current estimate of the cumulative effect of documentation and coding changes under the MS–DRG system that occurred during FYs 2008 and 2009 of −5.4 percent minus the existing −0.6 percent, −0.9 percent, and −2.9 percent adjustments.

3. Documentation and Coding Adjustment to the Puerto Rico-Specific Capital Rate

Under § 412.74, Puerto Rico hospitals are currently paid based on 75 percent of the national capital Federal rate and 25 percent of the Puerto Rico-specific capital rate. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50358 through 50359), we discussed the retrospective evaluation of the FY 2009 claims data from the March 2010 update of the MedPAR file of hospitals located in Puerto Rico using the same methodology used to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals. This analysis shows that the change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico was approximately 2.6 percent. (As discussed in that same final rule, the Puerto Rico-specific capital rate was not adjusted for the cumulative effects of documentation and coding changes in FY 2008 or FY 2009.) We also explained that we continue to believe that such an adjustment is appropriate because all hospitals have the same financial incentives for documentation and coding improvements, and the same ability to benefit from the resulting increase in

aggregate payments that do not reflect real changes in case-mix.

Given this case-mix increase due to changes in documentation and coding under the MS–DRGs, consistent with the adjustment we made to the FY 2011 national capital Federal rate (discussed above) and consistent with our adjustment to the FY 2011 Puerto Rico-specific standardized amount, under the Secretary's broad authority under section 1886(g) of the Act, we established an adjustment to the Puerto Rico-specific capital rate of –2.6 percent in FY 2011 for the cumulative increase in case-mix due to changes in documentation and coding under the MS–DRGs for FYs 2008 and 2009. In addition, consistent with our implementation of other prospective MS–DRG documentation and coding adjustments to the capital Federal rate and operating IPPS standardized amounts, we established that we will leave that −2.6 percent adjustment in place for subsequent fiscal years in order to ensure that changes in documentation and coding resulting from the adoption of the MS–DRGs do not lead to an increase in aggregate payments not reflective of an increase in real case-mix in subsequent years. The −2.6 percent adjustment to the capital Puerto Rico-specific rate that we made in FY 2011 reflects the entire amount of our current estimate of the effects of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico. Consequently, in the FY 2012 IPPS/LTCH PPS proposed rule, we did not propose to make any additional adjustments to the capital Puerto Rico-specific rate for FY 2012 for the effect of documentation and coding that did not reflect real changes in case-mix.

We did not receive any public comments on our proposal not to make any additional adjustments to the capital Puerto Rico-specific rate for FY 2012 for the effect of documentation and coding changes that did not reflect real changes in case-mix and, therefore, are adopting our proposal as final in this final rule.

F. Other Changes for FY 2012

The annual update to the capital IPPS national Federal and Puerto Rico-specific rates, as provided for at § 412.308(c), for FY 2012 is discussed in section III. of the Addendum to this final rule.

VI. Changes for Hospitals Excluded From the IPPS

A. Excluded Hospitals

Historically, 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)) 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 all 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.

Payment to children's hospitals and cancer hospitals that are excluded from the IPPS continues 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) of the regulations, RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25968), we proposed that the FY 2012 rate-of-increase percentage to be applied to the target amount for cancer and children's hospitals and RNHCIs would be the estimated FY 2012 percentage increase in the IPPS operating market basket, estimated to be 2.8 percent. 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. 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 remaining number of providers being paid based on reasonable cost subject to a ceiling (that is, 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. For FY 2012, we proposed to continue to use the IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs for the reasons discussed in the FY 2006 IPPS final rule.

In the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to use the revised and rebased FY 2006-based IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs for FY 2012. Therefore, based on IHS Global Insight, Inc.'s 2011 first quarter forecast, with historical data through the 2010 fourth quarter, we estimated that the FY 2012 update to the IPPS operating market basket would be 2.8 percent (that is, the estimate of the market basket rate-of-increase). However, we proposed 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 2012. Therefore, based on IHS Global Insight, Inc.'s 2011 second quarter forecast, with historical data through the 2011 first quarter, we estimate that the final FY 2012 update to the IPPS operating market basket is 3.0 percent. Moreover, consistent with our proposal that the percentage increase in the rate-of-increase limits for cancer and children's hospitals and RNHCIs would be the percentage increase in the FY 2012 IPPS operating market basket, the FY 2012 rate-of-increase percentage that is applied to the FY 2011 target amounts in order to calculate the final FY 2012 target amounts for cancer and children's hospital and RNHCIs is 3.0 percent, in accordance with the applicable regulations in 42 CFR 413.40.

We note that 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 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.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section IV. of the Addendum to this final rule for the specific final update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2012. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

B. Critical Access Hospital (CAH) Payment for Ambulance Services

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs) under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and that meet the CAH conditions of participation under 42 CFR Part 485, Subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR Part 413. Section 1834(l) of the Act sets forth the payment rules for ambulance services. Generally, payment to ambulance providers and suppliers for ambulance services are made under the ambulance fee schedule. Section 205 of Public Law 106–554 (BIPA) amended section 1834(l) of the Act by adding a paragraph (8) to that section, which provides that the Secretary shall pay the reasonable costs incurred in furnishing ambulance services if such services are furnished by a CAH (as defined in section 1861(mm)(1) of the Act), or by an entity that is owned and operated by a CAH, but only if the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of the CAH. The term ''provider of ambulance services'' includes all Medicare-participating providers that submit claims under Medicare for ambulance services (for example, hospitals, CAHs, skilled nursing facilities (SNFs), and home health agencies (HHAs)). The term ''supplier of ambulance services'' is defined as an entity that provides ambulance services and that is independent of any Medicare-participating or non-Medicare-participating provider. Section 205 was effective for services furnished on or after December 21, 2000. Regulations implementing section 1834(l)(8) of the Act are set forth at 42 CFR 413.70(b)(5).

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50361), we implemented section 3128(a) of the Affordable Care Act, which amended section 1834(l)(8) of the Act by inserting ''101 percent of'' before ''the reasonable costs.'' As such, section 3128(a) increased payment for ambulance services furnished by a qualifying CAH or entity owned and operated by a CAH to 101 percent of reasonable costs, effective for cost reporting periods beginning on or after January 1, 2004. We amended the regulations at § 413.70(b)(5)(i) to conform to this statutory change by stating that, effective for cost reporting periods beginning on or after January 1, 2004, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity furnishing those services is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity.

2. Requirement for CAH Ambulance Within a 35-Mile Location of a CAH or Entity

Section 413.70(b)(5) of the existing regulations states that payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is ''the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity''. However, the statutory language at section 1834(l)(8) of the Act states that a CAH is eligible to be paid based on 101 percent of reasonable costs for ambulance services furnished by the CAH or by an entity that is owned and operated by a CAH, but only if the CAH or the entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such CAH. Because the statute only requires that there be no other provider or supplier of ambulance services within a 35-mile drive of the CAH and does not address whether there is another provider or supplier of ambulance services within a 35-mile drive of the CAH-owned and operated entity, we believe that the existing regulation is not consistent with the plain reading of the statutory language at section 1834(l)(8) of the Act. In addition, we believe the plain reading of the statutory language at section 1834(l)(8) of the Act does not address the situation where there is no provider or supplier of ambulance services within a 35-mile drive of the CAH, but there is a CAH-owned and operated entity furnishing ambulance services that is more than a 35-mile drive from the CAH, thus creating a ''gap'' in the statutory language. That is, the statutory language does not address the situation where the entity that is owned and operated by the CAH is located *more* than a 35-mile drive from the CAH.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25969 through 25971), in order to ensure that the regulations are consistent with the plain language of section 1834(l)(8) of the Act, we proposed to revise § 413.70(b)(5)(i) by adding a new paragraph (C) to state that, effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or by a CAH-owned and operated entity is 101 percent of reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH (Figure 1). Under this proposed change, the CAH-owned and operated entity would be paid 101 percent of reasonable costs for its ambulance services only if there is no other provider or supplier of ambulance services within a 35-mile drive of the CAH. However, if there is a provider or supplier of ambulance services located within a 35-mile drive of the CAH (Figure 2), the CAH-owned and operated entity would not be paid at 101 percent of reasonable costs, but instead would be paid under the ambulance fee schedule.

Figure 1:

The CAH-owned and operated entity would be paid at 101 percent of reasonable costs for its ambulance services because there is no other provider or supplier of ambulance services within a 35-mile drive of the CAH.

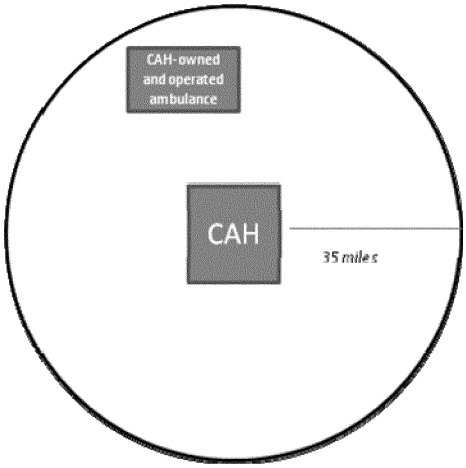
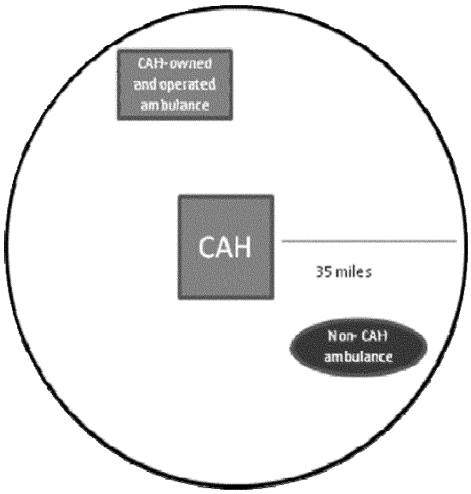


Figure 2:

The CAH-owned and operated entity would be paid under the ambulance fee schedule for its ambulance services because the CAH-owned and operated entity is not the only provider or supplier of ambulance services located within a 35-mile drive of the CAH.



In addition, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to establish a policy that would address the ''gap'' in the statutory language, that is, where the CAH-owned and operated entity furnishing ambulance services is more than a 35-mile drive from the CAH, but there is no other provider or supplier of ambulance services located within a 35-mile drive of the CAH. We proposed to include in the proposed new paragraph (C) of § 413.70(b)(5)(i) a provision which states that, effective for cost reporting periods beginning on or after October 1, 2011, if there is no provider or supplier of ambulance services within a 35-mile drive of the CAH and there is a CAH-owned and operated entity that is more than a 35-mile drive from the CAH, the CAH-owned and operated entity would be paid at 101 percent of reasonable costs for its ambulance services as long as that entity is the closest provider or supplier of ambulance services to the CAH (Figure 3). Allowing the CAH-owned and operated entity to be paid at 101 percent of reasonable costs if there is no other provider or supplier of ambulance services that is closer to the CAH is consistent with the original purpose of section 1834(l)(8) of the Act, which was intended to help ensure an adequate level of ambulance services in areas served by CAHs. The statute allows for reasonable cost-based payment only if there is no other provider or supplier of ambulance services within a 35-mile drive of the CAH. If there is another provider or supplier of ambulance services located within a 35-mile drive of the CAH, the statute does not allow for payment to the CAH or a CAH-owned and operated entity at 101 percent of reasonable costs because there is an adequate level of ambulance services available. Accordingly, where a CAH-owned and operated entity is located more than a 35-mile drive from the CAH, we proposed to allow payment at 101 percent of reasonable costs only if there is no other provider or supplier of ambulance services located closer to the CAH. If there is a closer provider or supplier of ambulance services, that closer provider or supplier would also be assuring an adequate level of ambulance services in the area served by the CAH, and there would be no need to pay the CAH-owned and operated entity at 101 percent of reasonable costs in order to ensure access to ambulance services. Therefore, if the CAH-owned and operated entity (located more than a 35-mile drive from the CAH) is not the closest provider or supplier of ambulance services to the CAH (Figure 4), the CAH-owned and operated entity would be reimbursed under the ambulance fee schedule.

Figure 3:

The CAH-owned and operated entity would be paid at 101 percent of reasonable costs for its ambulance services because even though the CAH-owned and operated entity is more than a 35-mile drive from the CAH, it is the closest provider or supplier of ambulance services to the CAH.

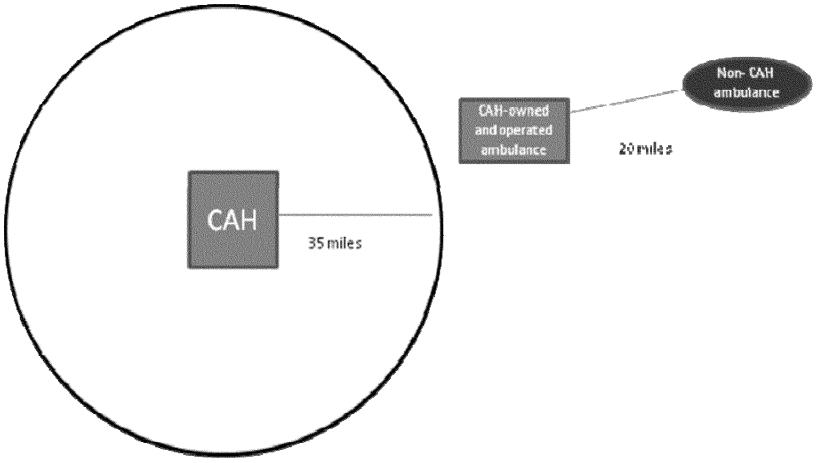
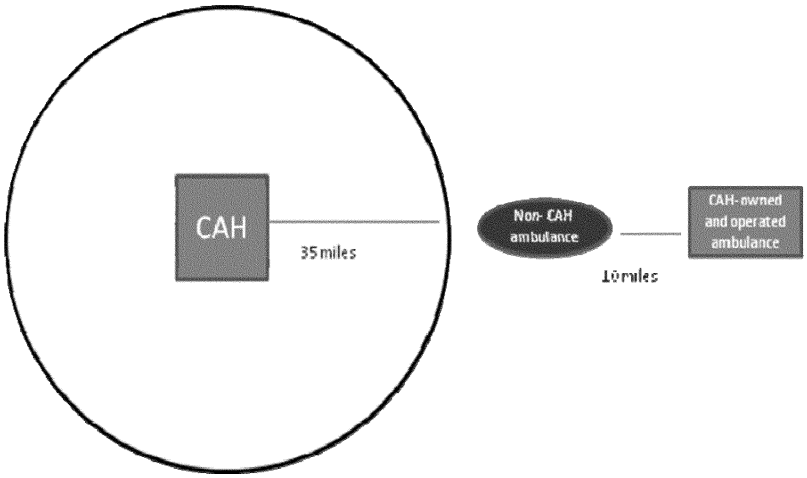


Figure 4:

The CAH-owned and operated entity would receive payment under the ambulance fee schedule for its ambulance services because there is another provider or supplier of ambulance services that is closer to the CAH than the CAH-owned and operated entity.



Comment: One commenter requested that CMS apply a similar policy as that proposed for CAH ambulance services to any provider-based department of a CAH.

Response: We believe that the commenter's request to address policies concerning other CAH provider-based departments is outside of the scope of the proposed rule. Our proposal only addressed the requirements that a CAH and CAH-owned and operated entity would need to meet in order to be paid 101 percent of reasonable costs for ambulance services. Therefore, we are not responding to this comment in this final rule, but may consider the commenter's suggestion in future rulemaking.

Comment: One commenter stated that, while the examples discussed in the proposed rule clearly specified how CAHs and CAH-owned and operated entities in certain situations would be paid, the commenter was aware of other situations that were not addressed in the proposed rule. The commenter stated that many facilities operate ambulance services in several locations and requested that CMS address the following scenario (referred to as ''scenario one'' in the remainder of this section):

''A CAH has a CAH-based ambulance on its campus. There is no other ambulance service within a 35-mile drive of the CAH. The CAH owns and operates a satellite of its ambulance service at a 45-mile drive from the CAH. Under this scenario, the CAH-based ambulance site would be paid at 101 percent of reasonable cost, but would the CAH-owned satellite be paid at 101 percent of costs or on the fee schedule? Note that the two sites represent different locations of the same ambulance entity.''

The commenter also requested that CMS address the following scenario (referred to as ''scenario two'' in the remainder of this section):

''In another scenario, assume that both the CAH and the CAH-owned entity's ambulance services would be paid at 101 percent of reasonable costs in the above situation. How would the CAH's ambulance services be reimbursed if there was a non-CAH owned or operated ambulance service

that was located between the CAH and its ambulance satellite site? For example, if the CAH-owned entity was located 45 miles from the CAH (which had its own ambulance onsite), but the independent ambulance was located 40 miles from the CAH? Would the CAH-owned entity 45 miles from the CAH be paid on a fee basis or at 101 percent of reasonable costs?''

Response: Regarding scenario one, the type of payment that the CAH and the CAH-owned and operated entity would receive for their ambulance services would depend on whether the CAH and the CAH-owned and operated entity operate as one legal entity or are two separate legal entities. If the CAH and the CAH-owned and operated entity are two separate legal entities, the fact that the CAH has an ambulance on its main campus would preclude the CAH-owned and operated entity from receiving payment at 101 percent of reasonable costs for its ambulance services because the CAH-owned and operated entity is not the only provider of ambulance services that is located within a 35-mile drive from the CAH. The CAH-owned and operated entity would not receive payment based on reasonable cost but, instead, would be paid using the ambulance fee schedule because there is a provider or supplier of ambulance services located within a 35-mile drive of the CAH, which is the ambulance stationed at the main CAH. However, if the CAH and the CAH-owned and operated entity are one legal entity, both the CAH and the CAH-owned and operated entity would be paid based on 101 percent of reasonable costs for their ambulance services as long as there is no other provider or supplier of ambulance services closer to the main CAH than the CAH-owned and operated entity.

For purposes of discussing scenario two, we assume that the CAH and the CAH-owned and operated entity are one legal entity. As described above, in scenario two, the CAH has an ambulance service on its main campus, a CAH-owned and operated entity is located a 45-mile drive from the CAH, and there is also a non-CAH ambulance that is located a 40-mile drive from the CAH. In this scenario, because the non-CAH ambulance is closer to the CAH than the CAH-owned and operated entity, the CAH-owned and operated entity would not receive payment at 101 percent of reasonable costs but rather would be paid using the ambulance fee schedule. However, because there is no other provider or supplier of ambulance services within a 35-mile drive of the main CAH, the main CAH would be paid based on 101 percent of reasonable costs for its ambulance services.

After consideration of the public comments we received, we are adopting our proposals without modification. Specifically, we are adopting, as final, the proposed revision of § 413.70(b)(5)(i) of the regulations by adding a new paragraph (C) to specify that, for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or by a CAH-owned and operated entity is 101 percent of reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH.

In addition, we are adopting, as final, our proposal to include in new § 413.70(b)(5)(i) (C), a provision to address the ''gap'' in the statutory language, where there is no other provider or supplier of ambulance services located within a 35-mile drive of the CAH, but there is a CAH-owned and operated entity furnishing ambulance services more than a 35-mile drive from the CAH. Specifically, for cost reporting periods beginning on or after October 1, 2011, if there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is a CAH-owned and operated entity that is more than a 35-mile drive from the CAH, the CAH-owned and operated entity will be paid at 101 percent of reasonable costs for its ambulance services as long as that entity is the closest provider or supplier of ambulance services to the CAH. However, if there is a provider or supplier of ambulance services that is closer to the CAH than the CAH-owned and operated entity, the CAH-owned and operated entity will be paid based on the ambulance fee schedule.

We also are finalizing a conforming change to § 413.70(b)(5)(i)(B) to make the effective date of that paragraph consistent with the effective date of the new paragraph (C).

C. Report of Adjustment (Exceptions) Payments

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, adjusting, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital or an excluded unit of a hospital must file its cost report for a fiscal year in accordance with § 413.24(f)(2). The fiscal intermediary or MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital or hospital unit receives the NPR, if its operating costs are in excess of the ceiling, the hospital or hospital unit may file a request for an adjustment payment. After the fiscal intermediary or MAC receives the hospital's or hospital unit's request in accordance with applicable regulations, the fiscal intermediary or MAC or CMS, depending on the type of adjustment requested, reviews the request and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 6 months after the date the request is filed because there are times when the applications are incomplete and additional information must be requested in order to have a completed application. However, in an attempt to provide interested parties with data on the most recent adjustments for which we do have data, we are publishing data on adjustment payments that were processed by the fiscal intermediary or MAC or CMS during FY 2010.

The table below includes the most recent data available from the fiscal intermediaries or MACs and CMS on adjustment payments that were adjudicated during FY 2010. As indicated above, the adjustments made during FY 2010 only pertain to cost reporting periods ending in years prior to FY 2009. Total adjustment payments given to excluded hospitals and hospital units during FY 2010 are $11,364,155. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of hospital	Number	Excess cost over ceiling	Adjustment payments
Psychiatric	1	$951,810	$884,441
Children's	1	377,648	305,160

Class of hospital	Number	Excess cost over ceiling	Adjustment payments
Cancer	2	18,108,765	10,174,554
Religious Nonmedical Health Care Institution (RNHCI)	0	0	0
Total			11,364,155

VII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2012

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 Social Security Act (the Act), effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines an LTCH as ''a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.'' Section 1886(d)(1)(B)(iv)(II) of the Act also provides an alternative definition of LTCHs: specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (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, the intent is to 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. 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. However, effective for cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR Part 412, Subpart O also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the June 6, 2003 **Federal Register**, we published a final rule that set forth the FY 2004 annual update of the payment rates for the Medicare PPS for inpatient hospital services furnished by LTCHs (68 FR 34122). It also changed the annual period for which the payment rates were to be effective, such that the annual updated rates were effective from July 1 through June 30 instead of from October 1 through September 30. We referred to the July through June time period as a ''long-term care hospital rate year'' (LTCH PPS rate year). In addition, we changed the publication schedule for the annual update to allow for an effective date of July 1. The payment amounts and factors used to determine the annual update of the LTCH PPS Federal rate are based on a LTCH PPS rate year. In the past, while the LTCH payment rate updates were effective July 1, the annual update of the DRG classifications and relative weights for LTCHs continued to be linked to the annual adjustments of

the acute care hospital inpatient DRGs and were effective each October 1.

As discussed in detail in the RY 2009 LTCH PPS final rule (73 FR 26797 through 26798), we again changed the schedule for the annual updates of the LTCH PPS Federal payment rates beginning with RY 2010. We consolidated the rulemaking cycle for the annual update of the LTCH PPS Federal payment rates and description of the methodology and data used to calculate these payment rates with the annual update of the MS–LTC–DRG classifications and associated weighting factors for LTCHs so that the updates to the rates and the relative weights now occur on the same schedule and appear in the same publication. As a result, the updates to the rates and the relative weights are now effective on October 1 (on a Federal fiscal year schedule), and the annual updates to the LTCH PPS Federal rates are no longer published with a July 1 effective date.

Public Law 110–173 (MMSEA) enacted on December 29, 2007, included provisions that have various effects on the LTCH PPS. In addition to amending section 1861 of the Act to add a subsection (ccc) which provided an additional definition of LTCHs, Public Law 110–173 also required the Secretary to submit, no later than 18 months after the date of enactment of the law, a report to Congress on a study of national long-term care hospital facility and patient criteria that included ''recommendations for such legislation and administrative actions, including timelines for the implementation of LTCH patient criteria or other actions, as the Secretary determines appropriate.'' The payment policy provisions under sections 114(c)(1) and (c)(2) of Public Law 110–173 focused on providing 3 years of relief for certain LTCHs from the percentage threshold payment adjustment policy at 42 CFR 412.534 and 412.536. However, because of the original implementation schedule of those sections of the regulations, the payment provisions had varying timeframes of applicability (73 FR 29701 through 29704). In addition, section 114(c)(3) of Public Law 110–173 provided that the Secretary shall not apply, for the 3-year period beginning on the date of enactment of the Act the revision to the short-stay outlier (SSO) policy that was finalized in the RY 2008 LTCH PPS final rule (72 FR 26904 and 26992). In addition, section 114(c)(4) of Public Law 110–173 provided that the Secretary shall not, for the 3-year period beginning on the date of enactment of the Act, make the one-time adjustment to the payment rates provided for in § 412.523(d)(3) or any similar provision (73 FR 26800 through 26804). The statute also provided that the base rate for RY 2008 be the same as the base rate for RY 2007 (the revised base rate, however, does not apply to discharges occurring on or after July 1, 2007, and before April 1, 2008) (73 FR 24875 through 24877). Section 114(d) of Public Law 110–173 established a 3-year moratorium (with specified exceptions) on the establishment and classification of new LTCHs, LTCH satellites, and on the increase in the number of LTCH beds in existing LTCHs or satellite facilities. Finally, section 114(f) of Public Law 110–173 provided for an expanded review of medical necessity for admission and continued stay at LTCHs.

In the RY 2009 LTCH PPS final rule (73 FR 26804 through 26812), we established the applicable Federal rates for RY 2009, consistent with section 1886(m)(2) of the Act as amended by Public Law 110–173. We also revised the regulations at § 412.523(d)(3) to change the methodology for the one-time budget neutrality adjustment and to comply with section 114(c)(4) of Public Law 110–173. Other policy revisions that were necessary as a result of the statutory changes of Public Law 110–173 were addressed in separate interim final rules with comment period (73 FR 24871 and 73 FR 29699). In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43976 through 43990), we addressed all of the public comments received and finalized these two interim final rules with comment period.

Section 4302 of the ARRA, Public Law 111–5, enacted on February 17, 2009, included several amendments to the provisions set forth in section 114 of Public Law 110–173. Specifically, section 4302(a) modified the effective dates of the provisions of section 114(c) of Public Law 110–173, described above, and added an additional category of LTCHs or satellite facilities that would not be subject to the percentage threshold payment adjustment at § 412.536 for a 3-year period. In addition, section 4302(a)(2)(A) of Public Law 111–5 added ''grandfathered'' satellites (specified in § 412.22(h)(3)(i) of the regulations) to those ''applicable'' LTCHs (specified in § 412.534(g) of the regulations) originally granted relief under section 114(c) of Public Law 110–173. We issued instructions to the fiscal intermediaries and MACs interpreting the provisions of section 4302 of Public Law 111–5 (Change Request 6444). In addition, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43990 through 43992), we implemented the provisions of section 4302 of Public Law 111–5 through an interim final rule with comment period. We received one timely comment regarding the provisions of section 4302 of Public Law 111–5 that were implemented through the interim final rule with comment period that was included in the FY 2010 IPPS/RY 2010 LTCH PPS final rule. We addressed this public comment and finalized the interim final rule with comment period in section VII.E. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50399).

As discussed in the FY 2011 IPPS/LTCH PPS final rule, a number of the provisions of the Affordable Care Act affected the policies, payment rates and factors under the LTCH PPS. Specifically, section 1886(m)(3)(A)(ii) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for each of rate years 2010 through 2019, any annual update to the standard Federal rate shall be reduced by the other adjustment specified in new section 1886(m)(4) of the Act. Furthermore, section 1886(m)(3)(A)(i) of the Act specifies that, for rate year 2012 and subsequent rate years, any annual update to the standard Federal rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(m)(3)(A)(ii) and sections 1886(m)(4)(A) and (B) of the Act require a 0.25 percentage point reduction for rate year 2010 and a 0.50 percentage point reduction for rate year 2011. 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. Furthermore, section 3401(p) of the Affordable Care Act specifies that the amendments made by section 3401(c) of such Act shall not apply to discharges occurring before April 1, 2010 (75 FR 50387 through 50390). Sections 3106 and 10312 of the Affordable Care Act together provide for a 2-year extension to the payment policies applicable to LTCHs and LTCH satellite facilities set forth in sections 114(c) and (d)(1) of the MMSEA, as amended by the ARRA. Specifically, sections 3106 and 10312 of the Affordable Care Act together result in the phrase ''3-year period'' being replaced with the phrase ''5-year period'' each place it appears in sections 114(c) and (d)(1) of MMSEA, as amended by the ARRA. As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50399 through 50400), sections 3106 and 10312 of the Affordable Care Act, which amended sections 114(c) and

(d)(1) of the MMSEA, as amended by the ARRA, result in the following:

• An additional 2-year delay in the application of the SSO payment adjustment, which would have applied the additional payment option of an ''IPPS comparable'' payment to LTCHs for certain SSO cases where the covered length of stay is less than or equal to the ''IPPS comparable threshold.'' Therefore, the Secretary will not apply this SSO payment adjustment for the 5-year period beginning on the date of enactment of MMSEA (December 29, 2007).

• An additional 2-year delay in the one-time prospective budget neutrality adjustment to the standard Federal rate (§ 412.523(d)(3)). Thus, the Secretary is precluded from making the one-time adjustment to standard Federal rate until December 29, 2012.

• An increase from 3 years to 5 years to the timeframes set forth in section 114(c) of the MMSEA as amended by the ARRA, thereby extending for an additional 2 years the delay in the application of the 25-percent payment threshold policy for certain LTCHs and LTCH satellite facilities (§§ 412.534 and 412.536), and extending for an additional 2 years, the increased percentage thresholds outlined at section 114(c)(2) of the MMSEA as amended by the ARRA.

• Additional 2-year extensions of the moratorium on the establishment of new LTCHs and LTCH satellite facilities and the moratorium on the increase of LTCH beds in existing LTCHs or satellite facilities as provided by section 114(d) of the MMSEA as amended by the ARRA. In general, section 114(d) of the MMSEA as amended by the ARRA precluded the establishment and classification of new LTCHs or LTCH satellite facilities or additional beds from being added to existing LTCHs or LTCH satellite facilities unless one of the specified exceptions to the particular moratorium was met.

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 (LOS) 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 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 healthcare transactions according to the applicable transactions and code sets standards.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2012

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 and 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.) We believe the MS–DRGs (and by extension, the MS–LTC–DRGs) represent a substantial improvement over the previous CMS DRGs in their ability to differentiate cases based on severity of illness and resource consumption.

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 2012, we are deleting one MS–DRG and creating two new MS–DRGs for a net gain of one MS–DRG. With these adopted changes, we have a total of 751 MS–DRG groupings for FY 2012. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In a departure from the IPPS, and as discussed in greater detail below in section VII.B.3.f. of this preamble, we 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 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).) We also account for adjustments to payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG). Furthermore, we made 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 weights should increase monotonically with severity from the lowest to highest severity level. (We discuss nonmonotonicity in greater detail and our methodology to adjust the MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights in section VII.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 secondary or additional diagnoses and the number of surgical procedures considered for MS–DRG assignment was limited to eight and six, respectively. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127), we established that, for claims submitted on the 5010 format beginning January 1, 2011, we would increase 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).

Upon the discharge of the patient from a LTCH, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). HIPAA Transactions and Code Sets Standards regulations at 45 CFR Parts 160 and 162 require that no later than October 16, 2003, all covered entities must comply with the applicable requirements of Subparts A and I through R of Part 162.

Among other requirements, those provisions direct covered entities to use the ASC X12N 837 Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, and the applicable standard medical data code sets for the institutional health care claim or equivalent encounter information transaction (45 CFR 162.1002 and 45 CFR 162.1102). 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.13. of this preamble for additional information on the annual revisions to the ICD–9–CM codes.)

With respect to the ICD–9–CM coding system, we have been discussing the conversion to the ICD–10–CM and the ICD–10–PCS coding systems for many years. As is discussed in detail in section II.G.11. of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50122 through 50127) and in section III.G.13 of this final rule, the ICD–10 coding systems applicable to hospital inpatient services will be implemented on October 1, 2013. In order for the industry to make the necessary conversions from ICD–9–CM to ICD–10–CM and ICD–10–PCS, we proposed, through the ICD–9–CM Coordination and Maintenance Committee, to consider a moratorium on updates to the ICD–9–CM and ICD–10 coding sets. We refer readers to section II.G.13. of this preamble for additional information on the adoption of the ICD–10–CM and ICD–10–PCS systems.

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), individual DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into three, two, or one level, 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 and 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 weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Changes to the MS–LTC–DRGs for FY 2012

As specified by our regulations at § 412.517(a), which requires 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, as we proposed, we are updating the MS–LTC–DRG classifications effective October 1, 2011, through September 30, 2012 (FY 2012) consistent with the changes to specific MS–DRG classifications presented in section II.G. of this final rule (that is, GROUPER Version 29.0). Therefore, the MS–LTC–DRGs for FY 2012 presented in this final rule are the same as the MS–DRGs that are being used under the IPPS for FY 2012. In addition, because the MS–LTC–DRGs for FY 2012 are the same as the MS–DRGs for FY 2012, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under Version 29.0 of the GROUPER discussed in section II.G. of the preamble of this final rule, including the changes to the MCE software and changes to the ICD–9–CM coding system, also are applicable under the LTCH PPS for FY 2012.

3. Development of the FY 2012 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

As we stated in the August 30, 2002 LTCH PPS final rule (67 FR 55984), 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. 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.

Although the adoption of the MS–LTC–DRGs resulted in some modifications of existing procedures for assigning weights in cases of zero volume and/or nonmonotonicity (as discussed in 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)), as we proposed, the basic methodology for developing the FY 2012 MS–LTC–DRG relative weights in this final rule continues to be determined in accordance with the general methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). 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 calculated a relative weight for each MS–LTC–DRG that represents the resources needed by an average

inpatient LTCH case in that MS–LTC–DRG. For example, cases in a MS–LTC–DRG with a relative weight of 2 will, on average, cost twice as much to treat as cases in a MS–LTC–DRG with a relative weight of 1.

b. Development of the MS–LTC–DRG Relative Weights for FY 2012

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 (RY 2008 LTCH PPS final rule (72 FR 26882 through 26884)). Consistent with § 412.517(b) and as we proposed, we applied a two-step budget neutrality methodology, which is based on the current year MS–LTC–DRG classifications and relative weights. (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).) Thus, for this final rule, the annual update to the MS–LTC–DRG classifications and relative weights for FY 2012 are based on the FY 2011 MS–LTC–DRG classifications and relative weights established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50613 through 50627).

c. Data

In this final rule, to calculate the MS–LTC–DRG relative weights for FY 2012, we obtained total charges from FY 2010 Medicare LTCH bill data from the March 2011 update of the FY 2010 MedPAR file, which are the best available data at this time, and used the Version 29.0 of the GROUPER to classify LTCH cases. For the proposed rule, we obtained total charges from FY 2010 Medicare LTCH bill data from the December 2010 update of the FY 2010 MedPAR file, which were the best available data at that time, and used the proposed Version 29.0 of the GROUPER to classify LTCH cases. Consistent with our historical policy, we also proposed to use more recent data if available and the final version of the GROUPER to develop the FY 2012 MS–LTC–DRG relative weights for the final rule. (76 FR 25976)

Consistent with our historical methodology and as we proposed, we excluded 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. In addition, as is the case with the IPPS, Medicare Advantage (Part C) claims are now included in the MedPAR files (74 FR 43808). Consistent with IPPS policy and as we proposed, we continued to exclude such claims in the calculations for the relative weights under the LTCH PPS that are used to determine payments for fee-for-service Medicare claims. Specifically, we removed any claims from the MedPAR files that have a GHO Paid indicator value of ''1,'' which effectively removes Medicare Advantage claims from the relative weight calculations (73 FR 48532). Therefore, in the development of the FY 2012 MS–LTC–DRG relative weights in this final 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 March 2011 update of the FY 2010 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 rehabilitation and wound care. Some case types (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. As we proposed, 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 used a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2012. We believe this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, we reduced 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, as we proposed, we standardized charges for each case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described below in section VII.B.3.g. (step 3) of the preamble of this final rule) 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. Treatment of Severity Levels in Developing the MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three

different categories of 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 were 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). In this final rule, as we proposed, we utilized these same three categories of MS–LTC–DRGs for purposes of determining the MS–LTC–DRG relative weights for FY 2012. (We provide in-depth discussions of our policy regarding weight-setting for low-volume MS–LTC–DRGs in section VII.B.3.f. of the preamble of this final rule and for no-volume MS–LTC–DRGs, under Step 5 in section VII.B.3.g. of the preamble of this final rule.)

As also noted above, while the LTCH PPS and the IPPS use the same patient classification system, the methodology that is used to set the DRG relative weights for use in each payment system differs because the overall volume of cases in the LTCH PPS is much less than in the IPPS. In general, consistent with our existing methodology and as we proposed, we used the following steps to determine the FY 2012 MS–LTC–DRG relative weights: (1) If an MS–LTC–DRG had at least 25 cases, it was assigned its own relative weight; (2) if an MS–LTC–DRG had between 1 and 24 cases, it was assigned to a quintile for which we computed a relative weight for all of the MS–LTC–DRGs assigned to that quintile; and (3) if an MS–LTC–DRG had no cases, it was cross-walked to another MS–LTC–DRG based upon clinical similarities to assign an appropriate relative weight (as described below in detail in Step 5 of section VII.B.3.g. of this preamble). Furthermore, in determining the FY 2012 MS–LTC–DRG relative weights, when necessary, we make adjustments to account for nonmonotonicity, as discussed in greater detail below in Step 6 of section VII.B.3.g. of this preamble. We refer readers to the discussion in the FY 2010 IPPS/RY LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Low-Volume MS–LTC–DRGs

In order to account for MS–LTC–DRGs with low volume (that is, with fewer than 25 LTCH cases), consistent with our existing methodology and as we proposed, for purposes of determining the FY 2012 MS–LTC–DRG relative weights, we employ the quintile methodology for low-volume MS–LTC–DRGs, such that we group those ''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 FY 2012 MS–LTC–DRG relative weights in this final rule, in cases where the initial assignment of a low-volume MS–LTC–DRG to quintiles resulted in nonmonotonicity within a base-DRG, in order to ensure appropriate Medicare payments, consistent with our historical methodology and as we proposed, we made adjustments to the treatment of low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail below in section VII.B.3.g. (Step 6) in this preamble.

In this final rule, using LTCH cases from the March 2011 update of the FY 2010 MedPAR file, we identified 277 MS–LTC–DRGs that contained between 1 and 24 cases. This list of MS–LTC–DRGs was then divided into one of the 5 low-volume quintiles, each containing a minimum of 55 MS–LTC–DRGs (277/5 = 55 with 2 MS–LTC–DRG as the remainder). We assigned a low-volume MS–LTC–DRG to a specific low-volume quintile by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Furthermore, because the number of MS–LTC–DRGs with less than 25 cases is not evenly divisible by 5, the average charge of the low-volume quintile was used to determine which of the low-volume quintiles would contain the 2 additional low-volume MS–LTC–DRGs. Specifically, after organizing the MS–LTC–DRGs by ascending order by average charge, we assigned the first fifth (1st through 55th) of low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The MS–LTC–DRGs with the highest average charge cases would be assigned into Quintile 5. Because the average charge of the 166th low-volume MS–LTC–DRG in the sorted list is closer to the average charge of the 165th low-volume MS–LTC–DRG (assigned to Quintile 3) than to the average charge of the 167th low-volume MS–LTC–DRG (assigned to Quintile 4), we assign it to Quintile 3 (such that Quintile 3 contains 56 low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). This process was repeated through the remaining low-volume MS–LTC–DRGs so that 3 of the 5 low-volume quintiles contain 55 MS–LTC–DRGs (Quintiles 1, 2, and 4) and the other 2 low-volume quintiles contain 56 MS–LTC–DRGs (Quintiles 3 and 5). Table 13A, which is listed in section VI. of the Addendum to this final rule and is available via the Internet, lists the composition of the low-volume quintiles for MS–LTC–DRGs for FY 2012.

Accordingly, in order to determine the FY 2012 relative weights for the MS–LTC–DRGs with low volume, as we proposed, we used the 5 low-volume quintiles described above. The composition of each of the 5 low-volume quintiles shown in Table 13A (listed in section VI. of the Addendum to this final rule and available via the Internet) was used in determining the FY 2012 MS–LTC–DRG relative weights (as shown in Table 11 listed in section VI. of the Addendum to this final rule and available via the Internet). We determined a relative weight and (geometric) average length of stay for each of the 5 low-volume quintiles using the methodology that we applied to the MS–LTC–DRGs (25 or more cases), as described in section VII.B.3.g. of the preamble of this final rule. We assigned the same relative weight and average length of stay to each of the low-volume MS–LTC–DRGs that made 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. We use the most recent available claims data in the MedPAR file to identify low-volume MS–LTC–DRGs and to calculate the relative weights based on our methodology.

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 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 FY 2012 MS–LTC–DRG Relative Weights

In the proposed rule, we proposed, in general, to determine the FY 2012 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).)

Comment: One commenter expressed concern that the inclusion of the ''low-volume'' MS–LTC–DRGs (MS–LTC–DRGs with between 1 and 24 cases in the data used to determine the relative weights) and the ''no volume'' MS–LTC–DRGs (MS–LTC–DRGs that have no LTCH cases in the data used to determine the relative weights) may inappropriately skew the relative weights. Based on the data from the proposed rule, there were 280 ''low-volume'' MS–LTC–DRGs and 237 ''no volume'' MS–LTC–DRGs, which represents approximately 68 percent of the 751 MS–LTC–DRGs proposed for FY 2012. The commenter stated that even though approximately 69 percent of the proposed MS–LTC–DRGs have few or no cases, they are still included in the relative weight calculations, and therefore may not accurately reflect the utilization of LTCH services.

Response: The commenter may find it helpful to review our detailed explanation of the application of the MS–DRG patient classification system used by the IPPS to the LTCH PPS, which required the establishment of the categories of ''no-volume'' and ''low volume'' MS–LTC–DRGs because LTCHs do not treat the full range of patients treated in IPPS hospitals (67 FR 55983 through 55995). We believe that the commenter may not fully understand how ''low-volume'' MS–LTC–DRGs and ''no volume'' MS–LTC–DRGs are treated in our relative weight methodology. The MS–LTC–DRG relative weights are determined based on the ratio of the estimated cost of the cases assigned to each MS–LTC–DRG (as proxied by total charges from the claims in the MedPAR data) to the cost of the all of the LTCH cases (for all MS–LTC–DRGs) in the database. Although the ''low-volume'' MS–LTC–DRGs represent approximately 37 percent of the 751 MS–LTC–DRGs proposed for FY 2012, the cases assigned to those the ''low-volume'' MS–LTC–DRGs only represented approximately 1.5 percent of the LTCH cases used to calculate the proposed relative weights. Similarly, while the ''no-volume'' MS–LTC–DRGs represent approximately 32 percent of the 751 MS–LTC–DRGs proposed for FY 2012, there were no cases assigned to the ''no-volume'' MS–LTC–DRGs, and therefore, no data from any claims for those MS–LTC–DRGs was used to determine the proposed relative weights. As described in greater detail below in section VII.B.3.g. (step 5) of this preamble, the relative weights for the ''no-volume'' MS–LTC–DRGs are assigned based on clinical similarity and relative costliness, and therefore, have no effect on the calculation of the relative weights.

For the reasons discussed above, we do not believe that inclusion of the ''low-volume'' MS–LTC–DRGs and the ''no volume'' MS–LTC–DRGs inappropriately skew the calculation of the relative weights such that the data do not accurately reflect the utilization of LTCH services. We continue to believe that our methodology for determining the relative weights for each MS–LTC–DRG appropriately account for the variations in cost per discharge and resource utilization among the payment groups in accordance with § 412.515. Therefore, in this final rule, we are adopting our proposed methodology as final without modification. In summary, for FY 2012, to determine the FY 2012 MS–LTC–DRG relative weights, we grouped LTCH cases to the appropriate 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 calculated the FY 2012 relative weights by first removing statistical outliers and cases with a length of stay of 7 days or less (as discussed in greater detail below). Next, we adjusted the number of cases in each 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 MS–LTC–DRG (or low-volume quintile) using the HSRV method.

Below we discuss in detail the steps for calculating the FY 2012 MS–LTC–DRG relative weights. We note that, as we stated in section VII.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 March 2011 update of the FY 2010 MedPAR file.

Step 1—Remove statistical outliers.

The first step in the calculation of the FY 2012 MS–LTC–DRG relative weights is to remove statistical outlier cases. Consistent with our historical relative weight methodology, we 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 were removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the 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 FY 2012 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a LTCH by including data from these very short-stays. Therefore, consistent with our historical relative weight methodology, in determining the FY 2012 MS–LTC–DRG relative weights, we removed 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 were 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 FY 2012 MS–LTC–DRG relative weights, consistent with our historical relative weight methodology, we adjusted 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 made this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the

MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full discharges with no adjustment in determining the FY 2012 MS–LTC–DRG relative weights would lower the FY 2012 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 adjusted 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 FY 2012 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we calculated the FY 2012 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each LTCH case, we calculated 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 was then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 was used for each LTCH.

For each MS–LTC–DRG, we calculated the FY 2012 relative weight by dividing the average of the adjusted hospital-specific relative charge values (from above) for the MS–LTC–DRG by the overall average hospital-specific relative charge value across all cases for all LTCHs. Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of cases. The LTCHs' hospital-specific relative charge values above were multiplied by these hospital-specific case-mix indexes. These hospital-specific case-mix adjusted relative charge values were then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process was continued until there was convergence between the weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a FY 2012 relative weight for MS–LTC–DRGs with no LTCH cases.

As we stated above, we determined the FY 2012 relative weight for each MS–LTC–DRG using total Medicare allowable total charges reported in the best available LTCH claims data (that is, the March 2011 update of the FY 2010 MedPAR file for this final rule). Using these data, we identified a number of MS–LTC–DRGs for which there were no LTCH cases in the database, such that no patients who would have been classified to those MS–LTC–DRGs were treated in LTCHs during FY 2010 and, therefore, no charge data were available for these MS–LTC–DRGs. Thus, in the process of determining the MS–LTC–DRG relative weights, we were unable to calculate relative weights for the 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 MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we assigned a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs and ''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 determined FY 2012 relative weights for the MS–LTC–DRGs with no LTCH cases in the March 2011 update of the FY 2010 MedPAR file used in this final rule (that is, ''no-volume'' MS–LTC–DRGs) by cross-walking each no-volume MS–LTC–DRG to another MS–LTC–DRG with a calculated relative weight (determined in accordance with the methodology described above). Then, the ''no-volume'' MS–LTC–DRG was assigned the same relative weight (and average length of stay) of the MS–LTC–DRG to which it was cross-walked (as described in greater detail below).

Of the 751 MS–LTC–DRGs for FY 2012, we identified 236 MS–LTC–DRGs for which there were no LTCH cases in the database (including the 8 ''transplant'' MS–LTC–DRGs and 2 ''error'' MS–LTC–DRGs). As stated above, we assigned relative weights for each of the 236 no-volume MS–LTC–DRGs (with the exception of the 8 ''transplant'' MS–LTC–DRGs and the 2 ''error'' MS–LTC–DRGs, which are discussed below) based on clinical similarity and relative costliness to one of the remaining 515 (751 − 236 = 515) MS–LTC–DRGs for which we were able to determine relative weights based on FY 2010 LTCH claims data using the steps described above. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as the MS–LTC–DRGs to which we crosswalked one of the 236 ''no volume'' MS–LTC–DRGs for purposes of determining a relative weight.) Then, we assigned the no-volume MS–LTC–DRG the relative weight of the cross-walked MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

For this final rule, as we proposed, we crosswalked the no-volume MS–LTC–DRG to an MS–LTC–DRG for which there were LTCH cases in the March 2011 update of the FY 2010 MedPAR file, and to which it was 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 MS–LTC–DRG to which a no-volume MS–LTC–DRG was cross-walked in order to assign an appropriate relative weight for the no-volume MS–LTC–DRGs in FY 2012. (For more detail on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2012, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on similar clinical similarity and relative costliness, generally require equivalent relative resource use.

We then assigned the relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2012. We note that if the cross-walked MS–LTC–DRG had 25 cases or more, its relative weight, which was calculated using the methodology described in Steps 1 through 4 above, was assigned to the no-volume MS–

LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to one of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2012. (As we noted above, in the infrequent case where nonmonotonicity involving a 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 final rule, a list of the no-volume MS–LTC–DRGs and the MS–LTC–DRG to which it was cross-walked (that is, the cross-walked MS–LTC–DRG) for FY 2012 is shown in Table 13B, which is listed in section VI. of the Addendum to this final rule and is available via the Internet.

To illustrate this methodology for determining the relative weights for the FY 2012 MS–LTC–DRGs with no LTCH cases, we are providing the following example, which refers to the no-volume MS–LTC–DRGs crosswalk information for FY 2012 provided in Table 13B.

Example: There were no cases in the FY 2010 MedPAR file used for this rule for MS–LTC–DRG 61 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that MS–LTC–DRG 70 (Nonspecific Cebrovascular Disorders with MCC) was similar clinically and based on resource use to MS–LTC–DRG 61. Therefore, we assigned the same relative weight of MS–LTC–DRG 70 of 0.8072 for FY 2012 to MS–LTC–DRG 61 (Table 11, which is listed in section VI. of the Addendum to this final 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 no-volume MS–LTC–DRGs and to determine the relative weights in this final rule.

Furthermore, for FY 2012, consistent with our historical relative weight methodology, we established MS–LTC–DRG relative weights of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 1); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 2); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 5); Liver Transplant without MCC (MS–LTC–DRG 6); Lung Transplant (MS–LTC–DRG 7); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 8); Pancreas Transplant (MS–LTC–DRG 10); and Kidney Transplant (MS–LTC–DRG 652). This is because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these eight transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).)

Step 6—Adjust the FY 2012 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 DRG is subdivided into either two levels or the base DRG is not subdivided. The two-level subdivisions could consist of the DRG with CC/MCC and the DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the DRG with MCC and the DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and will result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG without CC/MCC has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Consequently, in determining the FY 2012 MS–LTC–DRG relative weights in this final rule, consistent with our historical methodology we combined MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the FY 2012 MS–LTC–DRG relative weights in this final rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet.

Step 7—Calculate the FY 2012 budget neutrality factor.

As we established in the RY 2008 LTCH PPS final rule (72 FR 26882), under the broad authority conferred upon the Secretary to develop the LTCH PPS under section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554, beginning with the MS–LTC–DRG update for FY 2008, 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 (§ 412.517(b) in conjunction with § 412.503). (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).)

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 accordance 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 updated the MS–LTC–DRG classifications and relative weights for FY 2012 based on the most recent available LTCH data, and to apply a budget neutrality adjustment in determining the FY 2012 MS–LTC–DRG relative weights.

To ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we used our established two-step budget neutrality methodology. In this final rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2012, we calculated and applied a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 above) to ensure that estimated payments were not 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 MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average CMI.

To calculate the normalization factor for FY 2012 (the first step of our budget neutrality methodology), in this final rule, as we proposed, we used the following three steps: (1.a.) we used the most recent available LTCH claims data (FY 2010) and grouped them using the FY 2012 GROUPER (Version 29.0) and the recalibrated FY 2012 MS–LTC–DRG relative weights (determined in steps 1 through 6 of the Steps for Determining the FY 2012 MS–LTC–DRG Relative Weights above) to calculate the average CMI; (1.b.) we grouped the same LTCH claims data (FY 2010) using the FY 2011 GROUPER (Version 28.0) and FY 2011 MS–LTC–DRG relative weights and calculated the average CMI; and (1.c.) we computed the ratio of these average CMIs by dividing the average CMI for FY 2011 (determined in Step 1.b.) by the average CMI for FY 2012 (determined in step 1.a.). In determining the MS–LTC–DRG relative weights for FY 2012, each recalibrated MS–LTC–DRG relative weight was multiplied by 1.11520 in the first step of the budget neutrality methodology, which produced ''normalized relative weights.''

In the second step of our MS–LTC–DRG budget neutrality methodology, we determined 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 FY 2012 MS–LTC–DRG classifications and relative weights) are equal to estimated aggregate LTCH PPS payments before reclassification and recalibration (that is, the FY 2011 MS–LTC–DRG classifications and relative weights). Accordingly, consistent with our existing methodology, we used FY 2010 discharge data to simulate payments and compare estimated aggregate LTCH PPS payments using the FY 2011 MS–LTC–DRGs and relative weights to estimate aggregate LTCH PPS payments using the FY 2012 MS–LTC–DRGs and relative weights. Furthermore, consistent with our historical policy of using the best available data, we also used updated data to determine the budget neutrality adjustment factor for FY 2012 in the final rule.

For this final rule, as we proposed, we determined the FY 2012 budget neutrality adjustment factor using the following three steps: (2.a.) we simulated estimated total LTCH PPS payments using the normalized relative weights for FY 2012 and GROUPER Version 29.0 (as described above); (2.b.) we simulated estimated total LTCH PPS payments using the FY 2011 GROUPER (Version 28.0) and the FY 2011 MS–LTC–DRG relative weights shown in Table 11 of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50613 through 50626); and (2.c.) we calculated the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2011 GROUPER (Version 28.0) and the FY 2011 MS–LTC–DRG relative weights (determined in step 2.b.) by the estimated total LTCH PPS payments using the FY 2012 GROUPER (Version 29.0) and the normalized MS–LTC–DRG relative weights for FY 2012 (determined in Step 2.a.). In determining the FY 2012 MS–LTC–DRG relative weights, each normalized relative weight was multiplied by a budget neutrality factor of 0.994649 in the second step of the budget neutrality methodology to determine the budget neutral FY 2012 relative weight for each MS–LTC–DRG.

Accordingly, in determining the FY 2012 MS–LTC–DRG relative weights in this final rule, consistent with our existing methodology, we applied a normalization factor of 1.11520 and a budget neutrality factor of 0.994649 (computed as described above). Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet, lists the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used in determining SSO payments under § 412.529) for FY 2012. The FY 2012 MS–LTC–DRG relative weights in Table 11, which is listed in section VI. of the Addendum to this final rule and available via the Internet, reflect both the normalization factor of 1.11520 and the budget neutrality factor of 0.994649.

C. Quality Reporting Program for LTCHs

1. Background and Statutory Authority

CMS seeks to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by quality reporting programs coupled with public reporting of that information. Such quality reporting programs already exist for various settings such as hospital inpatient services via the Hospital Inpatient Quality Reporting (IQR) Program (formerly called the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program), hospital outpatient services via the Hospital Outpatient Quality Reporting (OQR) Program (formerly called the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) and physicians' and other eligible professionals' services via the Physician Quality Reporting System (formerly called the Physician Quality Reporting Initiative, or PQRI). We have also implemented quality reporting programs for home health agencies and skilled nursing facilities that are based on conditions of participation, and an end-stage renal disease quality incentive program (ESRD QIP) that links payment to performance.

Section 3004(a) of the Affordable Care Act authorizes an additional quality reporting program for LTCHs, by adding a new paragraph (5) to section 1886(m) of the Act. Section 1886(m)(5)(A)(i) of the Act requires that, for rate year 2014 and each subsequent rate year, the Secretary shall reduce any annual update to the standard Federal rate for discharges occurring during such rate year, by 2 percentage points for any LTCH that does not comply with quality data submission requirements with respect to an applicable rate year. We note that section 1886(m)(5) of the Act uses the term ''rate year.'' Beginning with the annual update to the LTCH PPS that took effect on October 1, 2009, we consolidated the rulemaking cycle for the annual update of the LTCH PPS

Federal payment rates with the annual update of the MS–LTC–DRG classifications and relative weights so that the annual updates to the rates and factors have an October 1 effective date and occur on the same schedule. To reflect this change to the annual payment rate update cycle, we revised the regulations at § 412.503 to specify that, beginning on or after October 1, 2009, the ''LTCH PPS rate year'' is defined as October 1 through September 30 (73 FR 26797 through 26798 and 26838). Beginning October 1, 2010, we changed from using the term ''rate year'' to ''fiscal year'' under the LTCH PPS in order to conform to the standard definition of the Federal fiscal year (October 1 through September 30). For LTCH PPS purposes, the term ''rate year'' and the term ''fiscal year'' both refer to the time period beginning October 1 and ending September 30. For more information regarding this terminology change, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50396 and 50397). For purposes of the discussion below, in order to eliminate any possible confusion that may be caused by using the term ''rate year'' with respect to the LTCH quality reporting program, we will use the term ''fiscal year'' rather than ''rate year.''

As provided at section 1886(m)(5)(A)(ii) of the Act, depending on the amount of the annual update for a particular year, a reduction of 2.0 percentage points may result in the annual update being less than 0.0 percent for a fiscal year and may result in payment rates under the LTCH PPS being less than payment rates for the preceding fiscal year. In addition, as set forth at section 1886(m)(5)(B) of the Act, any reduction based on failure to comply with the reporting requirements, as required by section 1886(m)(5)(A) of the Act, shall apply only with respect to the particular fiscal year involved, and any such reduction shall not be taken into account in computing the payment rate for subsequent fiscal years.

Section 1886(m)(5)(C) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, each LTCH shall submit to the Secretary data on quality measures as specified by the Secretary. Such data must be submitted in a form and manner, and at a time, specified by the Secretary. Generally, any measures selected by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act. This contract is currently held by the NQF. The NQF is a voluntary consensus 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 have generally adopted NQF-endorsed measures in our reporting programs.

However, section 1886(m)(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 entity with a contract under section 1890(a) of the Act (currently NQF), the Secretary may specify a measure(s) that is (are) 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 1886(m)(5)(D)(iii) of the Act, the Secretary shall publish, by no later than October 1, 2012, measures which shall be applicable with respect to the FY 2014 payment determination.

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making data submitted under the LTCH quality reporting program available to the public. The Secretary must ensure that each LTCH has the opportunity to review the data that are to be made public with respect to that facility prior to such data being made public. The Secretary must also report quality measures that relate to services furnished in LTCHs on the CMS Web site.

2. Quality Measures for the LTCH Quality Reporting Program for FY 2014

a. Considerations in the Selection of the Quality Measures

In implementing the LTCH quality reporting program, we believe that the development of a quality reporting program that is successful in promoting the delivery of high quality health care services in LTCHs is of paramount importance. As the statute provides in section 1886(m)(5)(D) of the Act, in establishing the LTCH quality reporting program, we must publish quality measures to be reported with respect to the FY 2014 payment determination no later than October 1, 2012. In order to meet that mandate, we sought to develop a quality reporting program that incorporates overarching health care aims and goals intended to facilitate quality care in a manner that is effective and meaningful, while remaining mindful of reporting burden and feasibility of data collection by LTCHs, in order to reduce and avoid duplicative reporting efforts when possible. We seek to efficiently collect information on valid, reliable, and relevant measures of quality and to share this information with the public, as provided under section 1886(m)(5)(E) of the Act.

Several provisions of the Affordable Care Act, taken together, direct the Secretary to establish a national strategy to provide a comprehensive plan and priorities to improve the delivery of health care services, patient health outcomes, and population health through a transparent, collaborative process. This strategy, the National Quality Strategy, was released by the Secretary (available on the Web site at: *http://www.healthcare.gov/center/reports/quality03212011a.html#es).* We have used the priorities of the National Quality Strategy to guide identification of the proposed quality measures for LTCHs under section 1886(m)(5) of the Act.

We also applied the following additional considerations and criteria in selecting the quality measures for LTCHs: whether a measure is included in, or facilitates alignment with, other Medicare and Medicaid programs; whether a measure addresses HHS priorities, such as prevention, care of chronic illness, high prevalence conditions, patient safety, patient and caregiver engagement, and care coordination; and whether a measure is evidence-based and may drive quality improvement as well as has a low probability of causing unintended adverse consequences, such as reduced LTCH admissions of higher risk patients.

Furthermore, at the Listening Session held on November 15, 2010, for the Affordable Care Act section 3004 quality reporting programs, we sought input, and invited comments and suggestions regarding quality reporting, quality measurement recommendations, prioritization, and feasibility. We sought additional input at a Special Open Door Forum held on December 16, 2010, for the Affordable Care Act section 3004 quality reporting programs. Transcripts for both the Listening Session and the Open Door Forum can be found on the CMS Web site at: *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting.*

In addition, we invited suggestions and input regarding the section 3004 quality reporting programs to be sent to us using the CMS Web site mail box *LTCH-IRF-Hospice-Quality-Reporting Comments@cms.hhs.gov* found at *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting.* We also received suggestions and input from a LTCH technical expert panel (TEP), convened by the CMS measure development contractor on January 31, 2011, that reviewed and prioritized the quality

measures identified by a LTCH environmental scan led by a CMS measure development contractor, Research Triangle Institute (RTI International), specifically for the LTCH quality reporting program. Specifically, this TEP reviewed measures found in the environmental scan and rated them for importance, scientific soundness, usability, and feasibility.

In summary, in selecting the quality measures discussed below, with applicability for FY 2014 and subsequent years, our goal is to achieve several objectives. First, the measures should relate to the general aims of better care for the individual, better population health, and lower cost through better quality. Second, the measures should promote improved quality specifically with regard to the priorities that are of most relevance to LTCHs. These include: patient safety, such as avoiding healthcare-associated infections (HAIs) and adverse events; better coordination of care; and person-centered and family-centered care. Third, the measures should address improved quality for the primary role of LTCHs, which is to furnish extended medical care to individuals with clinically complex problems, such as multiple acute or chronic conditions, that need hospital-level care for relatively extended periods of greater than 25 days.

b. LTCH Quality Measures for the FY 2014 Payment Determination

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25983), we proposed that, for the FY 2014 payment determination, LTCHs submit data on three quality measures: (1) Urinary Catheter-Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Bloodstream Infection (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened.

HAIs are a topic area widely acknowledged by HHS in the HHS Action Plan to Prevent HAIs (*http://www.hhs.gov/ash/initiatives/hai/actionplan/*), the Institute of Medicine, the National Priorities Partnership, and others as a high impact priority requiring measurement and improvement. Better care is one of the aims found in the National Quality Strategy, and patient safety is one of the priorities. Mitigating HAIs is essential in the improvement of patient safety, and, therefore, patient care. HAIs are among the leading causes of death in the United States and, therefore, are serious reportable events. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths per year.[58] HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs. Therefore, two of the three proposed quality measures, CAUTI and CLABSI, are HAI measures.

Other HAIs included in the HHS Action Plan to Prevent HAIs were under consideration for the LTCH quality reporting program beginning October 1, 2012. However, the TEP convened by the measure development contractor recommended the two infection events, urinary catheter-associated urinary tract infection and central line catheter-associated bloodstream infection (each an episode of an infection, such as CAUTI or CLABSI) as highly pertinent, and important for data collection as well as most ready and currently feasible for implementation in the LTCH setting. HAI quality measures are important for quality reporting, and we intend to propose additional HAI measures included in the HHS HAI Action Plan to Prevent HAIs through future rulemaking. These potential HAI quality measures are listed in our discussion of possible measures under consideration for future years. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25983 through 25985), we proposed the selection of the CAUTI and CAUTI events as the two initial HAI quality measures for the LTCH quality measure reporting program.

(1) FY 2014 LTCH Measure #1: Urinary Catheter-Associated Urinary Tract Infections (CAUTI)

The first measure we proposed for LTCHs for purposes of the FY 2014 payment determination is an application of the NQF-endorsed measure developed by CDC for hospital intensive care units (ICU) entitled (NQF #0138) ''Urinary Catheter-Associated Urinary Tract Infection [CAUTI] rate per 1,000 urinary catheter days, for Intensive Care Unit Patients'' to all LTCH care units. This measure was developed by the CDC to measure the percentage of patients with CAUTIs in the ICU context. At the time we developed the proposed rule, the measure we proposed to apply, NQF #0138, was undergoing measure maintenance review by NQF. We indicated that this review may result in a change in how the CDC calculates the aggregated data from using a rate for CAUTI, to the use of a standardized infection ratio (SIR) of healthcare associated catheter-associated urinary tract infections. We proposed to adopt the current measure in this rulemaking cycle. However, we also indicated that we intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking.

While it is fast becoming a medical best practice to avoid urinary catheter use whenever possible, this may not always be possible with the LTCH patient population, due to the severity of their primary illnesses as well as comorbidities. Patients who are exposed to indwelling urinary catheters have a significantly higher risk of developing urinary tract infections (UTIs).

UTIs are a common cause of morbidity and mortality. The HHS Action Plan to Prevent HAIs identified catheter associated urinary tract infections as the leading type of HAI that is largely preventable, and the occurrence of which can be drastically reduced in order to reduce adverse health care related events and avoid excess costs.

The urinary tract is the most common site of HAI, accounting for more than 30 percent of infections reported by acute care hospitals.[59] Healthcare-associated UTIs are commonly attributed to catheterization of the urinary tract.

CAUTI can lead to such complications as cystitis, pyelonephritis, gram-negative bacteremia, prostatitis, epididymitis, and orchitis in males and, less commonly, endocarditis, vertebral osteomyelitis, septic arthritis, endophthalmitis, and meningitis in all patients. Complications associated with CAUTI also include discomfort to the patient, prolonged hospital stay, and increased cost and mortality. Each year, more than 13,000 deaths are associated with UTIs.[2] Prevention of CAUTIs is discussed in the CDC/HICPAC document, Guideline for Prevention of Catheter-associated Urinary Tract Infections.[60]

The NQF-endorsed CAUTI measure we proposed is currently collected by the CDC via the National Healthcare Safety Network (NHSN) as part of State-mandated reporting and surveillance requirements for hospitals. CDC's NHSN is a secure Internet-based surveillance system that currently has data collection forms and data submission and reporting mechanism in place for

[58] McKibben L; Horan T: Guidance on public reporting of healthcare-associated infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005;33:217 through 226.

[59] Klevens RM, Edward JR, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160–166.

[60] Wong ES. Guideline for prevention of catheter-associated urinary tract infections. Infect Control 1981;2:126–30.

LTCHs. NHSN is currently used, in part, as one means by which certain State-mandated reporting and surveillance data are collected.

We recognize that the NQF has endorsed this measure for the short term, acute care ICU setting, but believe that this measure is highly relevant to LTCHs, in that urinary catheters are commonly used in the LTCH care setting. As previously noted, NQF #0138 is undergoing measure maintenance review by NQF. This review may result in a change in how CDC calculates the aggregated data from using a rate for CAUTI to the use of a SIR. We proposed to adopt the current measure in this rulemaking cycle. However, we indicated that we intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking. The TEP convened by the our measure development contractor on January 31, 2011, identified CAUTI as a high priority quality issue for LTCHs, and there was agreement by this TEP that this particular infection rate is worthy of surveillance within LTCHs. This measure is applicable for surveillance in long-term care units (CDC/NHSN Manual, Device-Associated Module, CAUTI Event, which is available on the CDC Web site at: *http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTIcurrent.pdf.*

Section 1886(m)(5)(D)(ii) of the Act 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 the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed measures for urinary catheter-associated urinary tract infections for the LTCH setting. We are unaware of any other measures for catheter-associated urinary tract infections that have been approved by voluntary consensus standards bodies and endorsed by NQF. We proposed to adopt an application of this NQF-endorsed (in the short-term acute care ICU setting) measure under the Secretary's authority to select non-NQF-endorsed measures.

As previously noted, NQF #0138 is undergoing measure maintenance review by NQF. This review may result in changes to this measure's specifications in how CDC calculates the aggregated data from using a rate for CAUTI to the use of a SIR. We proposed to adopt the current measure in this rulemaking cycle. However, we indicated that we intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking. We note that we intend to ask NQF to formally extend its endorsement of the CAUTI measure to the LTCH setting.

We solicited public comment on the proposed quality measure ''Urinary Catheter-Associated Urinary Tract Infections'' (CAUTI) in the FY 2012 IPPS/LTCH PPS.

Comment: The majority of commenters acknowledged that catheter-associated urinary tract infections are an important issue and supported this measure for use in quality measurement and reporting given the clinical severity of some LTCH patients. A few commenters expressed concern related to the clinical relevance, lack of uniformity, and relative usefulness compared to other catheter associated urinary tract infection measures for LTCHs. One commenter believed that no data were provided to support the selection of this HAI for LTCH settings.

Response: We appreciate the commenters' support in the use of this measure. We agree with the importance of catheter associated urinary tract infections. As an HAI, the CDC estimates that there are 449,334 CAUTIs and 13,000 deaths per year with an estimated associated cost of $340,000,000.[61] The catheter-associated urinary tract infection is the most common type of HAI, comprising some 30 percent of all HAIs. Furthermore and importantly, as indicated in the HHS National Action Plan to Prevent HAIs (*http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html*), catheter-associated urinary tract infection is also a leading type of HAI that is largely preventable.[62]

With respect to the other urinary tract infection measures referenced, we believe that the commenters are referring to other NQF endorsed measures that are based on urinary tract infections (not catheter-associated) or measured usage of a urinary catheters, not measures of Catheter Associated Urinary Tract Infection. As we have previously stated we are unaware of any other endorsed measure for Urinary Catheter Associated Urinary Tract Infection.

As for data in support of the selection of CAUTI for the LTCH setting, each year, more than 13,000 deaths are associated with UTIs.[63] Furthermore, CAUTI is included in the HHS National Action Plan to Prevent HAIs. LTCH patients often have medical complexities that necessitate the use of urinary catheters as an integral aspect of a patient's care, and the use of urinary catheters is common. Additionally, the TEP convened by the CMS measure developer contractor for LTCH measure development identified CAUTI as a high priority issue for LTCHs. Because the use of urinary catheters leads to risk of CAUTI, we believe that the CAUTI measure is appropriate for LTCHs and aligns with HHS priorities to reduce such infections.

Comment: Commenters commended the NQF endorsement process and suggested that the LTCH CAUTI measure undergo the same evaluation before being published in the final rule. Many commenters expressed concern that the CAUTI measure is not endorsed by the NQF for the LTCH setting. Some commenters suggested that CMS work with the CDC to test this measure and ''refine the measure'' prior to finalizing its use.

Response: We agree with the value of the NQF endorsement process. We are using the NQF endorsed CAUTI measure for Hospital ICU's and applying it to the LTCH setting. With regard to the comment that we ''refine the measure'' prior to the use of this measure, we interpret this to mean to further specify or specify the measure differently for LTCHs. Although the currently NQF endorsed CAUTI measure is not specifically NQF-endorsed for the LTCH setting, CAUTI events, from which the measure is calculated, are already being collected by some LTCHs through the use of the NHSN. We intend to use the same measure specifications as endorsed by NQF for Hospital ICUs as for LTCHs and collected through the NHSN.

Comment: Several commenters highlighted the need to risk-adjust the CAUTI measure. These commenters stated that some LTCH patients are at much higher risk of developing CAUTI than other lower risk patients. Several commenters expressed concern that lack of risk adjustment could possibly lead to unintended consequences such as reduced access for higher risk patients.

[61] Scott, RD. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. March 2009. Available at: *http://www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf.*

[62] Klevens RM, Edwards JR, Richards CL, Horan TC, Gaynes RP, Pollock DA, Cardo DM. Estimating healthcare-associated infection and deaths in U.S. hospitals, 2002. Public Health Reports 2007: 122:160–166. Available at *http://www.cdc.gov/ncidod/dhqp/pdf/hicpac/infections_deaths.pdf.*

[63] See note 2.

Response: The CAUTI measure as endorsed by NQF does include risk adjustment although not based on individual patient characteristics or comorbidities as suggested by commenters. Rather as endorsed by NQF, the CDC NHSN process uses facility type and location type information for risk adjustment by stratifying the results by facility and location type. The results are then reported as observed over expected based on the expected rate for the facility or location. In this case, measures would be calculated based on the expected rate for LTCHs, according to the data reported to the CDC. This is reported as a Standardized Infection Ratio (SIR). More information about the SIR can be found at the CDC Web site: *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf.*

Comment: Some commenters expressed concern with potential erroneous attribution of infections that may have resulted from catheter use in a previous setting. One commenter asked whether quality data related to CAUTI would be collected for all LTCH patients regardless of payer.

Response: With respect to erroneous attribution, the CDC's guidelines for HAI NHSN event reporting include a Transfer Rule. Under the Transfer Rule, CAUTIs that develop within 48 hours of transfer from a patient's previous patient transferring location to the receiving or admitting location, are not attributable to the admitting patient location, such as the LTCH setting. Therefore such CAUTIs are not included in the admitting LTCH's HAI event reporting, and are not included in the LTCH's CAUTI measure. In the HAI NHSN event reporting, admitting and transferring locations are defined using a unit identifier on the CDC's NSHN. We believe this appropriately addresses the potential risk of erroneous attribution for transferred patients. Additional information related to the ''Transfer Rule'' can be found on the CDC Web site at: *http://www.cdc.gov/nhsn/PDFs/slides/CAUTI.pdf.*

As stated in the proposed rule, the reporting of HAI events and meaningful HAI event surveillance by LTCHs using the CDC/NHSN requires the submission of HAI events, regardless of payer.

Comment: One commenter expressed concern that patients who were ''colonized'' with bacteria but without symptoms would be included as CAUTI and therefore opposed use of this measure.

Response: We interpret the commenter's use of the term ''colonized'' to mean a condition in which significant numbers of bacteria have colonized the urinary tract but there are no signs or symptoms of urinary tract infection. Patients with this condition do not meet CDC's current criteria for CAUTI. To meet CDC's criteria, asymptomatic patients must have a bacteremia involving at least one microorganism that is a uropathogen. Please refer to the CDC website for further information *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf*

After consideration of the public comments we received, we are finalizing the Urinary Catheter-Associated Urinary Tract Infection measure, as proposed, for the FY 2014 payment determination.

(2) FY 2014 Measure #2: Central Line Catheter-Associated Bloodstream Infection (CLABSI)

The second measure we proposed for LTCHs for the FY 2014 payment determination is an application of a CDC-developed NQF-endorsed measure for hospital ICU and high-risk nursery patients; (NQF #0139) ''Central Line Catheter-Associated Bloodstream Infection (CLABSI) Rate for ICU and High-Risk Nursery (HRN) Patients.'' This is a measure of the percentage of ICU and high-risk nursery patients who, over a certain amount of days, acquired central line catheter-associated bloodstream infections over a specified number of line days.

A central line is a catheter that health care providers often place in a large vein in the neck, chest, or groin to give medication or fluids or to collect blood for medical tests. Many LTCH patients have been discharged from short-term acute care hospital ICUs or ICU step-down units with these central lines already in place. In other situations, a central line IV may be inserted during the patient's stay at the LTCH. Bloodstream infections are usually serious infections typically causing a prolongation of hospital stay and increased cost and risk of mortality.[64] An estimated 248,000 bloodstream infections occur in U.S. hospitals each year.[65] Furthermore, CLABSIs result in thousands of deaths each year and billions of dollars in added costs to the U.S. healthcare system, yet these infections are preventable. The CDC is providing guidelines and tools to the health care community to help reduce central line catheter-associated bloodstream infections. Techniques to prevent CLABSI through proper central line management are addressed in CDC's Healthcare Infection Control Practices Advisory Committee Guidelines for the Prevention of Intravascular Catheter Related Infections.[66]

We recognize that NQF endorsement of this measure is limited to ICU and HRN patients in hospital settings, but believe that this measure is also highly relevant in the LTCH setting because intravascular, central venous catheters (also known as a ''central line'') are used frequently due to the fact that these types of hospitals care for patients with complex medical problems which require LTCH stays and intensive treatment.

The CMS measure development contractor convened a TEP on January 31, 2011, which identified CLASBIs as a high priority quality issue for LTCHs; there was agreement by the TEP that this particular infection rate is worthy of surveillance within LTCHs. This measure is applicable for surveillance in long-term hospital care units (CDC/NHSN Manual, Device-Associated Module, CLABSI Event, which is available at the CDC Web site at: *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf*).

Section 1886(m)(5)(D)(ii) of the Act 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 the NQF's consensus-endorsed measures, and were unable to identify any NQF endorsed measures for central line catheter-associated bloodstream infections for the LTCH setting. We are unaware of any other measures for CLABSI that have been approved by voluntary consensus standards bodies and endorsed by NQF. Therefore, we proposed to adopt an application of this NQF-endorsed (for ICU and HRN) measure under the Secretary's authority provided in section 1886(m)(5)(D)(ii) of the Act.

[64] CDC/NHSN Manual. Device-Associated Module, CLABSI Event. Available at *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf*, accessed on January 20, 2011.

[65] Klevens RM, Edward JR, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160–166.

[66] O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, et al. Guidelines for the prevention of intravascular catheter-related infections. *MMWR* 2002;51(No. RR–10:1–26.

We proposed to apply the measure specifications as endorsed by NQF. We also intend to ask NQF to formally extend its endorsement of the CLABSI measure to all care settings within the LTCH (that is, beyond the LTCH ICU).

We solicited public comment on the proposed quality measure ''Central Line Catheter-Associated Bloodstream Infection'' (CLABSI) in the FY 2012 IPPS/LTCH PPS proposed rule for the quality reporting program for LTCHs.

Comment: The majority of commenters supported the selection of CLABSI for use in quality measurement and reporting. One commenter believed that, of the three proposed measures, CLABSI is probably the best understood measure, and encouraged its adoption. Other commenters remarked positively on its clinical relevance given the clinical severity of some LTCH patients. However, one commenter questioned the clinical relevance of a CLABSI-based quality measure for LTCHs, and expressed concern that the majority of LTCH patients do not have central lines in LTCHs.

Response: We appreciate the commenters' support for the use the CLABSI measure. We agree with the importance of CLABSIs. Specifically, we believe collecting data on this quality measure is clinically relevant because CLABSIs are preventable, and can lead to poor outcomes such as sepsis and death. Further, as indicated in the HHS National Action Plan to Prevent HAIs (*http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html*), CLABSI is a leading type of HAI.

We also agree with commenter who stated that CLABSIs are clinically relevant to LTCHs. LTCH patients are often medically complex and central line catheters are used in the LTCH setting as part of patient care management. Therefore, as with other patients, LTCH patients are at risk for developing a CLABSI. For calendar year 2009, there were 4,522 LTCH claims in CMS data with ICD–9 codes for this infection, supporting both the relevance of this measure and the presence of central line catheter usage.

Comment: Some commenters commended the NQF endorsement process and some commenters expressed concern that the CLABSI measure is not NQF-endorsed for the LTCH setting and suggested that the LTCH CLABSI measure undergo the same evaluation before being published in the final rule. One commenter suggested that CMS work with the CDC to test this measure and ''refine the measure'' and that CMS seek NQF endorsement for use in LTCHs prior to finalizing its use.

Response: We agree with the value of the NQF endorsement process. We are using an NQF endorsed CLABSI measure for Hospital ICU's and applying it to the LTCH setting. With regard to the comment that we ''refine the measure'' prior to the use of this measure, we interpret this to mean to further specify or specify the measure differently for LTCHs. Although the currently NQF endorsed CAUTI measure is not specifically NQF-endorsed for the LTCH setting, CLABSI events, from which the measure is calculated, are already being submitted by some LTCHs through the use of the NHSN. We intend to use the same measure specifications as endorsed by NQF for Hospital ICUs as for LTCHs and collected through the NHSN.

Comment: Many commenters urged CMS to risk-adjust the CLABSI measure. These commenters stated that some LTCH patients were at much higher risk of developing CLABSI than other, lower risk, patients. Some commenters suggested that data for this measure be based upon the type of LTCH unit and that the measure consider those units associated with the highest risk of infection such as long-term care ventilator units that may utilize central line catheters more extensively. Some commenters noted that there are medical situations where an infection may be anticipated or occur despite best care efforts. Several commenters expressed concern that the perceived lack of risk adjustment could possibly lead to unintended consequences such as reduced access for higher risk patients. Some commenters appeared to express concern that the data provided were not at the individual level.

Response: The CLABSI measure as endorsed by NQF does include risk adjustment although not based on individual patient characteristics or comorbidities as suggested by commenters. Rather, as suggested by others and endorsed by NQF for ICUs, the CDC NHSN process uses facility type and location type information for risk adjustment by stratifying the results by facility and location type. The results are then reported as observed over expected based on the expected rate for the facility or location. In this case, measures would be calculated based on the expected rate for LTCHs or locations within the facility, based on the data reported to the CDC. This is reported as a Standardized Infection Ratio (SIR), described in detail at *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf.* The SIR is a summary statistic that risk adjusts by taking into account risk differences across patient population by stratifying by hospital location. This is the only type of summary statistic method that is used at this time, or that has historically been used by the CDC for the CLABSI and CAUTI measures. After extensive consultation with the CDC in this matter, we have determined that it is best to defer experts at CDC, who have recommended that SIR is the most appropriate method of summary statistic for taking risk differences in patient population into account. In addition, during a Technical Expert Panel (TEP) that was convened on July 7, 2011, many of the LTCH subject-matter experts opined that SIR is an appropriate and adequate method of taking risk differences in patient population into account for the CAUTI and CLABSI measures.

After consideration of the public comments we received, we are finalizing the Central Line Catheter-Associated Bloodstream Infection measure, as proposed, for the FY 2014 payment determination.

(3) FY 2014 Measure #3: Pressure Ulcers

The third measure we proposed for LTCHs for purposes of the FY 2014 payment determination is an application of a CMS-developed NQF-endorsed measure for short-stay nursing home patients: (NQF #0678, formerly assigned as NQF # NH–012–10) ''Percent of Residents with Pressure Ulcers that Are New or Have Worsened.'' This measure includes the percentage of patients who have one or more stage 2–4 pressure ulcers that are new or worsened from a previous assessment. Consistent in our support of the National Quality Strategy principles, mitigating the occurrence or worsening of pressure ulcers is essential in the improvement of patient safety and, therefore, patient care.

We recognize NQF endorsement of this measure is limited to short-stay nursing home patients, but believe that this measure is highly relevant and a high priority quality issue for the care of LTCH patients. Pressure ulcers are high-volume and high-cost adverse events across the spectrum of health care settings from acute hospitals to home health. Patients in the LTCH setting are medically complex, have functional limitations that often are severe, and, therefore, are at high risk for the development, or worsening, of pressure ulcers. Pressure ulcers are serious medical conditions and an important measure of quality. Pressure ulcers can lead to serious, life-threatening infections, which substantially increase the total cost of care. Furthermore, as we noted in the FY 2008 IPPS final rule with comment

period (72 FR 42705), in 2006 there were 322,946 reported cases of Medicare patients with a pressure ulcer as a secondary diagnosis—each case had an average charge of $40,381 for a hospital stay, for an annual total cost of 13 billion dollars. The prevalence of pressure ulcers in health care facilities is increasing, with some 2.5 million patients being treated annually for pressure ulcers in acute care facilities.[67] [68] In 2006, there were 503,300 acute hospital stays during which pressure ulcers were noted. This is a 78.9 percent increase from 1993 when there were approximately 281,300 hospital stays related to pressure ulcers.[69]

The CMS measure development contractor convened a TEP on January 31, 2011, which identified this topic as highly relevant and a high priority quality issue for the care of LTCH patients, and the application of this measure (NQF #0678) as appropriate for LTCHs.

Section 1886(m)(5)(D)(ii) of the Act 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 the NQF-endorsed measures, and we were unable to identify any NQF-endorsed measures for the monitoring of pressure ulcers that are new or worsened, for the LTCH setting. We are unaware of any other measure for the LTCH setting of new or worsened pressure ulcers that are approved by voluntary consensus standards bodies and endorsed by NQF. Therefore, we proposed to adopt an application of this NQF-endorsed (for short-stay nursing home patients) measure for the LTCH quality reporting program under the Secretary's authority set forth at section 1886(m)(5)(D)(ii) of the Act.

We solicited public comment on the proposed quality measure Percent of Residents with Pressure Ulcers that Are New or Have Worsened in the FY 2012 IPPS/LTCH PPS proposed rule for the quality reporting program for LTCHs.

Comment: Most commenters supported the selection of pressure ulcers for use in quality measurement and reporting. However, one commenter questioned the clinical relevance of this measure, and believed that there was a lack of supporting data in the proposed rule. Another commenter suggested that few studies have conclusively shown that ''standard interventions implemented today have been proven beyond a reasonable doubt to do anything at all to prevent pressure ulcers.''

Response: We appreciate the commenters' support of this measure.

We believe, as the data provided in the proposed rule suggests, that the development of new or worsened pressure ulcers is a very relevant clinical quality issue in all clinical settings, including LTCHs. Our measure development contractor convened a TEP on January 31, 2011, which identified this topic as highly relevant and a high priority quality issue for the care of LTCH patients, and the application of this measure (NQF 0678) as appropriate for LTCHs. Specifically, in LTCHs alone, claims submitted to CMS in 2009 included nearly 700 claims for stage one pressure ulcers; just over 2,600 claims for stage 2 pressure ulcers; just over 7,000 for stage 3 pressure ulcers; nearly 10,000 claims for stage 4 pressure ulcers and just over 1,100 claims for both stage 3 and stage 4 pressure ulcers; as well as nearly 800 claims for unstageable pressure ulcers. LTCH patients are often at an increased risk of pressure ulcer formation given their medical complexities, and often lack of mobility.

We disagree with the commenter who believed that few studies have conclusively shown that ''standard interventions implemented today have been proven beyond a reasonable doubt to do anything at all to prevent pressure ulcers.'' We believe that the evidence-based pressure ulcer prevention guidelines published by clinical experts, such as the National Pressure Ulcer Advisory Panel in conjunction with the European Pressure Ulcer Advisory Panel (NPUAP and EPUAP) (*http://www.npuap.org/resources.htm*) as well as the Institute for Clinical Systems Improvement, and others, suggest that pressure ulcer development and worsening can be reduced and mitigated through the application of such best practices.

Comment: Many commenters agreed that pressure ulcers are an important issue, and are important for quality measurement in the LTCH setting. However, one commenter expressed concern that the proposed pressure ulcer measure was developed for short-stay nursing home patients and suggested that patients in LTCHs require hospital-level, physician-led, post acute care, while patients in nursing homes have far lower medical acuity and resource use. Some commenters recommended harmonizing the LTCH pressure ulcer measure with Hospital IQR Program pressure ulcer measure which includes only Stages III and IV, suggesting that this would facilitate cross-site data comparisons that would be helpful for policy work to reduce patient harm, improve transitions of care, reduce preventable readmissions and related delivery system reforms. Commenters suggested the involvement of albumin levels in wound improvement. Commenters also suggested that CMS work to test this measure, ''refine the measure,'' and seek NQF endorsement for use in LTCHs prior to finalizing its use.

Response: We appreciate the many supportive comments as to the importance of the issues of pressure ulcers in the LTCH setting. Although we agree LTCHs are different than nursing homes in terms of patient types, we do not agree that the issue of pressure ulcers is substantially different in terms of preventability and treatment. With respect to harmonizing measures with the Hospital IQR Program, we believe that an assessment of patients as done for the nursing home measure is preferable for a pressure ulcer measure as opposed to a claims based measure relying on diagnosis codes. We believe the assessment provides more information particularly for worsening and improving pressure ulcers. As for the suggestion albumin levels are involved in wound improvement, this is not a risk factor as included in the NQF-endorsed measure we are adopting for application to the LTCH setting. Finally, as to the future refinement, we are applying the measure as endorsed by NQF for nursing homes.

Comment: Many commenters believed that the term ''worsening'' pressure ulcers was ambiguous. These commenters noted that inter-rater reliability of wound staging may vary significantly, and suggested that the term ''worsening'' be defined. Commenters also suggested that ''worsening'' be removed from the description and that CMS base the

[67] Russo CA, Steiner C, Spector W.: *Hospitalizations related to pressure ulcers among adults 18 years and older, 2006* (Healthcare Cost and Utilization Project Statistical Brief No. 64). December 2008. Available at: *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb64.pdf.*

[68] Institute for Healthcare Improvement: Relieve the pressure and reduce harm. May 21, 2007. Available at: *http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/ImprovementStories/FSRelievethePressureandReduceHarm.htm.*

[69] MacLean DS.: Preventing & managing pressure sores. *Caring for the Ages.* March 2003;4(3):34–7. Available at: *http://www.amda.com/publications/caring/march2003/policies.cfm.*

quality measure solely on the appearance of ''new'' pressure ulcers. Many commenters also suggested that this measure include an indicator for when a pressure ulcer is ''present on admission'' (POA), as is done with the Hospital IQR Program measure, Pressure Ulcers Stages III and IV. Some commenters indicated that it is difficult to accurately differentiate between worsening pressure ulcers and pressure ulcers that appear to worsen as part of the healing process before they get better, such as pressure ulcers that undergo debridement, or in instances when the patient has an episode of sepsis or hemodynamic instability. These commenters suggested that debridement often improves the overall condition of the wound but it is expected that it initially will increase the measurement of the wound. In addition, some commenters recommended adding a measure to identify healing pressure ulcers. One commenter suggested that the pressure ulcer measure should be defined as the number of patients per 1000 days who suffered a pressure ulcer.

Response: This proposed measure is an application of a measure that NQF-endorsed in the SNF setting. We do not agree that the measure is ambiguous or that it should be based solely on the appearance of new pressure ulcers. As specified for the LTCH setting, the measure, new or worsening pressure ulcers, is based on changes in skin integrity that occurs within the LTCH. With regard to the Hospital IQR Program, and the use of a present on admission (POA) indicator, it is important to note that the pressure ulcer measure in the Hospital IQR Program relies on claims codes to identify pressure ulcers. A POA indicator is necessary to avoid attributing to the hospital the development of a pressure ulcer when the pressure ulcer was present on admission. By contrast, the measure that we proposed for LTCHs is based on the direct assessment of patients, the first assessment of which is upon admission. The measure considers pressure ulcers that were present on admission based on the initial assessment in order to assess for any worsening of these pressure ulcers during the patients' stays.

Unstageable wounds include deep tissue injuries and pressure ulcers covered by nonremovable dressings, slough or eschar. These are not currently included in this measure since unstageable wounds cannot be measured, and therefore the presence of worsening cannot be determined. For example, a pressure ulcer that presents with slough or eschar cannot be staged, and is not considered worsened. Only after, and if, debridement occurs, and the dead tissue is removed, can such a wound be properly staged. If after wound debridement, the wound is staged and subsequently evaluated to have increased in the stage, the wound is considered worsened. However, such a wound may not be considered worsened if the stage remains unchanged after debridement and staging.

For additional information related to this measure, including definitions related to worsening, unstageable and the staging of the pressure ulcers, as well as topics such as the inability to stage pressure ulcers with eschar or slough, we refer readers to the Minimum Data Set 3.0 (MDS 3.0) Resident Assessment Instrument Manual, page 24 of Section M, Skin Conditions, which describes the NPUAP approach. This information can be found on the CMS Web site for the MDS 3.0: *http://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp#TopOfPage.*

Finally, with respect to the suggestion of a measure of healing pressure ulcers and measurement on the basis of 1000 patients, we will consider these suggestions for the future. However, as we have proposed, we are finalizing the application of the existing NQF endorsed specifications for pressure ulcers for the nursing home setting to LTCHs.

After consideration of the public comments we received, we are finalizing the Percent of Residents with Pressure Ulcers that Are New or Have Worsened measure, as proposed, for the FY 2014 payment determination.

3. Possible LTCH Quality Measures under Consideration for Future Years

As discussed below, we seek to achieve a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement. Therefore, as stated previously and as indicated in the proposed rule, we intend to propose, through future rulemaking, measures included in the HHS Action Plan to Prevent HAIs. As we also stated in the proposed rule, we intend to propose through future rulemaking measures related to ventilator care such as the NQF-endorsed Institute for Healthcare Improvement process measure, NQF #0302, Ventilator Bundle, which is a comprehensive ventilator care-bundle process measure that is designed to facilitate protocols such as weaning, and mitigate ventilator-related infections, such as ventilator-associated pneumonia, and other complications. We also intend to propose additional outcome measures such as those related to acute care rehospitalization. We are aware of the limits related to feasibility in data submission at the present time. For example, there is no feasible means to submit the ventilator bundle process measure at this at this time, and are therefore we are currently identifying the data elements necessary for this measure using a data subset from the Continuity Assessment Record and Evaluation (CARE) data set as well as a submission mechanism. We also intend to propose, through future rulemaking, additional measures, such as those related to symptom management, physical restraints, medication use, falls, infections, and function, using the data subsets of the CARE data set necessary for measure calculations.

In the proposed rule, we invited public comment and suggestions on the implementation of a standardized assessment instrument for LTCHs that would similarly support the calculation of quality measures. We also invited public comment on the measures and measures topics under consideration for future years set out below. In addition, we invited other suggestions and rationale to support the adoption of measures and topics not listed below.

POSSIBLE MEASURES AND MEASURE TOPICS FOR THE LTCH QUALITY REPORTING PROGRAM UNDER CONSIDERATION FOR FUTURE YEARS

Overarching Goal: Safety and Healthcare Acquired Conditions—HAIs
HAI reporting for: • Ventilator-associated Pneumonia.*** • Surgical site infection rate.*** • Multi-drug resistant organism infection.

POSSIBLE MEASURES AND MEASURE TOPICS FOR THE LTCH QUALITY REPORTING PROGRAM UNDER CONSIDERATION FOR FUTURE YEARS—Continued

Overarching Goal: Safety and Healthcare Acquired Conditions: Avoidable Adverse Events and Serious Reportable Events
• Unplanned acute care hospitalizations. • Mortality.*** • Blood Incompatibility.** • Foreign object retained after surgery.** • Manifestation of poor glycemic control.** • Air Embolism.** • Falls and trauma.** • Venous Thromboembolism.* • Injuries secondary to Poly-pharmacy. • Injuries related restraint use. • Medication errors.* • Stage III and IV Pressure Ulcer.**
Overarching Goal: Safety and Improvement Practices for Adverse Event Reduction
• Central line bundle.*** • Ventilator bundle.*** • Patient Immunization for Influenza.*** • Patient Immunization for Pneumonia.*** • Staff immunization.***
Overarching Goal: Safety—NQF Endorsed Nursing Sensitive Care Measures
• Patient Fall Rate.*** • Falls with Injury.*** • Pressure Ulcer Prevalence.*** • Restraint Prevalence (vest and limb only).*** • Skill mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract)*** Nursing care hours per patient day (RN, LPN, UAP).*** • Voluntary turnover for RN, APN, LPN, UAP.*** • Practice Environment Scale-Nursing Work Index.***

* Harmonizes with NQF Serious Reportable Events.
** Harmonizes with Hospital-Acquired Conditions–Present on Admission Program for IPPS hospitals.
*** Harmonizes with NQF-endorsed measures.

We solicited public comment on possible LTCH quality measures under consideration for future years.

Comment: Some commenters generally supported the future measures under consideration, and specifically supported several of the potential measures for LTCH quality reporting in future years, including: Staff immunization for influenza; measures for ventilator care and ventilator-associated pneumonia; surgical site infections; multi-drug resistant organism infections; readmissions; process measures related to reducing catheter-associated urinary tract infections and Stage III and IV pressure ulcers; glycemic control in diabetic patients; and MRSA bacteremia for multidrug-resistant organisms. Commenters also suggested adding to the list chronic obstructive pulmonary disease, C. *Difficile* SIR, process measures for management of cardiovascular conditions, including heart failure and atrial fibrillation, condition-specific readmissions, and a process measure for management of patient serum albumin levels as a replacement measure for pressure ulcers. In addition, commenters suggested that CMS use measures considered as ''best in class.'' Several commenters cautioned against the use of ventilator bundle process measure because of the burden related to this measure.

Response: We appreciate the commenters' support of the listed measures and measure topics, as well as the cautions expressed, and we will take their comments into consideration in determining whether to adopt the measures for the LTCH quality reporting program in the future. We also thank the commenters for their suggested additional measures for potential use in future reporting program years.

Comment: Commenters supported the use of the NHSN as a reporting system for future measure submission. Some commenters supported the use of the CARE data item set in collecting data in the future. Other commenters strongly recommended delaying implementation of the CARE data item set for future use until the PAC–PRD has been reported to Congress and undergone Congressional and public comments review. One commenter opposed the use of the data set used in the PAC–PRD.

Response: We thank the commenters for their feedback and support in the future use of the CARE data item set. CMS concluded its PAC–PRD and data collection using CARE in December, 2010. We plan to submit our report to Congress with findings by the close of 2011.

4. Data Submission Methods and Timelines

a. Method of Data Submission for HAIs

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25988 through 25890), we proposed to adopt two HAI quality measures, Central Line Catheter-Associated Bloodstream Infection (CLABSI) Event: CLABSI rate per 1000 central line days, and Urinary Catheter-Associated Urinary Tract Infection (CAUTI) Event: CAUTI rate per 1000 urinary catheter days. We proposed to use CDC/NHSN for data collection and reporting for these two HAI measures (*http://www.cdc.gov/nhsn/*).

As we noted above, the NHSN is a secure, Internet-based surveillance system. It is maintained by CDC, and can be utilized by all types of healthcare facilities in the United States, including

LTCHs, acute care hospitals that collect and report HAIs through the NHSN as part of our Hospital IQR Program, as well as psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, and ambulatory surgery centers. The NHSN enables health care facilities to submit their HAI event data, and access their data for the purposes of internal infection-surveillance.

Facilities can also use the NHSN to obtain information on clinical practices known to prevent HAIs, information on the incidence or prevalence of multidrug-resistant organisms within their organizations, and information on other adverse events. Some States use the NHSN as a means of collecting State law-mandated HAI reporting. NHSN collects data via a Web-based tool hosted by the CDC and available at: *http://www.cdc.nhsn.* This reporting service is provided free of charge to healthcare facilities. In addition, CDC may have the ability to receive NHSN measures data from electronic health records (EHRs) in the near future. Currently, the data reporting of these two HAI events is completed through the NHSN. More than 20 States require hospitals to report HAIs using NHSN, and CDC supports more than 4,000 hospitals that are using the NHSN. Over 200 LTCHs currently submit HAI data via the NHSN.

HAI event reporting and meaningful HAI event surveillance by the LTCH, using the CDC/NHSN requires the submission of all HAI events, regardless of payer. We believe delivery of high quality care in the LTCH setting is imperative. Collecting such quality data on all patients in the LTCH setting supports CMS' mission to ensure high quality care for Medicare beneficiaries. This will provide us with the most robust and accurate reflection of quality in the LTCH setting. Therefore, in order to facilitate and ensure that high quality care is delivered to Medicare beneficiaries in the LTCH setting, we proposed that quality data related to HAIs be collected on all LTCH patients, regardless of payer.

Currently the NHSN has data collection forms, data submission, and reporting mechanisms in place that are in use by LTCHs for both CLABSI and CAUTI measures. Details related to the procedures using the NHSN for data submission can be found at: *http://www.cdc.gov/nhsn.* Specifically, details related to the procedures of using the NHSN for data submission and information on definitions, numerator data, denominator data and data analyses for CLABSI Event: CLABSI rate per 1000 central line days calculated by dividing the number of CLABSI by the number of central line days and multiplying the result by 1000 can be found at *http://www.cdc.gov/nhsn/PatientSafety.html.* Details related to the CLABSI SIR can be found at *http://www.cdc.gov/hai/pdfs/stateplans/SIR_05_25_2010.pdf.* Details related to the procedures of using the NHSN for data submission and information on definitions, numerator data, denominator data and data analyses for CAUTI Event: CAUTI rate per 1000 urinary catheter days calculated by dividing the number of CAUTIs by the number of catheter days and multiplying the result by 1000 can also be found at *http://www.cdc.gov/nhsn/PatientSafety.html.*

The reporting procedures for these HAI events would not be affected by the use of the SIR instead of the current rate calculation. CDC performs those calculations. Further information related to the use of the SIRs can be found on the Web sites at: *http://www.hhs.gov/ash/initiatives/hai/appendices.html* and *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html.*

We solicited public comment on the proposed methods of data submission for the CLABSI and CAUTI measures in the FY 2012 IPPS/LTCH PPS proposed rule for the quality reporting program for LTCHs.

Comment: Several commenters supported the use of the NHSN for data reporting. However, some commenters questioned the readiness of the CDC's NHSN infrastructure to accept a greater volume of data by adding LTCH reporters. Several commenters expressed concerns with provider burden and resources required to enroll, train, and implement data reporting through the CDC's NHSN.

Response: CDC has indicated that the NHSN has undergone a major architectural redesign over the last year in response to the need to scale up to more users and to improve its functionality. Based on the current number of facilities reporting, the small number of additional LTCHs that we proposed to add equates to only a 5 percent increase in usage, which is not an appreciable burden on the system. CDC is confident that the changes it is making will meet the challenges of the proposed increase in NHSN usage.

Comment: One commenter suggested that the NHSN would create an additional burden as a new reporting system for the LTCHs that are not currently using NHSN for reporting.

Response: At this time, nearly half of all certified LTCHs report HAI events using the NHSN. As we discuss in more detail in section IX.J.3.b. of Appendix A to this final rule, we believe that the burdens associated with submitting data to the CDC via NHSN will be modest because many LTCHs are NHSN-registered and trained and have experience using this system. For LTCHs that have not used this system, the registration and training are free and require only a small amount of time. Finally, we estimate that the costs for data submission for the LTCHs that are not currently using the NHSN for both measures will be modest.

Comment: Several commenters supported the use of NHSN data for collection of data pertaining to CLABSI and CAUTI quality measures as well as additional future measures. One commenter suggested that CMS mandate the use of NHSN by making its use part of the Conditions of Participation (CoPs) for LTCHs. Several commenters recommended the use of existing data reporting mechanisms for data submission, including EHRs, in order to minimize burden, avoid duplication of efforts, improve accuracy, and align these quality-related data collection efforts with other quality assessment reporting efforts (for example, The Joint Commission). These commenters noted that introduction of a new data collection system could prove difficult for LTCHs not yet reporting information through this system, especially small or rural LTCHs, and some commenters suggested that CMS allow providers choice in submission systems.

Response: We thank the commenters for their support of the use of the NHSN for the data collection of the CAUTI and CLABSI measure. We also thank the commenter for the suggestion that we integrate the use of the NHSN as a part of the LTCH CoPs. However, we do not believe it is necessary to add such a requirement to the LTCH CoPs in order to require submission of the applicable data through the NHSN for the LTCH quality reporting program.

We wish to minimize any burdens associated with the LTCH quality reporting program. We intend to minimize burden where measures are already submitted through measure simplification, while still working to implement a quality reporting program that concentrates on providing safe, sound care for all patients receiving services in LTCHs. We chose the NHSN reporting system because implementation of this system has already been shown to be both feasible and useful in LTCH settings. The reporting of HAIs using the NHSN is provided free of charge by the CDC for acute and post acute settings. NHSN reporting for HAIs is already mandated or soon will be mandated in 11 States

and the District of Columbia. The CLABSI measure is already in place in 11 States and the District of Columbia. At the time of this final rule, CDC indicated that over 200 LTCHs, out of 439 certified LTCHs, report HAI events using the CDC via NHSN. During the 12-month period from April 2010 to March 2011, 58 LTCHs reported CLABSI for at least one month, and the same number reported CAUTI for at least one month. Over 4,000 hospitals currently submit safety reports to NHSN; and over 20 States require acute-care hospitals to participate. The CDC/NHSN HAI event reporting, therefore, provides an opportunity for alignment across healthcare settings and alignment with definitions between various healthcare settings as well as among all LTCHs.

Comment: Several commenters noted that data collected for NHSN does not include collection of individual patient level information, limiting the potential for more robust risk adjustment based on severity of illness and other patient-level risk factors. The commenters believed that the only real variables collected by NHSN for use in risk-adjustment for CAUTI and CLABSI are device days and device utilization.

Response: As previously discussed in response to another comment on risk adjustment for the two proposed NHSN measures, the risk adjustment methodology of the CDC, as endorsed by NQF uses risk stratification by facility type and location calculating observed over expected for a particular facility or location and reported as a Standardized Infection Ratio. We believe that this risk adjustment is sufficient as endorsed by NQF, and avoids adding to the complexity and reporting burden of the measures that would arise should we require detailed information on patient co-morbidities and characteristics.

After consideration of the public comments received, we are adopting as final our proposed method of data submission for HAIs using the CDC/NHSN, with the first reporting period to begin October 1, 2012, for the FY 2014 payment determination.

b. Timeline for Data Reporting Related to HAIs

CDC recommends that HAI reporting occur closest in time to the event, and further recommends that reporting occur no later than 30 days following the event. To facilitate HAI surveillance and reporting for these proposed measures for payment determination, we proposed an additional timeframe for reporting following the initial reporting period. We proposed a data submission timeframe for NHSN event reporting for these proposed LTCH quality reporting program HAI measures of October 1, 2012 through December 31, 2012 for the determination of FY 2014 annual payment update, and that LTCHs submit their data no later than May 15, 2013.

In order to better align with the current Hospital IQR Program HAI reporting processes (75 FR 20223), we also proposed that all subsequent LTCH quality reporting cycles will be based on a calendar year cycle (for example, beginning January 1, 2013 through December 31, 2013) for determination of the update to the standard Federal rate for each LTCH in FY 2015 and subsequent years. We proposed that, beginning in CY 2013, and for all subsequent years, LTCHs would submit HAI event data via the NHSN, for four consecutive quarters of the calendar year. For example, for the FY 2015 annual payment update to the standard Federal rate, LTCHs would submit HAI data collected in the first quarter of CY 2013, the second quarter of CY 2013, the third quarter of CY 2013, and the fourth quarter of CY 2013.

The timelines for submission of quality data on the CLABSI and CAUTI measures for the FY 2015 annual payment update that we proposed are set out below.

TIMELINES FOR SUBMISSION OF DATA ON THE CENTRAL LINE CATHETER-ASSOCIATED BLOODSTREAM INFECTIONS AND URINARY CATHETER-ASSOCIATED URINARY TRACT INFECTIONS (CAUTI & CLABSI) MEASURES FOR THE FY 2015 ANNUAL PAYMENT UPDATE

CY 2013 Infection event(s)	CDC–NHSN Collection and quarterly report generation time	Proposed submission deadlines for the LTCH quality reporting program FY 2015 payment determination
Q1 (January–March 2013)	January 31–August 15	August 15, 2013.
Q2 (April–June 2013)	April 30–November 15	November 15, 2013.
Q3 (July–September 2013)	July 31–February 15	February 15, 2014.
Q4 (October–December 2013)	October 31–May 15	May 15, 2014.

LTCHs would have until the final submission deadline for the LTCH quality reporting program to submit their quarterly data to the NHSN. After the final submission deadline has occurred for each CY 2013 quarter, CMS will receive a file from the CDC with the aggregated measurement rates of the specific calculations that have been generated by the NHSN for the LTCH quality reporting program and we will use those results for purposes of determining whether the LTCH met the requirements for the LTCH quality reporting program.

We invited public comments on the reporting cycle for LTCHs.

Comment: Many commenters recommended a 1-year delay in the publication of the CLABSI and CAUTI quality measures. These commenters suggested that the delay would allow time for administrative processes and procedures, training, NQF endorsement, validation of data, and the strengthening of the NHSN system, and/or addition of a POA indicator, while still allowing for data to be submitted in time to meet the requirements of section 1886 (m)(5)(A)(iii) of the Act for measure publication by October 1, 2012. Several commenters suggested the initial roll out of one quality measure at a time, for use in testing and evaluation of benefit. One commenter recommended that the CLABSI quality measure be implemented only after site-based testing.

Response: There is already current and successful use of the NHSN reporting infrastructure for HAI measures for over 200 of the 439 certified LTCHs. We are announcing these measures at this time to provide ample notice for facilities for the purposes of administrative procedures such as enrollment and training. We intend to announce specifications related to the HAI measures' data collection, submission, and reporting procedures on or before January 31, 2012. Specifically, we note that data collection does not begin until October 1, 2012. Therefore, there already exists a one year delay incorporated from the publication of these measures and when data collection begins for purposes of the FY 2014 payment determination. We also are working with the CDC for full implementation support.

After consideration of the public comments we received, we are adopting as final the proposed reporting cycle for data submission for HAIs for FY 2014 payment determination.

In alignment with the Hospital IQR Program, (75 FR 50223), we also proposed that once quarterly each LTCH will utilize an automated report function that will be made available to submitters in the NHSN, to generate a quarterly report containing individual LTCH-level numerator, denominator, and exclusion counts for these two HAI measures specifically. CDC will create an automated LTCH quality program report function and add it to NHSN's reporting functionalities. While LTCHs may be reporting other data elements to CDC for other reporting programs (that is, State-mandated surveillance programs), the quarterly LTCH quality program report that would be generated within NHSN would only contain those data elements needed to calculate the two measures currently being proposed for the LTCH quality reporting program. We would only receive this aggregated data from CDC.

We also proposed that any further details regarding, data submission and reporting requirements for HAI measures to be reported via NHSN would be posted on the CMS Web site at: *http://www.cms.gov/LTCH–IRF–Hospice-Quality-Reporting/* by no later than January 31, 2012.

Requirements for NHSN participation, measure specifications, and data collection can be found on the CDC Web site at: *http://www.cdc.gov/nhsn/*. LTCHs are encouraged to visit this Web site in order to view the NHSN enrollment and reporting requirements. Training resources are available there. In order to allow adequate time for enrollment in the NHSN, and for training to take place, should these measures be finalized, additional details related to this reporting program's requirements, such as when enrollment is due to occur, will be announced by no later than January 31, 2012, on the CMS Web site at: *http://www.cms.gov/LTCH–IRF–Hospice-Quality-Reporting/*. In the announcement, we would propose to provide guidance on the specifications, definitions and reporting requirements.

We sought comment on the alignment with the Hospital IQR Program reporting cycle.

Comment: Commenters expressed appreciation for the alignment of LTCH quality reporting program's data submission timelines with those in the Hospital IQR Program. Commenters also expressed appreciation that the LTCH quality reporting program follows the basic structure of the Hospital IQR Program. Several commenters requested that, like the Hospital IQR Program, there also be procedures and methodology for data validation, an appeals process, and that LTCHs be permitted to review their data 30 days before it is made available to the public.

Response: We appreciate the commenters' support. We will consider suggestions with regard to the procedures and processes that are to be put into place for the LTCH quality reporting program, and data validation methodology as well as an appeals processes in future rulemaking.

After consideration of the public comments we received, we are adopting as final the proposed timeline for data submission for HAIs for FY 2014 payment determination.

c. Method of Data Collection and Submission for the Pressure Ulcer Measure Data

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25989 through 25990), we proposed that the pressure ulcer data elements necessary to calculate the pressure ulcer measure would be identical to those data elements collected through the Minimum Data Set 3.0 (MDS 3.0), which is a reporting instrument used in nursing homes. The current MDS 3.0 pressure ulcer items evolved as an outgrowth of CMS' work to develop a standardized patient assessment instrument, referred to as CARE. The current MDS 3.0 pressure ulcer items are also currently used in the calculation of the NQF-endorsed nursing home pressure ulcer measure, Percent of Residents with Pressure Ulcers That Are New or Worsened [Short Stay] (NQF #0678, formerly NQF # NH–012–10). We note that the MDS data elements were supported by the National Pressure Ulcer Advisory Panel (NPUAP).

We believe that to support the standardized collection and calculation of the LTCH pressure ulcer quality measure will require the use of a subset of the standardized CARE instrument, and thus we proposed the use of a subset of the CARE instrument's assessment items for data collection. We will be using specifically the pressure ulcer data elements necessary to calculate the pressure ulcer measure, and those data items are identical to those data elements collected through the Minimum Data Set 3.0 (MDS 3.0). The current MDS 3.0 pressure ulcer data items can be found at the CMS Web site at: *https://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp.*[70] This data assessment subset will allow identical data elements to be collected in LTCHs and in nursing homes.

The CARE assessment instrument, was developed and tested in the post-acute care payment reform demonstration (which included LTCHs) as required by section 5008 of the Deficit Reduction Act (DRA), Public Law 109–171. It is a standardized assessment instrument that can be used across all post acute care sites to measure functional status and other factors during treatment and at discharge from each provider. (For more information, we refer readers to the following Web site: *http://www.pacdemo.rti.org.*) CARE was tested over the last 2 years in 199 providers, of which 28 were LTCHs. Participant feedback suggested most of these items are already collected by LTCHs during their intake process and in monitoring the patients' health status during the stay. Importantly, the CARE items meet Federal interoperable data standards and should be transferable by most data systems. A data reporting mechanism for transferring the data to CMS is currently under development. We anticipate that it will be similar to the current systems used to report assessment data for payment and quality monitoring in the other post acute care sites.

We believe that, for the collection of data necessary to calculate this pressure ulcer measure, using a CARE subset of standardized data elements to collect, report, and calculate the pressure ulcer quality measure will drive uniformity across settings which will lead to better quality of care in LTCHs and, ultimately, across the continuum of care settings. We also believe that the use of a standardized method of communication will lead to better informed decision making.

We stated in the proposed rule that if this proposal is finalized, additional details regarding the data elements needed to calculate this measure, submission requirements and specifications used for these data elements to calculate the pressure ulcer quality measure using a subset of CARE instrument will be published on the CMS Web site at *http://www.cms.gov/LTCH–IRF–Hospice-Quality-Reporting/* by no later than January 31, 2012.

We solicited public comment on the proposed methods of data submission for the pressure ulcer data in the FY

[70] *https://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp* (Look for Downloads. Select MDS 3.0 Item Subsets v1.002. Click on MDS 3.0 ALL Items. Scroll down to Section M, Skin Conditions, items M0100–M0900.)

2012 IPPS/LTCH PPS proposed rule for the LTCH quality reporting program.

Comment: Commenters suggested that CMS consider existing mechanisms for LTCHs to collect and report data on quality measures with the input of the LTCH provider community, and avoid any unnecessary duplication of reporting for other purposes.

Response: We are working with other reporting agencies toward measure simplification and reductions in potentially duplicative reporting.

After consideration of the public comments we received, we are adopting as final our mechanism for data submission to be similar to the current systems used to report assessment data for payment and quality monitoring in the other post acute care sites for the data submission mechanism for the pressure ulcer measure data elements as used in the NQF #0678, Percent of Residents with Pressure Ulcers that Are New or Worsened. As stated in the proposed rule, additional details regarding the data elements needed to calculate this measure, submission requirements and specifications used for these data elements to calculate the pressure ulcer quality measure will be published on the CMS Web site at *http://www.cms.gov/LTCH–IRF–Hospice-Quality-Reporting/* by no later than January 31, 2012.

We proposed to use standardized assessment data elements for data collection that would support the calculation of quality measures in the LTCHs. Specifically, we proposed to use a subset of data items from the CARE data set instrument for the collection of the data elements necessary to calculate the proposed quality measure, the Percent of New or Worsened Pressure Ulcers. This data subset is identical to the MDS 3.0 data elements for pressure ulcers, which constitute the specification for the NQF-endorsed pressure ulcer measure #0678 that we finalized earlier to apply to the LTCH setting.

We invited public comment on the use of a subset of CARE data items for the purposes data collection for this measure: Percent of Residents with Pressure Ulcers that Are New or Worsened. We also invited public comment on this proposal for the calculation of the quality measure for pressure ulcers.

Comment: Many commenters expressed concern about the use of CARE data elements for collecting data elements on new or worsening pressure ulcers in the LTCHs, asserting the data element set was not tested in the LTCH environment or approved by NQF.

Response: The proposed pressure ulcer measure is an NQF-endorsed measure when used in the nursing home setting. The data elements are identical to MDS 3.0 which constitutes the specifications of the proposed pressure ulcer measure for the LTCH setting. The measure uses data elements that have been tested in LTCHs during the PAC–PRD. The CARE data item set was also tested for reliability and validity in the LTCH environment during the PAC–PRD. The CARE data item set was used to collect over 8,500 assessments on patients in 28 LTCHs in different parts of the country. The items used to populate this measure have been tested for reliability in the LTCH setting, and have shown to have very high agreement. Furthermore, the data elements used to populate the pressure ulcer assessment are based on input from the National Pressure Ulcer Advisory Panel and the Wound Ostomy and Continence Nurses Society, two professional groups that set the standards used in all settings to measure pressure ulcer severity. As a result, we believe that the items are familiar to LTCH staff that assess patients for pressure ulcers.

Comment: One commenter expressed disappointment that these specifications of the CARE tool were not made public prior to the comment period.

Response: We proposed the use of data elements that are included in the CARE data item set and are included in the MDS 3.0. The MDS specifications are free and are available to the public through the CMS Web site: *http://www.cms.gov/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp#TopOfPage.* As specified, additional details regarding the submission requirements for the data elements needed to calculate this measure will be published on the CMS Web site at *http://www.cms.gov/LTCH-IRF-HOSPICE-Quality-Reporting/* no later than January 31, 2012. We are developing draft technical specifications and anticipate publication in the fall of 2011 with final technical specifications on or before January 31, 2012.

Comment: One commenter asked when and how often would the quality measure regarding new or worsening pressure ulcers be applied.

Response: We interpret the commenter's question regarding how often would the quality measure be applied to be referencing the number of assessments necessary to calculate the measure. There will be two assessments needed to calculate the measure. The data collected for this measure includes an initial assessment, obtained at the time of the admission, and a subsequent assessment. We expect to provide further details related to measure specifications and submission requirements on or before January 31, 2012.

After consideration of the public comments we received, we are adopting as final our method of data submission for the pressure ulcer measure, the use of the quality data elements as used in the NQF-endorsed pressure ulcer measure #0678, Percent of Residents with Pressure Ulcers that Are New or Worsened as required to calculate this measure.

d. Timeline for Data Reporting Related to Pressure Ulcers

The delivery of high quality care in the LTCH setting is imperative. We believe that collecting quality data on all patients in the LTCH setting supports CMS' mission to ensure quality care for Medicare beneficiaries. Collecting data on all patients provides the most robust and accurate reflection of quality in the LTCH setting. Accurate representation of quality provided in LTCHs is best conveyed using data related to pressure ulcers on all LTCH patients, regardless of payer. Thus, in order to facilitate and ensure this effort, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed that quality data related to pressure ulcers shall be collected on all LTCH patients, regardless of payer, using a subset of the CARE data collection instrument in accordance with the timetable and schedule set forth in section VII.C.4.b. of the preamble to the proposed rule. We stated in the proposed rule that we will provide further details about the data collection instrument on the CMS Web site *http://www.cms.gov/LTCH–IRF–Hospice-Quality-Reporting/* as these details become available.

We invited public comments on the proposed reporting cycle for LTCHs.

Comment: The majority of commenters, including those who supported use of pressure ulcers as a quality measure, strongly recommended delaying the implementation of the CARE data item set as part of regulatory mechanism for pressure ulcer until: results from CARE data item set demonstration have been reported to Congress and undergone Congressional and public comment review; the data items are validated in collaboration with experts in the field, and the tool has been NQF-endorsed. Many commenters suggested a 1-year delay. Other commenters suggested postponing the measure ''indefinitely'' or did not specify a desired timeframe.

Response: We concluded our PAC–PRD and data collection using CARE in

December 2010. We plan to submit its report to Congress with findings by the end of 2011. We did not propose the implementation of the entire data instrument, but rather a subset of tested, and reliable data elements. Further, the pressure ulcer measure data elements that populate this measure belong to an already NQF-endorsed measure for which testing was necessary for endorsement. These data elements are currently successfully submitted to CMS by over 16,000 nursing facilities. We are developing draft technical submission requirements and we expect to publish them in August 2011. We anticipate that we will announce final technical specifications related to the pressure ulcer measure data elements on or before January 31, 2012.

After consideration of the public comments we received, we are adopting as final the proposed timeline for data submission for the New or Worsened Pressure Ulcers measure and in accordance with the timetable and schedule set forth in section VII.C.4.b. of this preamble, with data collection to begin October 1, 2012 for the FY 2014 payment determination.

5. Public Reporting and Availability of Data Submitted

Under section 1886(m)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by LTCHs available to the public. Such procedures will ensure that a LTCH has the opportunity to review the data that is to be made public with respect to the LTCH prior to such data being made public. The Secretary will report quality measures that relate to services furnished in LTCHs on the CMS Web site. Currently, the agency is developing plans regarding the implementation of this provision. Procedures for public reporting will be proposed through future rule making. At this time, we have not established procedures or timelines for public reporting of data.

Comment: Several commenters requested the addition and specification of a standardized appeals process for all providers to ensure that any issues that arise in data aggregation and validation can be addressed. With respect to all three measures, commenters suggested that LTCHs should be permitted a 30-day window to review their data before the data are released to the public. Several commenters stated that there should be a data validation methodology procedure applied. Another commenter believed that measures required for public reporting should be endorsed by the NQF, and ideally by the Measures Application Partnership as well. For CAUTI and CLABSI, one commenter encouraged NQF, CMS, and the CDC to determine how best to educate the public with regard to SIRs, in order to make sure that consumers understand the meaning of SIRs prior to the start of public reporting. With respect to reporting of the pressure ulcer measure, one commenter wanted assurance that the CARE-based pressure ulcer measure was validated and viewed as appropriate by LTCHs before the information is shared with the public.

Response: We intend to adopt procedures that will ensure that an LTCH has the opportunity to review the data to be made public prior to the data being made public, and will such announce details related to such procedures in the future. Additionally, as required under section 1886(m)(5)(E) of the Act, we will report quality measures that relate to services furnished in LTCHs on a CMS Web site. Specifically, with regard to the comment suggesting that, prior to public reporting of the pressure ulcer measure, the agency ensure the measure was appropriately validated, we note that ongoing review to ensure appropriateness, validity and risk adjustment are integral aspects of quality measure maintenance, and we intend to ensure appropriate measure maintenance of all quality measures.

Comment: One commenter expressed appreciation that NHSN will be providing a separate reporting function that will automatically generate LTCH quality program reports.

Response: We appreciate the commenter's support.

D. Rebasing and Revising of the Market Basket Used Under the LTCH PPS

1. Background

The input price index (that is, the market basket) that was used to develop the LTCH PPS for FY 2003 was the ''excluded hospital with capital'' market basket. That market basket was based on 1997 Medicare cost report data and included data for Medicare-participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals. Although the term ''market basket'' technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term ''market basket,'' as used in this section, refers to an input price index.

Beginning with RY 2007, LTCH PPS payments were updated using a FY 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). We excluded cancer and children's hospitals from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at § 413.40. They are not paid under a PPS. Also, the FY 2002 cost structures for cancer and children's hospitals are noticeably different than the cost structures of the freestanding IRFs, freestanding IPFs, and LTCHs. A complete discussion of the FY 2002-based RPL market basket appears in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 21062), we expressed our interest in exploring the possibility of creating a stand-alone LTCH market basket that reflects the cost structures of only LTCH providers. However, as we discussed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43967 through 43968), we are conducting further research to assist us in understanding the reasons for the variations in costs and cost structure between freestanding IRFs and hospital-based IRFs. We also are researching the reasons for similar variations in costs and cost structure between freestanding IPFs and hospital-based IPFs. We remain unable to sufficiently understand the observed differences in costs and cost structures between hospital-based IRFs and freestanding IRFs and between hospital-based IPFs and freestanding IPFs. Therefore, we do not believe it is appropriate at this time to establish stand-alone market baskets for IRFs, IPFs, and LTCHs.

We are currently exploring the viability of creating two separate market baskets from the current RPL market basket: One market basket would include freestanding IRFs and freestanding IPFs and would be used to update payments under both the IPF and IRF payment systems. The other market basket would be a stand-alone LTCH market basket. Depending on the outcome of our research, we may propose a stand-alone LTCH market basket in the next LTCH PPS update cycle.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25990), we invited public comment on the possibility of using this type of market basket to update LTCH payments in the future.

Comment: Several commenters stated that CMS' ongoing work to develop a

market basket that is distinct to the LTCH PPS, and that recognizes the differences among LTCHs, IRFs, and IPFs, is worthwhile, given the unique role LTCHs play in treating high complexity, long-stay patients. Further, one commenter stated that there are a sufficient number of LTCHs to support a separate market basket, and CMS should have confidence that an LTCH-specific market basket would be a reflection of real inflationary changes to the costs of LTCH goods and services. Several commenters encouraged CMS to create a separate LTCH market basket for the FY 2013 LTCH PPS.

Response: We appreciate the commenters' support as we continue to investigate the feasibility of developing a LTCH-specific market basket.

Under the LTCH PPS for FY 2012, we proposed to rebase and revise the FY 2002-based RPL market basket by creating a FY 2008-based RPL market basket as described below. In the following discussion, we provide an overview of the market basket and describe the methodologies we proposed (and are adopting in this final rule) to use for purposes of determining the operating and capital portions of the FY 2008-based RPL market basket.

2. Overview of the FY 2008-Based RPL Market Basket

The FY 2008-based RPL market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in the proposed rule, we proposed to use FY 2008 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 or expenditure weights. Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

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 furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity of the provider's inputs be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so 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.

3. Rebasing and Revising of the RPL Market Basket

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25991), we invited public comments on our proposed methodological changes to the RPL 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 the proposed rule, we proposed to shift the base year cost structure for the RPL market basket from FY 2002 to FY 2008). ''Revising'' means changing data sources, price proxies, or methods, used to derive the input price index. For FY 2012, we proposed to rebase and revise the market basket used to update the LTCH PPS. A summary of the public comments we received and any changes we have made as a result of these public comments are included in the applicable areas of this section.

a. Development of Cost Categories

(1) Medicare Cost Reports

As we proposed and are adopting in this final rule, the FY 2008-based RPL market basket consists of several major cost categories derived from the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs, including wages and salaries, pharmaceuticals, professional liability insurance, capital, and a residual. These FY 2008 Medicare cost reports include providers whose cost report begin date is on or between October 1, 2007, and September 30, 2008. We used FY 2008 as the base year because we believe that the Medicare cost reports for this year represent the most recent, complete set of Medicare cost report data available for IRFs, IPFs, and LTCHs. However, there is an issue with obtaining data specifically for benefits and contract labor from this set of FY 2008 Medicare cost reports because IRFs, IPFs, and LTCHs were not required to complete the Medicare cost report worksheet from which these data were collected (Worksheet S–3, Part II). As a result, only a small number of providers (less than 30 percent) reported data for these categories, and we do not expect these FY 2008 data to improve over time. However, because IRFs, IPFs, and LTCHs were not required to submit data for Worksheet S–3, Part II in previous cost reporting years, we have always had this issue of incomplete Medicare cost report data for benefits and contract labor (including when we finalized the FY 2002-based RPL market basket). Due to the incomplete benefits and contract labor data for IRFs, IPFs, and LTCHs, we developed these cost weights using FY 2008 Medicare cost report data for IPPS hospitals (similar to the method that was used for the FY 2002-based RPL market basket). We provide additional detail on this approach later in this section.

Because our goal is to measure cost shares that are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries, we limited our selection of Medicare cost reports to those from hospitals that have a Medicare average length of stay that is within a comparable range of their total facility average length of stay. We believe this provides a more accurate reflection of the structure of costs for Medicare covered days. We used the cost reports of LTCHs and IRFs with Medicare average lengths of stay within 15 percent (that is, 15 percent higher or lower) of the total facility average length of stay for the hospital. This is the same edit we applied to derive the FY 2002-based RPL market basket and generally includes those LTCHs and IRFs with Medicare average length of stay within approximately 5 days of the facility average length of stay of the hospital.

As we proposed, we used a less stringent measure of Medicare average length of stay for IPFs. For this provider type, and in order to produce a robust sample size, we used those facilities' Medicare cost reports whose average length of stay is within 30 or 50 percent (depending on the total facility average length of stay) of the total facility average length of stay. This is the same edit we applied to derive the FY 2002-based RPL market basket.

We applied these length-of-stay edits to first obtain a set of cost reports for facilities that have a Medicare length of stay within a comparable range of their total facility length of stay. Using this set of Medicare cost reports, we then calculated cost weights for four cost categories and a residual as represented by all other costs directly from the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs (found in Table VII.D–1 below). These Medicare cost report cost weights were then supplemented with information obtained from other data sources (explained in more detail below) to derive the FY 2008-based RPL market basket cost weights.

TABLE VII.D–1—MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED DIRECTLY FROM FY 2008 MEDICARE COST REPORTS

Major cost categories	FY 2008-Based RPL market basket cost weights (percent)
Wages and Salaries	47.371
Professional Liability Insurance (Malpractice)	0.764
Pharmaceuticals	6.514
Capital	8.392
All other	36.959

Comment: One commenter expressed concern with CMS' proposal regarding length-of-stay edits associated with LTCHs and IRFs, which is to use only the cost reports of those facilities whose Medicare average lengths of stays are within 15 percent (that is, 15 percent higher or lower) of the total facility length of stay, and asked if CMS could identify the number of facilities that would fall out of these categories. The commenter based this request on the fact that there are only 440 LTCHs, and this exclusion could adversely impact the industry.

Response: As stated above, we proposed to limit our selection of Medicare cost reports to those cost reports from hospitals that have a Medicare average length of stay that is within a comparable range of their total facility average length of stay in order to measure the cost shares that are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries.

The length-of-stay edits utilized were developed specifically for each provider type (that is, IRFs, LTCHs, and IPFs). For LTCHs and IRFs, we used the cost reports with Medicare average lengths of stay within 15 percent (that is, 15 percent higher or lower) of the total facility average length of stay for the hospital. Applying this edit resulted in excluding about 12 percent of IRFs and LTCHs that, in the aggregate, had a facility length of stay that was 80 percent higher than their Medicare length of stay. The resulting sample of LTCHs and IRFs after the length-of-stay edit, in the aggregate, had a facility length of stay that was 2 percent higher than their Medicare length of stay. We believe applying this edit allows us to achieve our goal of creating a market basket that is reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries.

Comment: One commenter suggested that, because only a small number of providers (less than 30 percent) reported data for benefits and contract labor on their cost reports, CMS consider requiring all LTCHs to submit this information.

Response: Effective for cost reports beginning on or after May 1, 2010, CMS finalized a revised Hospital and Hospital Health Care Complex Cost Report, Form CMS 2552–10, which is available for download from the CMS Web page at *http://www.cms.gov/Transmittals/2010Trans/list.asp?intNumPerPage=10* by clicking on the link to CMS Transmittal #R1P240. Form CMS 2552–10 includes a new worksheet (Worksheet S–3, part V) which identifies the contract labor costs and benefit costs for the hospital complex and is applicable to subproviders and units. CMS anticipates that all providers will report these data so we are able to include the data in future market basket rebasings.

(2) Other Data Sources

In addition to the IRF, IPF and LTCH Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs, the other data sources we used to develop the FY 2008-based RPL market basket cost weights were the FY 2008 IPPS Medicare cost reports and the 2002 Benchmark Input-Output (I–O) Tables created by the Bureau of Economic Analysis (BEA), U.S. Department of Commerce. The FY 2008 Medicare cost reports include providers whose cost report begin date is on or between October 1, 2007, and September 30, 2008.

As noted above, the FY 2008-based RPL cost weights for benefits and contract labor were derived using FY 2008-based IPPS Medicare cost reports. We used these Medicare cost reports to calculate cost weights for ''Wages and Salaries,'' ''Employee Benefits,'' and ''Contract Labor'' for IPPS hospitals for FY 2008. For the Employee Benefits cost weight for the FY 2008-based RPL market basket, the ratio of the FY 2008 IPPS benefits cost weight to the FY 2008 IPPS Wages and Salaries cost weight was applied to the RPL Wages and Salaries cost weight. Similarly, the ratio of the FY 2008 IPPS Contract Labor cost weight to the FY 2008 IPPS Wages and Salaries cost weight was applied to the RPL Wages and Salaries cost weight to derive a Contract Labor cost weight for the FY 2008-based RPL market basket.

The ''All Other'' cost category is divided into other hospital expenditure category shares using the 2002 BEA Benchmark I–O data following the removal of the portions of the ''All Other'' cost category provided in Table VII.D–1 that are attributable to the benefits and contract labor cost categories. 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 complete set of data that are derived from the 2002 Economic Census. For the FY 2002-based RPL market basket, we used the 1997 Benchmark I–O data. As we proposed, we used the 2002 Benchmark I–O data for the FY 2008-based RPL market basket. Instead of using the less detailed Annual I–O data, we aged the 2002 Benchmark I–O data forward to 2008. The methodology we used 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.

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, then telephone services would represent 10 percent of the ''all other'' cost category of the RPL market basket.

Comment: One commenter supported our continued use of general acute hospital cost reports along with the

LTCH cost reports to develop the FY 2008-based RPL market basket.

Response: As stated above, we are finalizing our proposed methods for rebasing and revising the RPL market basket in this final rule, including the incorporation of cost report data from LTCHs and general acute care hospitals.

b. Final Cost Category Computation

As stated previously, for the FY 2012 rebasing proposal, we used the Medicare cost reports for IRFs, IPFs, and LTCHs to derive four major cost categories. The FY 2008-based RPL market basket includes two additional cost categories that were not broken out separately in the FY 2002-based RPL market basket: ''Administrative and Business Support Services'' and ''Financial Services.'' The inclusion of these two additional cost categories, which are derived using the Benchmark I–O data, is consistent with the addition of these two cost categories to the FY 2006-based IPPS market basket (74 FR 43845). We break out both categories so we can better match their respective expenses with more appropriate price proxies. A thorough discussion of our rationale for each of these cost categories is provided below in section VII.D.3.f. of this final rule. Also, the FY 2008-based RPL market basket excludes one cost category: ''Photographic Supplies.'' The 2002 Benchmark I–O weight for this category is considerably smaller than the 1997 Benchmark I–O weight, presently accounting for less than one-tenth of one percentage point of the RPL market basket. Therefore, we include the photographic supplies costs in the ''Chemicals'' cost category weight with other similar chemical products.

We did not propose to change our definition of the labor-related share. However, we did propose to rename our aggregate cost categories from ''Labor-intensive'' and ''Nonlabor-intensive'' services to ''Labor-related'' and ''Nonlabor-related'' services. This is consistent with the FY 2006-based IPPS market basket (74 FR 43845). As discussed in more detail below and similar to the FY 2002-based RPL market basket, we are classifying 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. In previous regulations, we grouped cost categories that met both of these criteria into labor-intensive services. We believe the new labels more accurately reflect the concepts that they are intended to convey. We did not propose to change our definition of the labor-related share because we continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

We did not receive any public comments that addressed our proposal to rename our aggregate cost categories from ''Labor-intensive'' and ''Nonlabor-intensive'' to ''Labor-related'' and ''Nonlabor-related'' services. Therefore, in this final rule, we are adopting our proposal to rename our aggregate cost categories without modification.

c. Selection of Price Proxies

After computing the FY 2008 cost weights for the rebased RPL market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for Professional Liability Insurance, all of the proxies for the operating portion of the FY 2008-based RPL market basket 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 these PPIs better reflect the actual price changes encountered by hospitals. For example, we are using 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 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 encountered by a producer, we used CPIs only if an appropriate PPI was not available, or if the expenditures were more similar to 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 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. The PPIs, CPIs, and ECIs selected meet these criteria.

Table VII.D–2 below sets forth the FY 2008-based RPL market basket, including cost categories and their respective weights and price proxies. For comparison purposes, the corresponding FY 2002-based RPL market basket cost weights also are listed. For example, ''Wages and Salaries'' are 49.447 percent of total costs in the FY 2008-based RPL market basket compared to 52.895 percent for the FY 2002-based RPL market basket. ''Employee Benefits'' are 12.831 percent in the FY 2008-based RPL market basket compared to 12.982 percent for the FY 2002-based RPL market basket. As a result, compensation costs (wages and salaries plus employee benefits) for the FY 2008-based RPL market basket are 62.278 percent of total costs compared to 65.877 percent for the FY 2002-based RPL market basket.

Following Table VII.D–2 is a summary outlining the choice of the proxies we proposed (and are adopting in this final rule) to use for the operating portion of the FY 2008-based RPL market basket. The price proxies for the capital portion are described in more detail in the capital methodology section below in section VII.D.3.d. of this final rule.

We note that the proxies for the operating portion of the FY 2008-based RPL market basket are the same as those used for the FY 2006-based IPPS operating market basket. Because these proxies meet our criteria of reliability, timeliness, availability, and relevance, we believe they are the best measures of price changes for the cost categories. For further discussion on the FY 2006-based IPPS market basket, we refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43843).

TABLE VII.D–2—FY 2008-BASED RPL MARKET BASKET COST CATEGORIES, WEIGHTS, AND PRICE PROXIES WITH FY 2002-BASED RPL MARKET BASKET COST WEIGHTS INCLUDED FOR COMPARISON

Cost categories	FY 2002-Based RPL market basket cost weights	FY 2008-Based RPL market basket cost weights	FY 2008-Based RPL market basket price proxies
1. Compensation	65.877	62.278	—
A. Wages and Salaries[1]	52.895	49.447	ECI for Wages and Salaries, Civilian Hospital Workers.
B. Employee Benefits[1]	12.982	12.831	ECI for Benefits, Civilian Hospital Workers.
2. Utilities	0.656	1.578	—
A. Electricity	0.351	1.125	PPI for Commercial Electric Power.
B. Fuel, Oil, and Gasoline	0.108	0.371	PPI for Petroleum Refineries.
C. Water and Sewage	0.197	0.082	CPI–U for Water and Sewerage Maintenance.
3. Professional Liability Insurance	1.161	0.764	CMS Hospital Professional Liability Insurance Premium Index.
4. All Other Products and Services	22.158	26.988	—
A. All Other Products	13.325	15.574	—
(1.) Pharmaceuticals	5.103	6.514	PPI for Pharmaceutical Preparations for Human Use (Prescriptions).
(2.) Food: Direct Purchases	0.873	2.959	PPI for Processed Foods and Feeds.
(3.) Food: Contract Services	0.620	0.392	CPI–U for Food Away From Home.
(4.) Chemicals[2]	1.100	1.100	Blend of Chemical PPIs.
(5.) Medical Instruments	1.014	1.795	PPI for Medical, Surgical, and Personal Aid Devices.
(6.) Photographic Supplies[2]	0.096	.....	—
(7.) Rubber and Plastics	1.052	1.131	PPI for Rubber and Plastic Products.
(8.) Paper and Printing Products	1.000	1.021	PPI for Converted Paper and Paperboard Products.
(9.) Apparel	0.207	0.210	PPI for Apparel.
(10.) Machinery and Equipment	0.297	0.106	PPI for Machinery and Equipment.
(11.) Miscellaneous Products	1.963	0.346	PPI for Finished Goods less Food and Energy.
B. All Other Services	8.833	11.414	—
(1.) Labor-related Services	5.111	4.681	—
(a.) Professional Fees: Labor-related[3]	2.892	2.114	ECI for Compensation for Professional and Related Occupations.
(b.) Administrative and Business Support Services[4]	n/a	0.422	ECI for Compensation for Office and Administrative Services.
(c.) All Other: Labor-Related Services[4]	2.219	2.145	ECI for Compensation for Private Service Occupations.
(2.) Nonlabor-Related Services	3.722	6.733	—
(a.) Professional Fees: Nonlabor-Related[3]	n/a	4.211	ECI for Compensation for Professional and Related Occupations.
(b.) Financial Services[5]	n/a	0.853	ECI for Compensation for Financial Activities.
(c.) Telephone Services	0.240	0.416	CPI–U for Telephone Services.
(d.) Postage	0.682	0.630	CPI–U for Postage.
(e.) All Other: Nonlabor-Related Services[5]	2.800	0.623	CPI–U for All Items less Food and Energy.
5. Capital-Related Costs	10.149	8.392	—
A. Depreciation	6.187	5.519	—
(1.) Fixed Assets	4.250	3.286	BEA chained price index for nonresidential construction for hospitals and special care facilities—vintage-weighted (26 years).
(2.) Movable Equipment	1.937	2.233	PPI for Machinery and Equipment—vintage-weighted (11 years).
B. Interest Costs	2.775	1.954	—
(1.) Government/Nonprofit	2.081	0.653	Average yield on domestic municipal bonds (Bond Buyer 20 bonds)—vintage-weighted (26 years).
(2.) For Profit	0.694	1.301	Average yield on Moody's Aaa bonds—vintage-weighted (26 years).
C. Other Capital-Related Costs	1.187	0.919	CPI–U for Residential Rent.
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 are using a blended PPI composed of the PPI for Industrial Gases, 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, we refer readers to section VII.D.3.c.(10) of the preamble of this final rule. In addition, we now include expenses related to Photographic Supplies in the Chemicals cost category due to the small cost weight associated with these expenses. We note that, although we are eliminating the specific cost category, these costs are still accounted for within the RPL market basket.

[3] The "Professional Fees: Labor-related" and "Professional Fees: Nonlabor-related" cost categories were included in one cost category called "Professional Fees" in the FY 2002-based RPL market basket. For more detail about how these new categories were derived, we refer readers to section VII.D.3.f. of the preamble of this final rule on the labor-related share.

[4] The Administrative and Business Support Services cost category was contained within the "All Other: Labor-intensive Services" cost category in the FY 2002-based RPL market basket. The "All Other: Labor-intensive Services" cost category is renamed the "All Other: Labor-related Services" cost category for the FY 2008-based RPL market basket.

[5] The "Financial Services" cost category was contained within the "All Other: Non-labor Intensive Services" cost category in the FY 2002-based RPL market basket. The "All Other: Non-labor Intensive Services" cost category is renamed the "All Other: Nonlabor-related Services" cost category for the FY 2008-based RPL market basket.

(1) Wages and Salaries

We are using the ECI for Wages and Salaries for Hospital Workers (All Civilian) (BLS series code CIU1026220000000I) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(2) Employee Benefits

We are using the ECI for Employee Benefits for Hospital Workers (All Civilian) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(3) Electricity

We are using the PPI for Commercial Electric Power (BLS series code WPU0542). This same proxy was used in the FY 2002-based RPL market basket.

(4) Fuel, Oil, and Gasoline

For the FY 2002-based RPL market basket, this category only included expenses classified under North American Industry Classification System (NAICS) 21 (Mining). We used the PPI for Commercial Natural Gas (BLS series code WPU0552) as a proxy for this cost category. For the FY 2008-based market basket, we added costs to this category that had previously been grouped in other categories. The added costs include petroleum-related expenses under NAICS 324110 (previously captured in the miscellaneous category), as well as petrochemical manufacturing classified under NAICS 325110 (previously captured in the chemicals category). These added costs represent 80 percent of the hospital industry's fuel, oil, and gasoline expenses (or 80 percent of this category). Because the majority of the industry's fuel, oil, and gasoline expenses originate from petroleum refineries (NAICS 324110), we are using the PPI for Petroleum Refineries (BLS series code PCU324110324110) as the proxy for this cost category.

(5) Water and Sewage

We are using the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(6) Professional Liability Insurance

We proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability 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). This same proxy was used in the FY 2002-based RPL market basket.

(7) Pharmaceuticals

We are using the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. We note that we did not make a change to the PPI that is used to proxy this cost category. Although there was a recent change to the BLS naming convention for this series, this is the same proxy that was used in the FY 2002-based RPL market basket.

(8) Food: Direct Purchases

We are using the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(9) Food: Contract Services

We are using the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(10) Chemicals

We are using 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–). Using the 2002 Benchmark I–O data, we found that these NAICS industries accounted for approximately 90 percent of the hospital industry's chemical expenses.

Therefore, we are using this blended index because we believe its composition better reflects the composition of the purchasing patterns of hospitals than does the PPI for Industrial Chemicals (BLS series code WPU061), the proxy used in the FY 2002-based RPL market basket. Table VII.D–3 below shows the weights for each of the four PPIs used to create the blended PPI, which we determined using the 2002 Benchmark I–O data.

TABLE VII.D–3—BLENDED CHEMICAL PPI WEIGHTS

Name	Weights (in percent)	NAICS
PPI for Industrial Gas Manufacturing	35	325120
PPI for Other Basic Inorganic Chemical Manufacturing	25	325180
PPI for Other Basic Organic Chemical Manufacturing	30	325190
PPI for Soap and Cleaning Compound Manufacturing	10	325610

(11) Medical Instruments

We are using the PPI for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156) to measure the price growth of this cost category. In the 1997 Benchmark I–O data, approximately half of the expenses classified in this category were for surgical and medical instruments. Therefore, we used the PPI for Surgical and Medical Instruments and Equipment (BLS series code WPU1562) to proxy this category in the FY 2002-based RPL market basket. The 2002 Benchmark I–O data show that surgical and medical instruments now represent only 33 percent of these expenses and that the largest expense category is

surgical appliance and supplies manufacturing (corresponding to BLS series code WPU1563). Due to this reallocation of costs over time, we are changing the price proxy for this cost category to the more aggregated PPI for Medical, Surgical, and Personal Aid Devices.

(12) Photographic Supplies

We are eliminating the cost category specific to photographic supplies for the FY 2008-based RPL market basket. These costs are now included in the Chemicals cost category because the costs are presently reported as all other chemical products. Notably, although we are eliminating the specific cost category, these costs are still accounted for within the RPL market basket.

(13) Rubber and Plastics

We are using the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(14) Paper and Printing Products

We are using the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(15) Apparel

We are using the PPI for Apparel (BLS series code WPU0381) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(16) Machinery and Equipment

We are using the PPI for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(17) Miscellaneous Products

We are using the PPI for Finished Goods Less Food and Energy (BLS series code WPUSOP3500) to measure the price growth of this cost category. Using this index avoids the double-counting of food and energy prices, which is already captured elsewhere in the market basket. This same proxy was used in the FY 2002-based RPL market basket.

(18) Professional Fees: Labor-Related

We are using the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS2020000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services. This same proxy was used in the FY 2002-based RPL market basket.

(19) Administrative and Business Support Services

We are using the ECI for Compensation for Office and Administrative Support Services (Private Industry) (BLS series code CIU2010000220000I) to measure the price growth of this category. Previously these costs were included in the All Other: Labor-intensive category (now renamed the All Other: Labor-related Services category), and were proxied by the ECI for Compensation for Service Occupations. We believe that this compensation index better reflects the changing price of labor associated with the provision of administrative services and its incorporation represents a technical improvement to the market basket.

(20) All Other: Labor-Related Services

We are using the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(21) Professional Fees: Nonlabor-Related

We are using the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS2020000120000I) to measure the price growth of this category. This is the same price proxy that we are using for the Professional Fees: Labor-related cost category.

(22) Financial Services

We are using the ECI for Compensation for Financial Activities (Private Industry) (BLS series code CIU201520A000000I) to measure the price growth of this cost category. Previously these costs were included in the All Other: Nonlabor-intensive category (now renamed the All Other: Nonlabor-related Services category), and were proxied by the CPI for All Items. We believe that this compensation index better reflects the changing price of labor associated with the provision of financial services and its incorporation represents a technical improvement to the market basket.

(23) Telephone Services

We are using the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(24) Postage

We are using the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(25) All Other: Nonlabor-Related Services

We are using the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. Previously these costs were proxied by the CPI for All Items in the FY 2002-based RPL market basket. We believe that using the CPI for All Items Less Food and Energy avoids the double counting of changes in food and energy prices, as they are already captured elsewhere in the market basket. Consequently, we believe that the incorporation of this proxy represents a technical improvement to the market basket.

We did not receive any public comments that addressed our proposed selection of price proxies to reflect the rate of price change for each expenditure category. Therefore, we are adopting our proposal as final without modification.

d. Methodology for Capital Portion of the RPL Market Basket

In the FY 2002-based RPL market basket, we did not have freestanding IRF, freestanding IPF, and LTCH 2002 Medicare cost report data for the capital-related cost weights, due to a change in the 2002 reporting requirements. Therefore, we used these hospitals' 2001 expenditure data for the capital cost categories of Depreciation, Interest, and Other Capital Expenses, and aged the data to a 2002 base year using relevant price proxies.

For the FY 2008-based RPL market basket, as we proposed, we calculated weights for the RPL market basket capital costs using the same set of FY 2008 Medicare cost reports used to develop the operating share for IRFs, IPFs, and LTCHs. To calculate the total capital cost weight, we first applied the same length-of-stay edits as applied when calculating the operating cost weights as described above in section VII.D.3.a. of this preamble. The resulting Capital-Related weight for the FY 2008 base year is 8.392 percent.

Lease expenses are unique in that they are not broken out as a separate cost category in the RPL market basket, but rather are proportionally distributed amongst the cost categories of

Depreciation, Interest, and Other Capital-related Costs, reflecting the assumption that the underlying cost structure of leases is similar to that of capital costs in general. As was done in the FY 2002-based RPL market basket, we first assumed 10 percent of lease expenses represents overhead and assigned those costs to the Other Capital-Related Costs category accordingly. The remaining lease expenses were distributed across the three cost categories based on the respective weights of Depreciation, Interest, and Other Capital-related Costs not including lease expenses.

Depreciation contains two subcategories: (1) Building and Fixed Equipment (or Fixed Assets); and (2) Movable Equipment. The apportionment between building and fixed equipment and movable equipment was determined using the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs. This methodology was also used to compute the apportionment used in the FY 2002-based RPL market basket (71 FR 27815).

The total Interest cost category is split between government/nonprofit interest and for-profit interest. The FY 2002-based RPL market basket allocated 75 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 25 percent of the Interest cost weight was allocated to For-profit interest and was proxied by the average yield on Moody's Aaa bonds (70 FR 47912). This was based on the FY 2002-based IPPS capital input price index (70 FR 23406) due to insufficient Medicare cost report data for freestanding IRFs, freestanding IPFs, and LTCHs. For the FY 2008-based RPL market basket, as we proposed, we derived the split using the FY 2008 Medicare cost report data on interest expenses for government/nonprofit and for-profit freestanding IRFs, freestanding IPFs, and LTCHs. Based on these data, we calculated a 33/67 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 for RPL providers. As stated above, we first applied the average length of stay edits (as described in section VII.D.3.a. of this preamble) prior to calculating this split. Therefore, we used cost reports that are reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries. Using data specific to government/nonprofit and for-profit freestanding IRFs, freestanding IPFs, and LTCHs as well as the application of these length of stay edits are the primary reasons for the difference in this split relative to the FY 2002-based RPL market basket.

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 capital portion of the FY 2008-based RPL market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital 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.

Vintage weights are an integral part of the FY 2008-based RPL market basket. 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 capital portion of the FY 2008-based RPL market basket would reflect the annual price changes associated with capital costs, and would be a useful simplification of the actual capital investment process. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for Medicare capital-related costs. The capital component of the FY 2008-based RPL market basket would reflect 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 an appropriate 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 2008.

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. For the FY 2002-based RPL market basket, due to insufficient Medicare cost report data for freestanding IRFs, freestanding IPFs, and LTCHs, we used 2001 Medicare cost reports for IPPS hospitals to determine the expected life of building and fixed equipment and movable equipment (71 FR 27816). The FY 2002-based RPL market basket was based on an expected average life of building and fixed equipment of 23 years. It used 11 years as the average expected life for moveable equipment. We believed that this data source reflected the latest relative cost structure of depreciation expenses for hospitals at the time and was analogous to freestanding IRFs, freestanding IPFs, and LTCHs.

The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated useful life of an asset if depreciation were to continue at current year levels, assuming straight-line depreciation. Following a similar method to what was applied for the FY 2002-based RPL market basket, we used the average expected life of building and fixed equipment to be equal to 26 years, and the average expected life of movable equipment to be 11 years. These expected lives are calculated using FY 2008 Medicare cost reports for IPPS hospitals since we are currently unable to obtain robust measures of the expected lives for building and fixed equipment and movable equipment using the Medicare cost reports from freestanding IRFs, freestanding IPFs, and LTCHs.

As we proposed, we also used the building and fixed equipment and movable equipment weights derived from FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs 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. 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 the 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 from 2008 back to 1963, we averaged twenty 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 26-year periods. We used the average of each year across the twenty 26-year periods to determine the average building and fixed equipment vintage weights for the FY 2008-based RPL market basket.

For the 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. This is the same proxy used for the FY 2002-based RPL market basket. Based on our determination that movable equipment has an expected life of 11 years, the vintage weights for movable equipment represent the average expenditure for movable equipment over an 11-year period. With real movable equipment purchase estimates available from 2008 back to 1963, thirty-five 11-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 11-year period are calculated by dividing the real movable capital purchase amount for any given year by the total amount of purchases in the 11-year period. This calculation was done for each year in the 11-year period and for each of the thirty-five 11-year periods. We used the average of each year across the thirty-five 11-year periods to determine the average movable equipment vintage weights for the FY 2008-based RPL market basket.

For the 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 from 2008 back to 1963, twenty 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 26-year periods. We used the average of each year across the twenty 26-year periods to determine the average interest vintage weights for the FY 2008-based RPL market basket. The vintage weights for the capital portion of the FY 2002-based RPL market basket and the FY 2008-based RPL market basket are presented in Table VII.D–4 below.

TABLE VII.D–4—FY 2002 AND FY 2008 VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year	Building and fixed equipment		Movable equipment		Interest	
	FY 2002 23 years	FY 2008 26 years	FY 2002 11 years	FY 2008 11 years	FY 2002 23 years	FY 2008 26 years
1	0.021	0.021	0.065	0.071	0.010	0.010
2	0.022	0.023	0.071	0.075	0.012	0.012
3	0.025	0.025	0.077	0.080	0.014	0.014
4	0.027	0.027	0.082	0.083	0.016	0.016
5	0.029	0.028	0.086	0.085	0.019	0.018
6	0.031	0.030	0.091	0.089	0.023	0.020
7	0.033	0.031	0.095	0.092	0.026	0.021
8	0.035	0.033	0.100	0.098	0.029	0.024
9	0.038	0.035	0.106	0.103	0.033	0.026
10	0.040	0.037	0.112	0.109	0.036	0.029
11	0.042	0.039	0.117	0.116	0.039	0.033
12	0.045	0.041	.....	.....	0.043	0.035
13	0.047	0.042	.....	.....	0.048	0.038
14	0.049	0.043	.....	.....	0.053	0.041
15	0.051	0.044	.....	.....	0.056	0.043
16	0.053	0.045	.....	.....	0.059	0.046
17	0.056	0.046	.....	.....	0.062	0.049
18	0.057	0.047	.....	.....	0.064	0.052
19	0.058	0.047	.....	.....	0.066	0.053
20	0.060	0.045	.....	.....	0.070	0.053
21	0.060	0.045	.....	.....	0.071	0.055

TABLE VII.D–4—FY 2002 AND FY 2008 VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES—Continued

Year	Building and fixed equipment		Movable equipment		Interest	
	FY 2002 23 years	FY 2008 26 years	FY 2002 11 years	FY 2008 11 years	FY 2002 23 years	FY 2008 26 years
22	0.061	0.045			0.074	0.056
23	0.061	0.046			0.076	0.060
24		0.046				0.063
25		0.045				0.064
26		0.046				0.068
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

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 use the same price proxies for the capital portion of the FY 2008-based RPL market basket that were used in the FY 2002-based RPL market basket with the exception of the Boeckh Construction Index. We replaced the Boeckh Construction Index with BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities. The BEA index represents construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers. Although these price indices move similarly over time, we believe that it is more technically appropriate to use an index that is more specific to the hospital industry. We believe these are the most appropriate proxies for hospital capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

The price proxies (prior to any vintage weighting) for each of the capital cost categories are the same as those used for the FY 2006-based Capital Input Price Index (CIPI) as described in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857).

e. FY 2012 Market Basket Update for LTCHs

For FY 2012 (that is, October 1, 2011 through September 30, 2012), as we proposed, we are using an estimate of the FY 2008-based RPL market basket update based on the best available data. Consistent with historical practice, we estimate the RPL market basket update for the LTCH PPS based on IHS Global Insight, Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Based on IGI's first quarter 2011 forecast with history through the fourth quarter of 2010, the projected market basket update for FY 2012 was 2.8 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we proposed a market basket update of 2.8 percent for FY 2012. We also proposed that if more recent data became subsequently available (for example, a more recent estimate of the market basket), we would use such data, if appropriate, to determine the FY 2012 annual update in the final rule. For this final rule, we are incorporating a more recent estimate of the market basket update and MFP adjustment. Based on IGI's second quarter 2011 forecast with history through the first quarter of 2011, the projected market basket update for FY 2012 is 2.9 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are finalizing a market basket update of 2.9 percent for FY 2012. (As discussed in greater detail in section V.A.2. of the Addendum to this final rule, we are providing for an annual update of 1.8 percent to the LTCH PPS standard Federal rate for FY 2012 under § 412.523(c)(3)(viii) of the regulations.)

Using the FY 2002-based RPL market basket and IGI's second quarter 2011 forecast for the market basket components, the FY 2012 market basket update would be 3.0 percent (before taking into account any statutory adjustment). Table VII.D–5 below compares the FY 2008-based RPL market basket and the FY 2002-based RPL market basket percent changes.

TABLE VII.D–5—FY 2002-BASED AND FY 2008-BASED RPL MARKET BASKET PERCENT CHANGES; FY 2006 THROUGH FY 2014

Fiscal year (FY)	FY 2002-Based RPL market basket index percent change	FY 2008-Based RPL market basket index percent change
Historical data:		
FY 2006	3.9	3.7
FY 2007	3.4	3.4
FY 2008	3.8	3.7
FY 2009	2.5	2.7
FY 2010	2.3	2.2
Average 2006–2010	3.2	3.1
Forecast:		
FY 2011	2.7	2.7
FY 2012	3.0	2.9
FY 2013	3.0	2.9
FY 2014	3.0	3.0
Average 2011–2014	2.9	2.9

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.
Source: IHS Global Insight, Inc. second quarter 2011 forecast.

For FY 2012, the FY 2008-based RPL market basket update (2.9 percent) is slightly lower than the market basket update based on the FY 2002-based RPL market basket. The lower total compensation weight in the FY 2008-based RPL market basket (62.278 percent) relative to the FY 2002-based RPL market basket (65.877 percent), absent other factors, would have resulted in a slightly lower market basket update using the FY 2008-based RPL market basket. However, this impact is partially offset by the larger weight associated with the Professional Fees category. In both market baskets, these expenditures are proxied by the ECI for Compensation for Professional and Related Services. The weight for Professional Fees in the FY 2002-based RPL market basket is 2.892 percent compared to 6.325 percent in the FY 2008-based RPL market basket. The net effect is that the market basket update is slightly lower for FY 2012 based on the FY 2008-based RPL market basket relative to the FY 2002-based RPL market basket.

f. Labor-Related Share

As discussed in section V.B. of the Addendum to this final rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS payments to account for differences in LTCH area wage levels (§ 412.525(c)). The labor-related portion of the LTCH PPS standard Federal rate, hereafter referred to as the labor-related share, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index.

The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. Given this, based on our definition of the labor-related share, we include in the labor-related share the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Business Support Services, All Other: Labor-related Services (previously referred to in the FY 2002-based RPL market basket as labor-intensive), and a portion of the Capital-Related cost weight.

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.

As stated in the RY 2007 LTCH PPS final rule (71 FR 27829), the labor-related share was defined as the sum of the relative importance of the labor-related share of operating costs (Wages and Salaries, Employee Benefits, Professional Fees, and All Other: Labor-intensive Services), and a portion of Capital costs of the RPL market basket based on FY 2002 data. Therefore, to determine the labor-related share for the LTCH PPS for FY 2011, we used the FY 2002-based RPL market basket cost weights relative importance to determine the labor-related share for the LTCH PPS.

For the FY 2008-based RPL market basket rebasing, the inclusion of the Administrative and Business Support Services cost category into the labor-related share remains consistent with the current labor-related share because this cost category was previously included in the Labor-intensive cost category. As previously stated, we established a separate Administrative and Business Support Service cost category so that we can use the ECI for Compensation for Office and Administrative Support Services to more precisely proxy these specific expenses.

For the FY 2002-based RPL market basket, we assumed that all nonmedical professional services (including accounting and auditing services, engineering services, legal services, and management and consulting services) were purchased in the local labor market and, therefore, all of their associated fees varied with the local labor market. As a result, we previously included 100 percent of these costs in the labor-related share. In an effort to more accurately determine the share of professional fees that should be included in the labor-related share, we surveyed hospitals regarding the proportion of those fees that go to companies that are located beyond their own local labor market (the results are discussed below).

We continue to look for ways to refine our market basket approach to more accurately account for the proportion of costs influenced by the local labor market. To that end, we conducted a survey of hospitals to empirically determine the proportion of contracted professional services purchased by the industry that are attributable to local firms and the proportion that are purchased from national firms. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and received no comments.

With approval from the Office of Management and Budget (OMB), we contacted a sample of IPPS hospitals and received responses to our survey from 108 hospitals. We believe that these data serve as an appropriate proxy for the purchasing patterns of professional services for LTCHs as they are also institutional providers of health care services. Using data on full-time equivalents (FTEs) to allocate responding hospitals across strata (region of the country and urban/rural status), we calculated post-stratification weights. Based on these weighted results, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

We applied each of these percentages to its respective Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-related costs. The Professional Fees: Labor-related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-related costs. This is the methodology that we used to separate the FY 2008-based RPL market basket professional fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories.

In addition to the professional services listed above, we also classified expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees cost category as was done in previous rebasings. The NAICS 55 data are mostly comprised of corporate, subsidiary, and regional managing offices, or otherwise referred to as home offices. Formerly, all of the expenses within this category were considered to vary with, or be influenced by, the local labor market and were thus included in the labor-related share. Because many hospitals are not located in the same geographic area as their home office, we analyzed data from a variety of sources in order to determine what proportion of these

costs should be appropriately included in the labor-related share.

Using data primarily from the Medicare cost reports and a CMS database of Home Office Medicare Records (HOMER) (a database that provides city and state information (addresses) for home offices), we were able to determine that 19 percent of the total number of freestanding IRFs, freestanding IPFs, and LTCHs that had home offices had those home offices located in their respective local labor markets—defined as being in the same Metropolitan Statistical Area (MSA).

The Medicare cost report requires hospitals to report their home office provider numbers. Using the HOMER database to determine the home office location for each home office provider number, we compared the location of the provider with the location of the hospital's home office. We then placed providers into one of the following three groups:

- Group 1—Provider and home office are located in different States.
- Group 2—Provider and home office are located in the same State and same city.
- Group 3—Provider and home office are located in the same State and different city.

We found that 63 percent of the providers with home offices were classified into Group 1 (that is, different State) and, thus, these providers were determined to not be located in the same local labor market as their home office. Although there were a very limited number of exceptions (that is, providers located in different States but the same MSA as their home office), the 63 percent estimate was unchanged.

We found that 9 percent of all providers with home offices were classified into Group 2 (that is, same State and same city and, therefore, the same MSA). Consequently, these providers were determined to be located in the same local labor market as their home offices.

We found that 27 percent of all providers with home offices were classified into Group 3 (that is, same State and different city). Using data from the Census Bureau to determine the specific MSA for both the provider and its home office, we found that 10 percent of all providers with home offices were identified as being in the same State, a different city, but the same MSA.

Pooling these results, we were able to determine that approximately 19 percent of providers with home offices had home offices located within their local labor market (that is, 9 percent of providers with home offices had their home offices in the same State and city (and, thus, the same MSA), and 10 percent of providers with home offices had their home offices in the same State, a different city, but the same MSA). We apportion the NAICS 55 expense data by this percentage. Thus, we classified 19 percent of these costs into the Professional Fees: Labor-related cost category and the remaining 81 percent into the Professional Fees: Nonlabor-related Services cost category.

Using this method and the IGI's forecast for the first quarter 2011 of the FY 2008-based RPL market basket, the proposed LTCH labor-related share for FY 2012 was the sum of the FY 2012 relative importance of each labor-related cost category. Consistent with our policy for updating the labor-related share with the most recent available data, the labor-related share for this final rule reflects IGI's second quarter 2011 forecast of the FY 2008-based RPL market basket. Table VII.D–6 below shows the FY 2012 relative importance labor-related share using the FY 2008-based RPL market basket and the FY 2011 relative importance labor-related share using the FY 2002-based RPL market basket.

TABLE VII.D–6—COMPARISON OF THE FY 2011 RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE FY 2002-BASED RPL MARKET BASKET AND THE FY 2012 RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE FY 2008-BASED RPL MARKET BASKET

	FY 2011 Relative importance labor-related share [1]	FY 2012 Relative importance labor-related share [2]
Wages and Salaries	52.449	48.984
Employee Benefits	13.971	12.998
Professional Fees: Labor-Related	2.855	2.072
Administrative and Business Support Services	.....	0.416
All Other: Labor-Related Services	2.109	2.094
Subtotal	71.384	66.564
Labor-Related Portion of Capital Costs (46%)	3.887	3.635
Total Labor-Related Share	75.271	70.199

[1] Published in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50391) and based on the second quarter 2010 IGI forecast.
[2] Based on the second quarter 2011 IGI forecast.

The labor-related share for FY 2012 is the sum of the FY 2012 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 2008) and FY 2012. The sum of the relative importance for FY 2012 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All Other: Labor-related Services) is 66.564 percent, as shown in Table VII.D–6 above. We are providing that the portion of Capital that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the FY 2002-based RPL market basket. Because the relative importance for Capital-Related Costs is 7.903 percent of the FY 2008-based RPL market basket in FY 2012, we multiplied 46 percent by 7.903 percent to determine the labor-related share of Capital for FY 2012. The result is 3.635 percent, which we added to 66.564 percent for the operating cost amount to determine the total labor-related share for FY 2012. Thus, the labor-related share that we are using for the LTCH PPS in FY 2012 is 70.199 percent. This labor-related share is determined using the same methodology as employed in calculating all previous LTCH labor-related shares.

Comment: Several commenters questioned the 5-percentage point reduction in the labor-related share

(from approximately 75 to approximately 70 percent) for the LTCH PPS, after the labor-related share has been relatively constant over the last several years. One commenter stated that this 5-percentage point reduction in the labor-related share, at one time, will have a substantial adverse impact. The commenters requested that CMS not use limited size data that result in the revision of the FY 2012 labor-related share by nearly 5 percentage points. One commenter remarked that the reduction reflects a dramatic change in the labor-related share from one year to the next.

Response: The reduction in the labor-related share from FY 2011 to FY 2012 is primarily the result of rebasing the RPL market basket from a FY 2002 base year to a FY 2008 base year, and reflects use of a more recent cost structure of freestanding IRFs, freestanding IPFs, and LTCHs. As displayed in Table VII.D–2, the rebasing of the RPL market basket from a FY 2002 base year to a FY 2008 base year resulted in a decrease in the compensation cost weight of approximately 3.6 percentage points from 65.877 percent to 62.278 percent. We found during our most recent rebasing process that the compensation cost weight had begun to gradually decrease over the time period from 2003 to 2008.

The decrease in the base year compensation cost weight is accounting for over three-quarters of the total decrease from the FY 2011 labor-related share and the FY 2012 labor-related share (of approximately 5 percentage points). The remaining decrease in the labor-related share is primarily the result of the treatment of professional fees as labor-related or nonlabor-related.

The FY 2012 labor-related share reflects the most recently available and complete set of Medicare cost reports, and thus reflects the updated and appropriate proportion of costs that are related to, influenced by, or vary with the local labor market for IRFs, IPFs, and LTCHs.

Comment: One commenter specifically called into question the methodology used for estimating the allocation of professional fees; specifically stating concerns that the sample size used was too small (108 hospitals), the survey results may be old and no longer valid, that there is no indication that CMS conducted a statistically valid sample for estimating the allocation of professional fees, and that it would have been more appropriate for CMS to survey LTCH's for this information.

Response: We disagree with the commenter's rationale in regard to the calculation of the labor-related share for FY 2012. A method that distributes professional fees based on empirical research and data represents a technical improvement to the construction of the market basket, where previously 100 percent of professional fees were assumed to vary with the local labor market. The actual survey results are for the year 2008, and are the most recent data available at the time of this final rule. In response to the concerns about the sample size of 108 hospitals and the validity of the survey results, we provide more detail on the survey conducted below. We note that these same survey results were used in the IPPS market basket rebasing for the FY 2010 IPPS final rule (74 FR 43853) and the RPL market basket rebasing for the FY 2012 IPF final rule (76 FR 26445 through 26447).

The survey's methods unfolded in the following manner: Through an independent contractor, a small sample of 12 hospitals were initially pre-tested in order to ensure the understandability of the survey questions. The survey prompted sample institutions to select from multiple choice answers the proportions of their professional fees that are purchased from firms located outside of their respective local labor market. The multiple choice answers for each type of professional service included the following options: 0 percent of fees; 1–20 percent of fees; 21–40 percent of fees; 41–60 percent of fees; 61–80 percent of fees; 81–99 percent of fees; and 100 percent of fees. All respondents were assured that the information they provided would be kept strictly confidential.

Understanding that larger, urban-based hospitals (and those located in areas with area wage indexes greater than 1.0) are most likely to be impacted by the survey's results, we used data on full-time equivalents (FTEs) to represent the sizes of hospitals and selected hospitals with probability proportional to their sizes across strata when drawing the full sample. Strata were formed by Census Region and Urban/Rural Status. The distributions of the hospital population, as well as weighted distributions for the responders, by Urban/Rural Status (including data on hospital size) and Census Region were as follows:

	All hospitals percent distribution and average FTE size	Responding hospitals percent distribution and average FTE size
Total	100%/994	100%/1,156
Total Rurals	30%/388	25%/449
Total Urbans	70%/1,255	75%/1,460
Total Northeast Region	15%/1,442	20%/1,078
Total Mid-West Region	23%/1,062	24%/1,656
Total South Region	42%/843	37%/944
Total West Region	20%/899	19%/1,081

Sample weights were calculated as the inverse of the selection probability and were subsequently adjusted for nonresponse bias by strata and post-stratified to derive final weights. This type of application represents a common survey approach and is based on valid and widely-accepted statistical techniques.

For the estimates of the nationwide proportion of nonmedical professional services fees purchased outside of the local labor market, we first examined the data on multiple levels. First, we found that fewer than 30 percent of the responding hospitals paid 100 percent of their professional fees to vendors located within their local labor market. Conversely, we found that roughly 20 percent of responding hospitals reported that 81 percent or more of their professional services fees are paid to vendors located outside of their local labor market.

In determining the specific and appropriate proportions of professional fees to consider labor-related and nonlabor-related, we generated weighted averages from the data in the following manner:

- For any multiple choice answer where the standard error associated with the weighted counts for that

answer was less than 30 percent, we multiplied the weighted counts associated with that answer by the midpoint of the range within that answer. For example, for Accounting and Auditing services, if a weighted count of 500 hospitals responded that they pay ''1 to 20 percent'' of their professional fees for these services to firms located outside of their local labor market, we would multiply 500 times 10 percent. We repeat this for each possible multiple choice answer.

- For any multiple choice answer where the standard error associated with the weighted counts for that answer exceeded 30 percent, we multiplied the weighted hospital counts by the low point of the range. Using a similar example as above, if a weighted count of 300 hospitals responded that they pay ''1 to 20 percent'' of their professional fees for these services to firms located outside of their local labor market, and the standard error on that estimate was greater than 30 percent, we would multiply 300 times 1 percent.

- After applying one of these two techniques to each answer, dependent on its associated standard error, we took a weighted average of the results to determine the final proportion to be excluded from the labor-related share for each of the four types of professional services surveyed.

Given the information provided above, we believe that the estimates based on this survey are valid.

Comment: One commenter recommended that CMS phase in this change in the labor-related share over a 2- to 3-year period to allow LTCHs a longer period of time to absorb the impact of this reduction to the labor-related share.

Response: We do not agree with this recommendation. In this final rule we are finalizing our methodology for calculating the labor-related share for FY 2012 using the FY 2008-based RPL market basket and the most recent forecast data available (which is IHS Global Insight Inc.'s second quarter 2011 forecast). This is also the same forecast we are using to derive the FY 2012 market basket update for this final rule. As the updated labor-related share reflects the current proportion of costs that are related to, vary with, or influenced by the local labor market, we believe it is appropriate to incorporate the results in full into the FY 2012 payment update.

E. Changes to the LTCH Payment Rates and Other Changes to the FY 2012 LTCH PPS

1. Overview of Development of the LTCH Payment Rates

The LTCH PPS was effective beginning with a LTCH's first cost reporting period beginning on or after October 1, 2002. Therefore, beginning with their FY 2003 cost reporting period, LTCHs were paid, during a 5-year transition period, a total LTCH prospective payment that was comprised of an increasing proportion of the LTCH PPS Federal rate and a decreasing proportion based on reasonable cost-based principles, unless the hospital made a one-time election to receive payment based on 100 percent of the Federal rate, as specified in § 412.533. New LTCHs (as defined at § 412.23(e)(4)) were paid based on 100 percent of the Federal rate, with no phase-in transition payments.

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 use to update the LTCH PPS standard Federal rate for FY 2012, that is, effective for LTCH discharges occurring on or after October 1, 2011 through September 30, 2012.

For further details on the development of the FY 2003 standard Federal rate, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the LTCH PPS Federal rate, 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); RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); and FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444).

The update to the LTCH PPS standard Federal rate for FY 2012 is presented in section V.A. of the Addendum to this final rule. The components of the annual market basket update to the LTCH PPS standard Federal rate for FY 2012 are discussed below. In addition, as discussed below in section VII.E.3. of this preamble, beginning in FY 2012, in addition to the update factor, we make an adjustment to the standard Federal rate to account for the estimated effect of any changes to the area wage level adjustment on estimated aggregate LTCH PPS payments.

2. FY 2012 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. With the initial implementation of the LTCH PPS for FY 2003, we established the use of the excluded hospital with capital market basket as the LTCH PPS market basket (67 FR 56016 through 56017). (For further details on the development of the excluded hospital with capital market basket, we refer readers to the RY 2004 LTCH PPS final rule (68 FR 34134 through 34137).) The development of the initial LTCH PPS standard Federal rate for FY 2003, using the excluded hospital with capital market basket, is discussed in further detail in the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56033).

Beginning in RY 2007, we adopted the rehabilitation, psychiatric, long-term care (RPL) hospital market basket based on FY 2002 data as the appropriate market basket of goods and services under the LTCH PPS for discharges occurring on or after July 1, 2006. As discussed in the RY 2007 LTCH PPS final rule (71 FR 27810), based on our research, we did not develop a market basket specific to LTCH services. We were unable to create a separate market basket specifically for LTCHs at that time due to the small number of facilities and the limited amount of data that was reported. (For further details on the development of the FY 2002-based RPL market basket, we refer readers to the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).)

As discussed in greater detail in section VII.D. of this preamble, we are revising and rebasing the market basket used under the LTCH PPS for FY 2012. Specifically, we are adopting a newly created FY 2008-based RPL market basket (described in section VII.D. of this preamble). Also, in section VII.D. of this preamble, we discuss our continued interest in exploring the possibility of creating a stand-alone LTCH market basket that reflects the cost structures of only LTCH providers.

b. Revision of Certain Market Basket Updates as Required by the Affordable Care Act

Several provisions of the Affordable Care Act affect the policies and payment rates under the LTCH PPS. 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'' as discussed in section VII.E.2.d. of this preamble) 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. We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we have 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 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 employ ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

c. Market Basket Under the LTCH PPS for FY 2012

As noted above and as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50389), when we initially created the FY 2002-based RPL market basket, we were unable to create a separate market basket specifically for LTCHs due, in part, to the small number of facilities and the limited data that were provided in the Medicare cost reports. Over the last several years, however, the number of LTCHs submitting valid Medicare cost report data has increased. Based on this development, as well as our desire to move from one RPL market basket to three stand-alone and provider-specific market baskets (for IRFs, IPFs, and LTCHs, respectively), we have begun to explore the viability of creating these market baskets for future use. However, as we discussed in the RY 2010 LTCH PPS final rule (74 FR 43967 through 43968), we are conducting further research to assist us in understanding the reasons for the variations in costs and cost structure between freestanding IRFs and hospital-based IRFs. We also are researching the reasons for similar variations in costs and cost structure between freestanding IPFs and hospital-based IPFs. Therefore, we do not believe it is appropriate at this time to propose stand-alone market baskets for IRFs, IPFs, and LTCHs, and we believe that it is appropriate to continue to use the RPL market basket for LTCHs, IRFs, and IPFs under their respective PPSs.

We continue to believe that the RPL market basket appropriately reflects the cost structure of LTCHs, for the reasons discussed when we adopted the RPL market basket for use under the LTCH PPS in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817). For the reasons explained above, as we proposed, we are continuing to use the RPL market basket under the LTCH PPS for FY 2012. However, as discussed in greater detail in section VII.D. of this preamble, we are finalizing our proposal to rebase and revise the FY 2002-based RPL market basket by creating a FY 2008-based RPL market basket. As we discussed in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26006), currently, we are exploring the viability of creating two separate market baskets from the current RPL market basket: One market basket would include freestanding IRFs and freestanding IPFs and would be used to update payments under both the IPF and IRF payment systems. The other market basket would be a stand-alone LTCH market basket. Depending on the outcome of our research, we may propose a stand-alone LTCH market basket in the next LTCH PPS update cycle.

In that same proposed rule, we invited public comment on the possibility of using this type of market basket to update LTCH payments in the future. Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we proposed to use the FY 2008-based RPL market basket (described in section VII.D. of this preamble) under the LTCH PPS for FY 2012, which we continue to believe appropriately reflects the cost structure of LTCHs.

Comment: One commenter supported CMS' work to rebase and revise the market basket used for LTCHs, and asked if it would be possible to identify separate LTCH market baskets for hospitals-within-hospitals and freestanding facilities, further stating that CMS mentions there are cost differences between free standing IPFs and hospital-based IPF facilities, and also for IRF facilities, but CMS does not make the same statement for LTCHs. The commenter asked if this is an ongoing item of study, or if it is CMS' belief that there are no cost differences between freestanding LTCHs and hospital-within-hospital LTCHs. The commenter encouraged CMS to consider having a differentiation for freestanding LTCHs and hospital-within-hospital LTCHs.

Response: The FY 2008-based RPL market basket reflects all LTCH facilities, including both freestanding LTCHs and hospitals-within-hospitals. We are continuing to analyze all aspects of a possible stand-alone LTCH market basket, including the contributions of hospital-within-hospital LTCHs on such a market basket. Any future changes to the market basket used to update LTCHs, including the possible introduction of a LTCH-specific market basket, would be proposed and subject to notice and comment rulemaking.

Comment: Several commenters supported CMS' work to rebase and revise the FY 2002-based RPL market basket to a FY 2008-based RPL market basket. These commenters also stated their support for CMS' inclusion of LTCH cost reports to develop the FY 2008-based RPL market basket.

Response: We appreciate the support for this policy. As we proposed, in this final rule, we are finalizing our proposed methods for rebasing and revising the RPL market basket to a FY 2008-based RPL market basket.

d. Productivity Adjustment

Section 1886(m)(3)(A)(i) of the Act specifies that, for FY 2012 and subsequent years, any annual update to the standard Federal rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting

period, or other annual period) (the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private non-farm business MFP. We refer readers to the BLS Web site at *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data.

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 described in section IV.K.3. of this preamble, we derived the FY 2012 MFP adjustment applied to the operating IPPS applicable percentage increase using a projection of MFP that is currently produced by IHS Global Insight, Inc. (IGI). For a detailed description of the model currently used by IGI to project MFP, as well as a description of how the MFP adjustment was calculated for FY 2012, we refer readers to section IV.K.3 of this preamble. We proposed that if more recent data became 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 2012 market basket update and MFP adjustment in the final rule. The current estimate of the MFP adjustment for FY 2012 based on IGI's second quarter 2011 forecast is 1.0 percent. Consistent with the statute, we reduce the FY 2012 market basket update of the LTCH PPS standard Federal rate using this same FY 2012 MFP adjustment.

To determine the market basket update for LTCHs for FY 2012, as reduced by the MFP adjustment, consistent with the approach under the IPPS for FY 2012 (discussed in section IV.K.3. of this preamble), we subtracted the FY 2012 MFP percentage adjustment from the FY 2012 market basket update. Following application of the productivity adjustment, the adjusted market basket update (that is, the full market basket increase less the MFP adjustment) is then reduced by the ''other adjustment'' as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. The market basket update for FY 2012, which reflects both the MFP adjustment and the ''other adjustment'' as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act, is described in section VII.E.2.e. of this preamble.

e. Annual Market Basket Update for LTCHs for FY 2012

Consistent with our historical practice, we estimate the market basket update based on IGI's forecast using the most recent available data.For the proposed rule, based on IGI's first quarter 2011 forecast, the FY 2012 market basket estimate for the LTCH PPS using the FY 2008-based RPL market basket was 2.8 percent. For this final rule, based on IGI's second quarter 2011 forecast, the FY 2012 estimate of the FY 2008-based RPL market basket update is 2.9 percent.

Section 1886(m)(3)(A)(i) of the Act specifies that, for FY 2012 (and subsequent years), any annual update to the standard Federal rate shall be reduced by the productivity adjustment (referred to as ''the MFP adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act. Furthermore, section 1886(m)(3)(A)(ii) of the Act specifies that, for each of RYs 2010 through 2019, any annual update to the standard Federal rate shall be reduced by the other adjustment specified in section 1886(m)(4) of the Act. Specifically, section 1886(m)(4)(C) of the Act requires a 0.1 percentage point reduction to the annual update to the LTCH PPS standard Federal rate for FY 2012.

In accordance with section 1886(m)(3)(A)(i) of the Act, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26006), we proposed to reduce the FY 2012 full market basket estimate of 2.8 percent (based on the first quarter 2011 forecast of the FY 2008-based RPL market basket) by the proposed FY 2012 MFP adjustment (that is, the 10-year moving average of MFP for the period ending FY 2012, as described in section VII.E.2.d of the preamble of the proposed rule) of 1.2 percent (based on IGI's first quarter 2011 forecast). Following application of the proposed productivity adjustment, the proposed adjusted market basket update of 1.6 percent (2.8 percent minus 1.2 percentage points) was then reduced by 0.1 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(C) of the Act. Accordingly, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26007), we proposed an annual market basket update under the LTCH PPS for FY 2012 of 1.5 percent (that is, the most recent estimate of the proposed LTCH PPS market basket update of 2.8 percent less the proposed MFP adjustment of 1.2 percentage points less the 0.1 percentage point required under section 1886(m)(4)(C) of the Act. In that same proposed rule, we proposed to revise § 412.523(c)(3) of the regulations by adding a new paragraph (viii), which would specify that the standard Federal rate for FY 2012 is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.5 percent.

Again, consistent with our historical practice of using the most recent available data, we proposed that if more recent data became available when we developed the final rule, we would use such data, if appropriate, in determining the final market basket update under the LTCH PPS for FY 2012. Therefore, in this final rule, consistent with our proposal, we are establishing an annual market basket update under the LTCH PPS for FY 2012 of 1.8 percent (that is, the most recent estimate of the LTCH PPS market basket update of 2.9 percent less the MFP adjustment of 1.0 percentage point less the 0.1 percentage point required under section 1886(m)(4)(C) of the Act). This is based on IGI's second quarter 2011 forecast. Consistent with our proposal, we are revising § 412.523(c)(3) by adding a new paragraph (viii), which specifies that the standard Federal rate for FY 2012 is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.8 percent.

3. Budget Neutrality Adjustment for the Changes to the Area Wage Level Adjustment

As described in section V.B. of the Addendum to this final rule, when the LTCH PPS was implemented, 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. Historically, in general, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. However, there are currently no statutory or regulatory requirements that state that any updates or adjustments to the LTCH PPS area wage level adjustment (that is, the wage index or the labor-related share) be budget neutral, such that estimated aggregate LTCH PPS payments would be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment.

As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56015), when we implemented the

LTCH PPS, we established a 5-year transition to the full area wage level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable full LTCH PPS wage index values are used to make payments under the LTCH PPS. As discussed in section VII.D. of this preamble, we are finalizing our proposal to revise and rebase the market basket used under the LTCH PPS for FY 2012. We also are finalizing our proposal to update the labor-related share for FY 2012 based on this market basket. Concurrent with those proposals, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26007), we took the opportunity to revisit our approach for the annual update of the area wage level adjustment. We discussed that, in order to mitigate estimated yearly fluctuations in estimated aggregate LTCH PPS payments, as have been suggested in the past, we have given further consideration to the issue of establishing a budget neutrality requirement for any changes to the area wage level adjustment. Therefore, under the broad authority conferred upon the Secretary under section 123 of the BBRA, as amended by section 307(b) of the BIPA, to develop the LTCH PPS, we proposed under § 412.525(c) that, beginning with the adjustment for area wage levels for FY 2012, any changes to the wage index values or labor-related share would be made 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 such changes to the area wage level adjustment.

Under this proposal, we proposed to determine an area wage level adjustment budget neutrality factor that would be applied to the standard Federal rate to ensure that any changes to the area wage level adjustment would be budget neutral such that any changes to the wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. We also proposed the steps (described below) we would follow to determine an area wage level adjustment budget neutrality factor that would be applied to the standard Federal rate that would ensure that the any update to the wage index values and to the labor-related share would be adopted in a budget neutral manner. Under this proposal, we proposed to revise the existing regulations at § 412.523(d) to add a new paragraph (4) to specify that, beginning in FY 2012, we adjust the standard Federal rate by a factor that accounts for the estimated effect of any adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments. We also proposed to revise existing § 412.525(c) to reflect our current policy of updating the labor-related share annually. (76 FR 26007)

Comment: A few commenters opposed the proposed budget neutrality requirement for changes to the LTCH PPS area wage adjustment for FY 2012. The commenters believed that CMS had not provided adequate justification for why such an adjustment is needed now when CMS has not contemplated one in past years, and requested that CMS provide data to justify this change in policy.

Response: We do not agree with the commenters that we did not provide adequate justification for why we are revisiting our approach for the annual update of the area wage level adjustment at this time. As we stated in the FY 2102 IPPS/LTCH PPS proposed rule (76 FR 26007), we believe establishing a budget neutrality requirement for any changes to the area wage level adjustment would mitigate estimated yearly fluctuations in estimated aggregate LTCH PPS payments. Each labor market area's wage index value is calculated as the ratio of that labor market area's average hourly wage to the national average hourly wage. The annual update to the wage index is only intended to reflect changes in hospital labor costs in each geographic labor market area relative to the change in the national average hospital labor costs for all areas. Because the area wage adjustment is a measure of relative hospital labor costs, it is not intended to result in changes (increases or decreases) in aggregate payments. LTCH payments rates are updated annually to account for changes in hospital labor costs by the price growth reflected in the labor-related categories of the applicable LTCH PPS market basket update. For example, if nationally each hospital's labor costs increased by 5 percent, although labor costs have increased, the area wage index (which is the ratio of the area's average hourly wage to the national average hourly wage) would not change because the relative measure of the area's labor costs as compared to the national average labor costs has not changed. In fact, aggregate payments will increase based on changes to the labor portion of the market basket. Moreover, a budget neutrality requirement for any changes to the area wage level adjustment is consistent with our policy under other hospital PPSs, such as the IPPS, IRF PPS, and IPF PPS. We note that none of the commenters provided policy or technical justifications for not budget neutralizing for changes to the LTCH PPS area wage adjustment.

Therefore, for the reasons stated above, in this final rule, we are adopting our proposal to establish a budget neutrality requirement for any changes to the area wage adjustment without modification, beginning in FY 2012.

We did not receive any public comments on our proposed methodology (steps) for determining an area wage level adjustment budget neutrality factor that would be applied to the standard Federal rate. We also did not receive any public comments on our proposed changes to the regulations at § 412.523(d) and § 412.525(c) under our area wage level adjustment budget neutrality proposal. Therefore, as discussed below, we are adopting these proposals in this final rule.

In this final rule, under the broad authority conferred upon the Secretary under section 123 of the BBRA, as amended by section 307(b) of the BIPA, to develop the LTCH PPS, as we proposed, under § 412.525(c)(2), we are establishing a budget neutrality requirement for any changes to the adjustment for area wage levels, beginning in FY 2012. Under this policy, any changes to the wage index values or labor-related share will be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected, that is, will be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without such changes to the area wage level adjustment. We also are determining under this budget neutrality requirement, as we proposed, 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. As we proposed, we are revising the existing regulations at § 412.523(d) to add a new paragraph (4), which specifies that, beginning in FY 2012, we adjust the standard Federal rate by a factor that accounts for the estimated effect of any adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS

payments. In addition, as we proposed, we are revising existing § 412.525(c) to reflect our current policy of updating the labor-related share annually.

For this final rule, consistent with our proposal, we used the following methodology to determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal rate under at § 412.523(d)(4) for FY 2012 to account for the estimated effect of any adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments:

- Step 1—We simulate estimated aggregate LTCH PPS payments using the FY 2011 wage index values as established in Tables 12A and 12B of the Addendum to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50627 through 50646) and the FY 2011 labor-related share of 75.271 percent as established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50391 and 50445).
- Step 2—We simulate estimated aggregate LTCH PPS payments using the FY 2012 wage index values as shown in Tables 12A and 12B of the Addendum to this final rule and the FY 2012 labor-related share of 70.199 percent (based on the latest available data as discussed in section VII.D.3.f. of this preamble).
- Step 3—We calculate the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2011 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS payments using the proposed FY 2012 area wage level adjustments (calculated in Step 2) to determine the area wage level adjustment budget neutrality factor.
- Step 4—We then apply the FY 2012 area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2012 LTCH PPS standard Federal rate after the application of the FY 2012 annual update (discussed in section V.A.2. of the Addendum to this final rule). As explained above, this factor is applied to the FY 2012 standard Federal rate to ensure that the FY 2012 update to the wage index values and to the labor-related share (discussed in section V.B. of the Addendum to this final rule) are adopted in a budget neutral manner.

For this final rule, using the steps in the methodology described above, we determined a FY 2012 area wage level adjustment budget neutrality factor of 0.99775. Accordingly, in section V.A.2. of the Addendum to this final rule, to determine the FY 2012 LTCH PPS standard Federal rate, we applied an area wage level adjustment budget neutrality factor of 0.99775, in accordance with § 412.523(d)(4). Accordingly, the FY 2012 LTCH PPS standard Federal rate shown in Table 1E of the Addendum to this final rule reflects this adjustment.

4. Greater Than 25-Day Average Length of Stay Requirement for LTCHs

Section 1886(d)(1)(B) of the Act lists hospitals that are excluded from the IPPS. Section 1886(d)(1)(B)(iv) of the Act specifies the exclusion from the IPPS for ''a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.'' The average length of stay requirement was established as the sole prerequisite for a hospital seeking to be excluded from the IPPS under this provider category. Section 114(a) of the MMSEA of 2007 amended section 1861 of the Act by adding a new subsection (ccc), which further defined LTCHs. Thus, a hospital's classification as an LTCH has depended, in large part, upon whether an acute care hospital met the greater than 25 days average length of stay requirement. Once the hospital was classified as such under this criterion, the ability for the hospital to continue its exclusion from the IPPS and be paid as an LTCH depended, in part, upon its continuing to meet that criterion.

The regulations at 42 CFR 412.23(e)(1) and (e)(2) set forth the requirements a hospital must meet in order to be excluded from the IPPS and be paid as an LTCH. Specifically, § 412.23(e)(1) requires that a hospital must have a provider agreement under 42 CFR Part 489 to participate as a Medicare hospital, and § 412.23(e)(2) provides that a hospital must meet the LTCH average length of stay of greater than 25 days policy. The methodology for calculating the average length of stay is specified at § 412.23(e)(3). A detailed explanation of the procedural features of the average length of stay policy was included in the FY 2003 LTCH PPS final rule, which implemented the LTCH PPS (67 FR 55970 through 55974)).

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26008), we proposed to clarify two existing CMS policies related to the greater than 25 days average length of stay requirement policy: (1) The determination of the average length of stay for a hospital seeking exclusion under the IPPS to be paid as an LTCH or an existing LTCH undergoes a change of ownership; and (2) the inclusion of Medicare Advantage days in calculating the average length of stay.

a. Determination of the Average Length of Stay When There Is a Change of Ownership

Under § 412.23(e)(3)(iv) of the regulations, we implemented a policy regarding the application of the average length of stay methodology, where a hospital (that is either seeking LTCH status, or is an existing LTCH) has undergone a change of ownership. Specifically, in the event of a change of ownership, the regulation provides:

''If a hospital has undergone a change of ownership (as described in § 489.18 of this chapter) at the start of a cost reporting period or at any time within the period of at least 5 months of the preceding 6-month period, the hospital may be excluded from the prospective payment system as a long-term care hospital for a cost reporting period if, for the period of at least 5 months of the 6 months immediately preceding the start of the period (including time before the change of ownership), the hospital has the required average length of stay, continuously operated as a hospital, and continuously participated as a hospital in Medicare.''

Section 412.23(e)(3)(iv) institutes a procedure by which the average length of stay of a hospital seeking LTCH status or an existing LTCH is evaluated by its fiscal intermediary or MAC to determine whether or not the facility that is being sold meets the requirements for LTCH status. Because the sale of the facility, in effect, ends the seller's cost reporting period (§ 413.24(f)(1)), and triggers the beginning of the purchaser's first cost reporting period, the period of time that is evaluated is the ''at least 5 months of the 6 months immediately preceding the period (including time before the change of ownership'' to determine the average length of stay that will result in the hospital that meets the requirements for LTCH status. If the average length of stay data indicates that, for this period of time, the hospital met the required average length of stay of greater than 25 days, then the new owner's hospital will achieve IPPS exclusion and LTCH status. On the other hand, if the data indicate that the hospital does not meet the required average length of stay, the hospital will instead be paid under the IPPS under its new ownership. We understand that there has been some confusion in the provider community regarding the specific applicability of this regulation to a change of ownership of an existing LTCH. Accordingly, in the proposed rule, we proposed to clarify this policy in regulation text by revising § 412.23(e)(3)(iv) to specifically address the circumstance of a hospital that has not as yet been classified as an LTCH

and wishes to be classified as an LTCH based on data from the hospital's discharges occurring both before and after the change of ownership. Moreover, in an effort to provide greater clarity, we also proposed to establish a separate provision in the regulations (proposed paragraph (e)(3)(v) under § 412.23) to directly address LTCH status where there is a change of ownership of an existing LTCH. The sale of an existing LTCH, which triggers the beginning of a new cost reporting period under the new owner (413.24(f)(1)), is a situation where we believe it is appropriate to review whether the hospital that is being sold has been functioning as an LTCH, that is, has been treating patients for on average length of stay of greater than 25 days, before allowing the new owner to continue to be paid for services provided at the hospital under the LTCH PPS. Therefore, we proposed that where there has been a change of ownership of an existing LTCH, the hospital will continue to be excluded from the inpatient prospective payment system as a long-term care hospital for the cost reporting period beginning with the change of ownership only if for the period of at least 5 months of the 6 months immediately preceding the change of ownership, the hospital meets the required average length of stay. We note that, conversely, under this proposed policy, if the hospital fails to meet the required average length of stay criterion, after this evaluation, and if it is an acute-care hospital, it will be paid instead under the IPPS effective with the day of the change of ownership, that is, the start of the new owner's cost reporting period.

Accordingly, we proposed to clarify our existing policy as described above by (1) revising existing § 412.23(e)(3)(iv), to specifically address LTCH status in instances where a hospital is seeking IPPS exclusion and payment under the LTCH PPS but a change of ownership has occurred, and (2) proposed to establish a new § 412.23(e)(3)(v) to specifically address the issue of LTCH status for existing LTCHs undergoing a change of ownership.

Comment: One commenter did not understand the clarification that CMS proposed, noting that the only distinction between § 412.23(e)(3)(iv) and § 412.23(e)(3)(v) appeared to be a ''new [30 day] notice requirement * * * applicable only to existing LTCHs, but not to newly qualifying LTCHs.'' This commenter also requested that CMS resolve an ''inconsistency'' between the preamble language and the regulation text language regarding the definition of the 5 months of the 6 months that is to be evaluated. The commenter indicated that the preamble states that the period in question is ''* * * at least 5 months of the 6 months immediately preceding the change of ownership * * * '' but the regulation text at § 412.23(e)(3)(v) states ''* * * at least 5 months of the 6 months immediately preceding the start of the hospital's next cost reporting period before the change of ownership * * *.'' Another commenter expressed concern about CMS recognizing the distinction between the sale of an LTCH that would trigger the average length of stay review specified in proposed § 412.23(e)(3)(v) and the transfer of an LTCH to a related party that could take place during a corporate reorganization of an integrated hospital system.

Response: In response to the commenter's lack of clarity about the similarities between existing § 412.23(e)(iv) and proposed §§ 412.23(e)(3)(iv) and (e)(3)(v), we emphasize that we have proposed to clarify existing policy, not to change it. The two ''new'' regulations that we proposed are limited to LTCH changes of ownership under either of two specific situations: A hospital that is sold prior to achieving LTCH status (§ 412.23(e)(3)(iv)); and the sale of an existing LTCH (§ 412.23(e)(3)(v)). Our goal in proposing this clarification of our existing LTCH change of ownership policy at § 412.23(e)(iv) was to divide the regulation that was causing confusion among the provider community because it formerly covered change of ownership in both situations—LTCHs under development and existing LTCHs—into two separate regulations. The new regulation at § 412.23(e)(3)(v) cited the already existing requirement for a 30-day notice to CMS for a hospital undergoing a ''change of ownership or control, including changes in authorized official(s) or delegated official(s) * * *'' at § 424.516(e). We included the 30-day notice because we have been informed by our regional offices that, in the past, compliance with this 30-day notice requirement by existing LTCHs that are being sold has been somewhat inconsistent and may not have been understood to apply to LTCHs. Because of ongoing communication between the hospital wishing to qualify as a LTCH and CMS when a hospital is applying to CMS for LTCH status, CMS regional office staff do not report this to be a problem during the LTCH qualifying period. However, the notice requirement at § 424.516(e) applies to all providers and suppliers enrolled in the Medicare program.

We appreciate the commenter bringing to our attention the lack of conformity between the preamble language and the regulation text at § 412.23(e)(3)(v) regarding the 5 months of the 6 months period in question for the evaluation of the average length of stay calculation. Because, as we note in the preamble, a change of ownership triggers the start of a new cost reporting period, in order to clarify this regulation text, in this final rule, we are revising the regulation text to state ''* * * at least 5 months of the 6 months immediately preceding the change of ownership.

In response to the commenter who requested that we specify that a corporate reorganization of an integrated hospital system that includes an LTCH would not trigger an evaluation of the LTCH's average length of stay, we note that if a business transaction relating to an LTCH meets the definition of a change of ownership under § 489.18, it would be governed by the applicable regulation at § 412.23(e)(3).

After consideration of the public comments we received, we are finalizing our clarification of our change of ownership policy for LTCHs at §§ 412.23(e)(3)(iv) and (e)(3)(v).

b. Inclusion of Medicare Advantage (MA) Days in the Average Length of Stay Calculation

With the passage of the Balanced Budget Act of 1997, Medicare beneficiaries were given the option to receive their Medicare benefits through private health insurance plans instead of through the original Medicare plan (Parts A and B). These programs were known as Medicare+Choice or Part C plans (Section 1851 through 1859 of the Act, implemented in 42 CFR Part 422). Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the compensation and business practices changed for insurers that offer these plans, and ''Medicare+Choice'' plans became known as Medicare Advantage (MA) plans.)

When CMS implemented the LTCH PPS beginning in FY 2003, we revised the then-existing policy for calculating the average length of stay for LTCHs described at then § 412.23(e)(2)(i). Under the TEFRA payment system, the average length of stay was determined by ''* * * dividing the number of total inpatient days * * * by the total discharges for the hospital's most recent complete cost reporting period * * *'' However, beginning with FY 2003, under the newly implemented LTCH PPS, the calculation was based on ''dividing the total number of covered

and noncovered days of stay of Medicare inpatients * * * by the total Medicare discharges for the hospital's most recent complete cost reporting period'' (§ 412.23(e)(3)(i)). The rationale for this change, as noted in the preamble to the FY 2003 LTCH PPS final rule, is that ''LTCHs exist as a provider type in order to treat Medicare patients requiring complex long-term hospital-level care. We believe that a hospital's right to qualify for payments under the prospective payment system for LTCHs should result from the actual provision of clinically appropriate care to Medicare LTCH patients * * *'' (67 FR 55971).

Although the policy since the start of the LTCH PPS has been for all LTCH patients being paid for by Medicare to be included in the average length of stay calculation, until recently, we were unable to include data for Medicare Advantage (MA) patients in our calculations because our database did not capture discharge data on claims paid by an MA plan. (In contrast, patients who still had private insurance as their primary health coverage and for whom Medicare was a secondary payer, were included in the calculations because the portion of their claims covered by Medicare was paid by Part A and was therefore included in our database.)

On July 20, 2007, we issued Change Request 5647 that required the submission by hospitals (IPPS, IRFs, and LTCHs) of ''information only'' (not for payment) bills for their MA patients to their fiscal intermediaries or MACs beginning with FY 2007. The stated goal of capturing these MA data was that the data were needed for disproportionate share payments (DSH) under the IPPS, low-income patient (LIP) payments under the IRF PPS, and for short-stay outlier (SSO) payments under the LTCH PPS. An additional one-time notification, Change Request 6821, issued on June 7, 2010, reiterated the requirements of Change Request 5647 for the reporting of MA days for DHS and LIP data and also noted ''[i]n addition, this data is used for other purposes such as determining LTCH short stay outlier payments and evaluating the greater than 25 days length of stay requirement of Medicare patients for LTCHs.''

Although the inclusion of MA days in the average length of stay calculation has been CMS' policy under the LTCH PPS because, at the outset of the LTCH PPS, we specified that the average length of stay calculation was based on ''all covered'' and on ''all covered days of stay of Medicare patients'' (§ 412.23(e)(2)), we acknowledge that, in practice, MA days were not included due to limitations in our ability to capture the data. We have been informed by some members of the provider community that it was not their understanding that MA data should be included in determining a LTCH's average length of stay, and that, in some cases, the inclusion of these data could substantially lower their average length of stay, thus threatening their status as LTCHs. Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26008 and 26009), we proposed to clarify our existing policy at 42 CFR 412.23(e)(3) on the calculation of the average length of stay to specify that all data on all Medicare inpatient days, including MA days, shall be included in the average length of stay calculation.

Comment: A number of commenters urged CMS to establish a specific effective date for this policy, and one of these commenters requested that we confirm that the existing ''* * * at least 5 months of the preceding 6 month'' cure period would still be in effect for an LTCH failing to meet the average length of stay requirement as a result of the inclusion of MA days in the average length of stay calculation. Several commenters challenged CMS' assertion that the inclusion of MA days was ''clarification of existing policy'' and argued that the inclusion of MA days in the average length of stay calculation was a new policy. Therefore, the commenters urged CMS to study the impact on LTCHs of instituting this ''new policy,'' while instructing Medicare contractors not to include MA days in the average length of stay calculation until this evaluation was completed and then, to subject the policy to notice and comment rulemaking. Several commenters expressed concern because contracts currently in place between some LTCHs and managed care organizations limit the LTCH lengths of stay of beneficiaries who are enrolled in those plans. The inclusion of those MA days, the commenters feared, would result in a decrease in some LTCHs' average length of stay, and thereby threatens their LTCH status.

One commenter opposed the inclusion of MA days in the average length of stay calculation for LTCHs, arguing that the managed care payment model is radically different than the fee-for-service model and, therefore, is incompatible with the ''average of greater than 25 day'' length of stay requirement for LTCHs. Because the inclusion of such days in the average length of stay calculation could negatively impact LTCH status, the commenter warned that inclusion of MA days could lead to some LTCHs denying care to beneficiaries who have elected to enroll in MA plans.

Response: While we understand the commenters' concern about the impact of counting MA days in an LTCHs' average length of stay calculation, we reassert that the inclusion of such days has been contemplated since the establishment of the LTCH PPS (67 FR 55970 through 55975) and delayed only by previous technical limitations on CMS' ability to obtain the MA data. Our regulations at § 412.23(e)(2)(i) specify that the average length of stay calculation is based on ''* * * all covered and noncovered days of stay of Medicare patients * * *.'' ''All covered and noncovered days of stay of Medicare patients'' includes the days of stay of Medicare managed care patients. Additionally, as noted in this preamble, on July 20, 2007, in Change Request 5647, we required the submission of data on MA patients by hospitals (IPPS hospitals, IRFs, and LTCHs), and on June 7, 2010, in Change Request 6821, we reiterated this requirement while also specifying that the data would be used for ''* * * evaluating the greater than 25 days length of stay requirement of Medicare patients for LTCHs.'' The inclusion of MA days in the LTCH average length of stay requirement is not a new policy, but rather the implementation of a long-stated step that is now technically feasible for the Medicare program. We had determined that it was appropriate to discuss this issue as a ''clarification'' in the FY 2012 IPPS/LTCH PPS proposed rule, and solicited public comments because it was brought to our attention that the above noted change requests had resulted in some confusion in the provider community. We also understand the concern that several of the commenters have about the impact that the shorter lengths of stay negotiated by managed care organizations could have on retaining LTCH status. Therefore, we are finalizing the clarification of our policy with an effective date for the inclusion of MA days in the average length of stay calculation for LTCH cost reporting periods beginning on or after January 1, 2012. We also are instructing our contractors not to remove LTCH designation from any LTCH based on the fact that it fails to meet the average length of stay requirement solely due to the inclusion of MA days in its average length of stay calculation until cost reporting periods beginning on or after January 1, 2012. In response to the commenter's concern, we also are confirming our longstanding policy

regarding the evaluation of data from ''* * * at least 5 months of the preceding 6 month'' ''cure'' period for an LTCH that fails to meet the average length of stay requirement. Therefore, even after January 1, 2012, a hospital will be able to maintain its LTCH status if it has a greater than 25-day average length of stay (including MA days) for at least 5 months of the 6 months prior to the beginning of the cost reporting period when it would lose its LTCH status if it did not meet the average length of stay requirement.

In response to the commenter who objected to the inclusion of data from beneficiaries who elected to enroll in managed care plans rather than traditional Medicare in the average length of stay calculation, arguing that the MA model is not compatible with the average length of stay policy, which is based on a fee-for-service payment model, we note that Medicare Advantage (as Medicare + Choice) is a statutory creation (section 1851 through 1859 of the Act) for payment for services provided to Medicare patients. The exclusion of LTCHs from the IPPS as acute care hospitals for patients with ''* * *an average inpatient length of stay (as determined by the Secretary) of greater than 25 days (section 1886(d)(1)(B)(iv) of the Act) is a description of a hospital treating long length of stay patients. By regulation, we have prescribed that the test is based on Medicare patients rather than all of the hospital's patients. Congressional action could mandate a determination that MA patients should not be included. However, thus far, although Congress has addressed the LTCH PPS, it has not addressed the exclusion of MA days from the greater than 25-day average length of stay determination. Finally, our experience in meeting with LTCH trade associations, the medical and administrative leadership of LTCHs, and our site visits to numerous LTCHs, as well as our recent data on LTCH inpatient censuses, do not confirm the commenter's warnings about reduced MA patient access to LTCHs that will result should MA patient days be included in the average length of stay calculation.

After consideration of the public comments we received, we are finalizing our proposed clarification but with an effective date for inclusion of MA days in the average length of stay calculation for LTCH cost reporting periods beginning on or after January 1, 2012.

F. Application of LTCH Moratorium on the Increase in Beds at Section 114(d)(1)(B) of Public Law 110–173 (MMSEA) to LTCHs and LTCH Satellite Facilities Established or Classified as Such Under Section 114(d)(2) of Public Law 110–173

Under section 114(d) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), Congress established one moratorium on the establishment or classification of new LTCHs and LTCH satellite facilities and a second moratorium on the increase in the number of LTCH beds in ''existing hospitals and satellite facilities.'' This section 114(d) provision was amended by section 4302(b) of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) and implemented in interim final rules issued in the **Federal Register** on May 22, 2008, and August 27, 2009 (73 FR 29704 through 29707 and 74 FR 43990 through 43992, respectively), and finalized in the FY 2010 and FY 2011 IPPS/LTCH PPS final rules (74 FR 43985 through 43990 and 75 FR 50397 through 50399, respectively). With the passage of the Affordable Care Act on March 23, 2010, these moratoria were extended under sections 3016 and 10312 for an additional 2 years, through December 29, 2012. The extension was implemented in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50400).

Specific exceptions to each moratorium are included in the statute and permit both the continued establishment or classification of an LTCH or LTCH satellite facility and an increase in LTCH beds at a statutorily defined ''existing'' hospital or satellite facility, respectively. Under section 114(d)(2) of the MMSEA, as of December 29, 2007, the preclusion on the establishment or classification of a new LTCH or LTCH satellite facility as of December 29, 2007, would not apply if the hospital met one of the following three exceptions:

- The LTCH began its qualifying period for payment as a LTCH under 42 CFR 412.23(e) on or before the date of enactment of the MMSEA (section 114(d)(2)(A));
- The LTCH has a binding written agreement with an outside, unrelated party for the actual construction, renovation, lease, or demolition for a LTCH and had expended before December 29, 2007, at least 10 percent of the estimated cost of the project or, if less, $2.5 million (section 114(d)(2)(B)); or
- The LTCH has obtained an approved certificate of need (CON) in a State where one is required on or before December 29, 2007 (section 114(d)(2)(C)).

Section 114(d)(3) of the MMSEA, as originally enacted, provided an exception to the moratorium on an increase in beds at an existing LTCH or LTCH satellite facility, if an existing LTCH or satellite facility is located in a State where there is only one other LTCH; and the LTCH or satellite facility requests an increase in beds following the closure or decrease in the number of beds of another LTCH in the State. Section 4302(b) of the ARRA amended this MMSEA provision to specify an additional exception to the moratorium on the increase in bed number if the hospital or facility obtained a certificate of need for an increase in beds that is in a State for which such certificate of need is required and that the CON was issued on or after April 1, 2005, and before December 29, 2007.

In implementing these two moratorium provisions, we required that each hospital or entity submit details of its individual circumstance for evaluation by CMS regional offices and contractors in order to determine whether a specific statutory exception was applicable to the particular situation (74 FR 43985 through 43990). We note that, based upon these exceptions (73 FR 29707), CMS records indicate that, as of January 1, 2011, 50 new LTCHs and 8 new LTCH satellites have been established or classified after December 29, 2007, the date MMSEA was enacted. (Data on additional beds developed in existing LTCHs and LTCH satellite facilities under the CON exception provided by section 4302(b) of the ARRA are maintained by States.)

Sections 3106 and 10312 of the Affordable Care Act provided a 2-year extension of both moratoria initially established by section 114(d)(1) of the MMSEA (which provided for an original 3-year application), indicating that Congress continues to believe that it is appropriate to continue to stem the increase in the number of LTCHs and LTCH satellite facilities and LTCH beds.

As noted above, section 114(d)(1)(B) of the MMSEA established a moratorium on the increase of LTCH beds in existing LTCHs or satellite facilities. Section 114(d)(4) of the MMSEA defines ''an existing hospital or satellite facility'' as a hospital or satellite facility that received payment under the LTCH PPS *as of* December 29, 2007, the date of enactment of the MMSEA. By definition, LTCHs or satellite facilities that were established or classified as such under an exception at section 114(d)(2) to the moratorium under section 114(d)(1)(A) first received payments under the LTCH PPS *after*

December 29, 2007, and therefore, would not fall under the definition of ''an existing hospital or satellite facility'' to whom the moratorium on the increase in bed numbers at section 114(d)(1)(B) applies. However, we do not believe that it was Congress' intent to allow this subset of hospitals and satellite facilities established or classified after the enactment of MMSEA unlimited bed growth and expansion. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26010), we noted that continued Congressional concern regarding the increase in the number of LTCHs and satellite facilities and LTCH beds is indicated in the 2-year extension of the moratorium provided by sections 3106 and 10312 of the Affordable Care Act.

Section 123 of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA of 1999) (Pub. L. 106–113), as amended by section 307 (b) of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), confers upon the Secretary discretion in creating the LTCH PPS as the payment system for LTCHs beginning in FY 2003. Furthermore, the Secretary has authority, under the general rulemaking authority of sections 1102(a) and 1871(a) of the Act, to establish rules and regulations as necessary to administer the Medicare program and for the efficient administration of the Medicare program. Consistent with these authorities, therefore, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26010), we proposed that, effective October 1, 2011, the moratorium established under section 114(d)(1)(B) of the MMSEA, and implemented at 42 CFR 412.23(e)(7) be applied to those LTCHs and LTCH satellite facilities established or classified as such pursuant to the exceptions at section 114(d)(2) to the moratorium specified under section 114(d)(1)(B) of the MMSEA, as implemented at 42 CFR 412.23(e)(6). Specifically, we proposed to limit the number of beds in these facilities to the number of beds that were certified by Medicare at the LTCH or satellite facility when it was first paid under the LTCH PPS. We proposed to amend § 412.23 by adding a new paragraph (e)(8) to specify this policy. We believe that this policy captures the essence of the original statutory moratoria and the subsequent extension of the moratoria for an additional 2 years—which was to limit growth in the number of LTCHs and LTCH satellite facilities and LTCH beds payable under Medicare—while recognizing the inherent fairness in allowing those projects already underway that represented substantial investment, planning, and State commitment to be completed.

Comment: One commenter supported CMS' position on extending the moratorium on increasing the number of beds in ''existing'' LTCHs to those LTCHs and satellites established pursuant to exceptions provided in the statute.

Response: We appreciate the commenter's support for the proposed policy.

Comment: Three commenters urged CMS not to implement the extension of the moratorium to ''new'' LTCHs and LTCH satellites. These commenters noted that had Congress wished to extend the original moratorium on an increase in the number of beds in existing LTCHs and LTCH satellites that was first promulgated in MMSEA to LTCHs and LTCH satellites that had been established under one of the exceptions to the moratorium on the establishment of new LTCHs and LTCH satellites, Congress could have utilized either the ARRA or the Affordable Care Act for such a purpose. One of the commenters cited a longstanding Supreme Court decision (*Chevron U.S.A.* v. *NRDC,* 467 U.S. 837, 842–843 (1984)) which established the standard for determining the validity of regulatory provisions. The commenter stated that under *Chevron's* two-pronged test: (1) if it is determined that Congress has directly spoken to ''* * * the precise question at issue'' then ''* * * we must give effect to the unambiguously expressed intent of Congress;'' but (2) if the statute is ''silent or ambiguous with respect to the specific issue'' it need only be asked whether the regulation is ''based on a permissible construction of the statute.'' This commenter argued that because the MMSEA specified that the moratorium on bed increases applied to ''existing LTCHs and satellites,'' the extension of the moratorium by CMS to LTCHs and LTCH satellites that did not exist at the time of the legislation but were established under an exception, would be a violation of the *Chevron* Court decision.

Response: We do not agree that the failure to include a specific extension of the moratorium on bed increases to those LTCHs and LTCH satellite facilities originally excepted from the moratoria established under the MMSEA (new LTCHs and LTCH satellite facilities) in either the ARRA or the Affordable Care Act indicates that Congress intended to allow such LTCHs and LTCH satellite facilities unlimited authority to expand their bed numbers while restricting the growth of ''existing'' LTCHs. We also disagree with the commenters' arguments that the statute precisely answers the question at issue. We believe the discussion above describing our understanding of Congress' intent as well as the law governing the authorities for creating the LTCH PPS and the authorities to establish rules and regulations as necessary to administer the Medicare program and for the efficient administration of the Medicare program provide an appropriate and sufficient basis for the agency to finalize this policy as proposed. Moreover, we emphasize that, in finalizing this policy as proposed, we do not believe that it was Congress' intent to allow the one subgroup of LTCHs and LTCH satellite facilities established after the enactment of the MMSEA unlimited bed growth and expansion, particularly while extending both of the moratoria applicable to ''existing'' LTCHs and LTCH satellite facilities an additional 2 years in sections 3106 and 10312 of the Affordable Care Act.

Comment: One commenter requested that, if CMS finalizes the proposed policy, ''a specific exclusion'' be applied to any ''new'' LTCH that had increased its bed capacity beyond the number of beds that were certified by Medicare when it was first paid under the LTCH PPS.

Response: We agree with the commenter that it is possible that some ''new'' LTCHs have already increased their bed numbers beyond those that existed when they were first certified by Medicare and paid under the LTCH PPS. In consideration of this possibility, we are revising the proposed regulation text at § 412.23(e)(8) that we are adopting as final to indicate that the moratorium on increases in bed numbers for LTCHs and LTCH satellites that were established under one of the exceptions to the moratorium applies to the number of beds at the LTCH as of October 1, 2011.

After consideration of the public comments we received, in this final rule, we are adopting our proposed addition of new § 412.23(e)(8) with the modification noted above. That is, we are specifying that effective October 1, 2011 and ending December 28, 2012, the moratorium established under section 114(d)(1)(B) of the MMSEA, and implemented at 42 CFR 412.23(e)(7) will be applied to those LTCHs and LTCH satellite facilities established or classified as such pursuant to the exceptions at section 114(d)(2) to the

moratorium specified under section 114(d)(1)(B) of the MMSEA, as implemented at § 412.23(e)(6). Specifically, we are modifying the language to limit the number of beds in these facilities to the number of beds to those ''that were certified by Medicare at the LTCH or satellite facility as of October 1, 2011'' to replace the proposed language of the ''initial number of Medicare certified beds established under paragraph (e)(6)(ii). * * *''.

VIII. 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 2011 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2012 are addressed in Appendix B to this final rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's Web site at: *http://www.medpac.gov.*

IX. 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/AcuteInpatientPPS.* We listed the data files and the cost for each file, if applicable, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26010 through 26012).

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 the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 226012 through 26015), we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). We discuss and respond to any public comments we received in each individual section.

2. ICRs for Add-On Payments for New Services and Technologies

Section II.I.1. of the preamble of the proposed rule and this final 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 2012 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 detailed the burden associated with this requirement in the September 7, 2001, IPPS final rule (66 FR 46902). As stated in that final rule, collection of the information for this requirement is conducted on an individual case-by-case basis. We believe the associated burden is thereby exempt from the PRA as stipulated under 5 CFR 1320.3(h)(6). Similarly, we also 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, and 2012, we received 1, 4, 5, 3, and 3 applications, respectively.

We did not receive any public comments regarding these information collections.

3. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

The Hospital Inpatient Quality Reporting (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. We are currently seeking reinstatement of the information collection and will publish the required 60-day and 30-day notices in the **Federal Register** to solicit public comments.

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. New 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. We are currently seeking reinstatement of the information collection and will publish the required 60-day and 30-day notices in the **Federal Register** to solicit public comments.is currently approved under OMB control number 0938–1022.

For the FY 2014 and FY 2015 payment updates, we intend to seek OMB approval for a revised information collection request using the same OMB control number (0938–1022). In the revised request, we will add five measures that we adopted in the FY 2011 IPPS/LTCH PPS final rule (four chart-abstracted measures and an HAI measure (Surgical Site Infection (SSI)) to be collected via NSHN for the FY 2014 payment determination. In addition, we

are adding one HAI measure (CAUTI) also to be collected via NHSN, one structural measure and one claims-based measure that we are adopting in this final rule for the FY 2014 payment determination. We estimate that the changes to our FY 2014 payment determination measure set will increase the collection burden on hospitals by approximately 3,260,175 hours per year. Because the currently approved CDC information collection request for the NHSN (OCN: 0920–0666) does not include all of the respondents associated with the Hospital IQR Program, we intend to request a separate OMB control number for the measures to be collected via the NHSN.

With respect to the four new chart-abstracted measures for the FY 2014 payment determination, hospitals will be required to submit data on patients who receive inpatient acute care hospital services. Specifically, with respect to the two EDT measures and two Global Immunization measures, hospitals will need to collect information on patients who receive inpatient acute care hospital services regarding EDT, as well as influenza and pneumonia vaccination information for all inpatients for which hospitals currently collect only for patients admitted for pneumonia. We estimate that hospitals will incur an additional 3,500,000 burden hours resulting from the addition of these four measures for the FY 2014 payment determination. We estimate that hospitals will submit approximately 3,500,000 cases annually for these 4 measures, and the information needed to calculate these measures requires an average of 1 hour to abstract from medical records for each case.

The HAI measure (Surgical Site Infection (SSI)) that we added in the FY 2011 IPPS/LTCH PPS final rule for the FY 2014 payment determination and the HAI measure that we are adding in this final rule for the FY 2014 payment determination (CAUTI) are structured to keep additional burden to a minimum because they are to be collected via NHSN. More than 4,000 hospitals in 29 States are already using NHSN to comply with State-mandated reporting. Although these HAI measures will add burden for hospitals, we believe that the additional burden will be lessened because hospitals will already be using NHSN to report the CLABSI measure for the FY 2013 payment determination. In addition, as mentioned above, not all hospitals will experience any additional burden because many hospitals already submit data to this system either voluntarily or as part of mandatory State reporting requirements for HAIs. The burden associated with these requirements is the time and effort associated with collecting and submitting the additional data. We estimate that hospitals will need about 500,000 additional hours to report Surgical Site Infection (SSI), and CAUTI event data and denominator information into the system.

The structural measure we are adding for the FY 2014 payment determination will require hospitals to indicate whether they are participating in a systematic qualified clinical database for registry for General Surgery and, if so, to identify the registry. We estimate that 3,500 hospitals will spend about 5 minutes each to answer this question each year, resulting in an estimated total increase of 175 hours in terms of the total burden to hospitals each year.

We also are adding one new claims-based measure for the FY 2014 payment determination. We do not believe that this claims-based measure will create any additional burden for hospitals because it will be collected and calculated by CMS based on the Medicare FFS claims the hospitals have already submitted to CMS.

We believe that the overall burden on hospitals will be reduced to some extent by the policy we finalized in the FY 2011 IPPS/LTCH PPS final rule to retire two measures (PN–2 and PN–7) beginning with the FY 2014 payment determination. Burden will be further reduced because, in this final rule, beginning with the FY 2014 payment determination, we are retiring or suspending data collection for eight additional measures (AMI–1 Aspirin at Arrival, AMI–3 ACE/ARB, AMI–4 Smoking Cessation, AMI–5 Beta-Blocker at Discharge, HF–4 Smoking Cessation, PN–4 Smoking Cessation, PN–5c Antibiotic within 6 Hours of Arrival and SCIP Inf-6 Appropriate Hair Removal), beginning with discharges occurring on January 1, 2012. We estimate that the retirement or suspension of these measures will reduce the burden to hospitals by a total of 740,000 hours including reductions of 170,000 hours for abstracting AMI measures, 220,000 hours for abstracting PN measures, 50,000 hours for abstracting HF measures, and 300,000 hours for abstracting SCIP measures.

We also are adding two new chart-abstracted measure sets to the Hospital IQR Program for FY 2015: Stroke (eight measures) and Venous Thromboembolism (VTE) (six measures). Both measure sets are of great importance to the Medicare population, with stroke affecting about 795,000 people each year (American Stroke Association). Both stroke and VTE measures are currently collected by The Joint Commission for accreditation and certification purposes. Both measure sets use complementary data elements to our current SCIP, VTE, and AMI measure sets, thus reducing the chart-abstraction burden. The burden associated with these measure sets is the time and effort associated with collecting and submitting the additional data. We estimate that each chart-abstracted measure set will require about 1 hour to abstract. We anticipate the number of subsection (d) hospitals participating in the Hospital IQR Program to be approximately 3,500. The number of charts to be abstracted by all participating hospitals is estimated to be 180,000 per year for the Stroke measure set, and 6,000,000 per year for the VTE measure set. In total, our addition of the Stroke and VTE measure sets is estimated to increase the burden to hospitals by 6,180,000 hours per year.

We also are adding three new HAI measures to be collected via NHSN to the Hospital IQR Program for FY 2015: (1) Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia measure; (2) C. *Difficile* SIR measure; and (3) Healthcare Personnel Influenza vaccination measure. The information needed for these measures will be collected via NHSN, and, therefore, is structured to keep additional burden to a minimum because more than 4,000 hospitals in 29 States are already using NHSN to comply with State-mandated reporting. Although this will add burden to hospitals, the initial setup and acclimation to the NHSN system will have already occurred with the adoption of the CLABSI measure for the Hospital IQR Program for the FY 2013 payment determination. In addition, as mentioned above, not all hospitals will experience any additional burden since many hospitals already submit data to this system either voluntarily or as part of mandatory State reporting requirements for HAIs. The burden associated with this section is the time and effort associated with collecting and submitting the additional data. With respect to the new HAI measures for the FY 2015 payment determination, we estimate that an additional 1,500,000 burden hours per year (500,000 hours per measure) will be incurred by hospitals to report data on these measures.

We estimate that our changes to the FY 2015 Hospital IQR Program measure set will increase the collection burden to hospitals by approximately 7,680,000 hours per year.

We have stated our intention to explore mechanisms for data submission using electronic health

records (EHRs) (73 FR 48614; 74 FR 43866, 43892; 75 FR 50189). Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and 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 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 automatic collection and reporting of data through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and that at a future date, currently targeted to be FY 2015, hospitals will be able to switch solely to EHR-based reporting of data that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

4. ICRs for the Occupational Mix Adjustment to the FY 2012 Index (Hospital Wage Index Occupational Mix Survey)

Section II.D. of the preamble of the proposed rule and this final rule discusses the occupational mix adjustment to the final FY 2012 wage index. While the preamble does not contain any new ICRs, it is important to 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; however, it is currently approved under OMB control number 0938–0907, with an expiration date of February 28, 2013.

5. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.I.3. of the preamble of the proposed rule and this final rule discusses 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 is currently approved under OMB control number 0938–0573, with an expiration date of December 31, 2011.

We did not receive any public comments on this information collection requirement.

6. ICRs for the Quality Reporting Program for LTCHs

In section VII.C. of the preamble of the proposed rule and this final rule, we discuss three quality reporting measures for LTCHs for FY 2014: (1) Catheter Associated Urinary Tract Infections (CAUTI); (2) Central Line Associated Blood Stream Infection Event (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened.

As proposed, we will collect the HAI CLABSI and CAUTI quality measures through the use of the CDC/NHSN (*http://www.cdc.gov/nhsn/*). We will require that LTCH facilities report data on each patient in their facility who has been diagnosed with either a catheter associated urinary tract infection or a central line associated bloodstream infection.

The NHSN is a secure, Internet-based surveillance system which is maintained and managed by CDC. Many LTCHs already submit data to the NHSN either voluntarily or as part of mandatory State reporting requirements for HAIs. There are currently 439 certified LTCHs and, according to CDC, 80 of these LTCHs already submit HAI data to NHSN. For these LTCHs, the burden of complying with the requirements of the quality reporting program will be reduced because these LTCHs are familiar with the NHSN submission process.

We provide financial incentives to IPPS hospitals to report data regarding certain HAIs via NHSN as part of the Hospital IQR Program. We adopted the CLABSI quality measure under the Hospital IQR Program for the FY 2013 payment determination and are adopting the CAUTI measure for the FY 2014 payment determination. In addition, hospitals in 29 States are already using NHSN, and CDC supports more than 4,000 hospitals that are already using NHSN. Many LTCHs are integrated into or are part of large inpatient hospital systems. We believe that these hospital systems have gained the requisite knowledge and experience with the submission of data about HAIs via NHSN, under the Hospital IQR Program, State law, or voluntarily. Therefore, the transition to reporting HAIs via the NHSN for these LTCHs may be less burdensome.

The burden associated with these quality measures is the time and effort associated with collecting and submitting the data concerning CAUTI and CLABSI to NHSN for LTCHs that are not currently reporting such data. During the 12-month period from April 2010 to March 2011, 58 LTCHs reported CLABSI for at least one month, and the same number reported CAUTI for at least one month. For LTCHs that already submit data regarding these HAIs to NHSN, there should be little, if any, additional burden. For LTCHs who submit data to NHSN for other HAIs, but not CAUTI and CLABSI data, there may be some burden. However, we believe that this burden will be significantly decreased because these LTCHs are already enrolled in the NHSN system and are already familiar with the NHSN data submission process.

There are currently 435 LTCHs in the United States paid under the LTCH PPS. We estimate that each LTCH will submit approximately 12 NHSN submissions (6 CAUTI and 6 CLABSI) per month (144 per LTCH annually). This equates to a total of approximately 62,640 submissions of HAI data to NHSN from all LTCHs paid under the LTCH PPS per year. We estimate that each NHSN assessment will take approximately 25 minutes to complete. This time estimate consists of 10 minutes of clinical (for example, nursing time) needed to collect the clinical data and 15 minutes of clerical time necessary to enter the data into the NHSN data base. 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 to all LTCHs paid under the LTCH PPS for reporting to NHSN is 26,100 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 provider will be $1,739 and the total yearly cost to all LTCHs paid under the LTCH PPS for the

submission of CAUTI and CLABSI data to NHSN would be $756,326.[71] The aforementioned requirements are subject to the PRA and the associated burden hours will be accounted for in a revision to the information collection request currently approved as OCN 0920–0666.

With respect to the pressure ulcer measure, we will post the specification for the pressure ulcer measure on our Web site along with the specific data elements necessary to be collected by no later than January 31, 2012. We expect that the specific data items needed are part of the Continuity Assessment Record & Evaluation (CARE) data item set. We developed the CARE as required by section 5008 of the Deficit Reduction Act of 2005. In 2011, CARE underwent revisions. The revised CARE data item set now consists of a compilation of items from a comprehensive CMS standardized item library. The revised Medicare CARE data item set is intended to be used to: (1) Standardize program information on Medicare beneficiaries' acuity at discharge from acute hospitals, (2) document medical severity, functional status and other factors related to outcomes and resource utilization at admission, discharge, and interim times during post acute treatment, (3) understand the relationship between severity of illness, functional status, social support factors, and resource utilization; and (4) report quality measure data to CMS.

Because the CMS CARE pressure ulcer data item set has not previously been introduced in the LTCH setting, there will be some initial burdens associated with the introduction of this data item set. These initial costs will mainly be incurred in the training of the facility staff. However, there should be little, if any, additional education required, in regards to the collection of the data, because pressure ulcer assessment should be a vital part of good patient care and daily in-house patient chart documentation.

LTCHs participating in the LTCH Quality Reporting Program will be required to perform the CARE pressure ulcer assessment on each patient upon admission and again upon discharge. We believe that it is necessary to obtain admission and discharge pressure ulcer assessments on all patients admitted to LTCH facilities in order to obtain full and complete statistical data regarding the quality of care provided by the facility to the patients receiving care in that facility. The delivery of high quality care in the LTCH setting is imperative. We believe that collecting quality data on all patients in the LTCH setting supports our mission to insure quality care for Medicare beneficiaries. Collecting data on all patients provides the most robust and accurate reflection of quality in the LTCH setting. Accurate representation of quality provided in LTCHs is best conveyed using data related to pressure ulcers on all LTCH patients, regardless of payer, using a subset of the CARE data item set. An admission assessment is necessary in order to assess for either the presence or absence of pressure ulcers upon admission. If pressure ulcers are detected upon admission, they must be properly assessed, staged and documented. Upon discharge, an assessment is needed to determine if any worsening of the pressure ulcers occurred during the LTCH stay. If no pressure ulcers had been noted on the admission assessment, then a discharge pressure ulcer assessment would be necessary in order to assess whether the patient had developed any new pressure ulcers during the LTCH stay.

At the time of publication of this final rule, CMS has not completed development of the information collection instrument that LTCHs would have to submit to comply with the reporting requirements regarding the CARE pressure ulcer assessment. Because the CARE data item set is still undergoing development, we cannot assign a complete burden estimate at this time. Once the CARE data item set has been completed and finalized, we will publish the required 60-day and 30-day **Federal Register** notices to solicit public comments on this data reporting method and to announce the submission of the information collection request to OMB for its review and approval.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 476

Health care, Health professional, Health record, Peer Review Organization (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this final rule, the Centers for Medicare & Medicaid Services confirms the interim rule published March 14, 2011, at 76 FR 13515, is confirmed as final without change and is amending 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 Public Law 106–113 (113 Stat. 1501A–332).

■ 2. Section 412.23 is amended by—

■ a. In paragraph (e)(3)(i), removing the cross-reference ''paragraph (e)(3)(ii) through (e)(3)(iv) of this section'' and adding in its place the cross-reference ''paragraphs (e)(3)(ii) through (v) of this section''.

■ b. Revising paragraph (e)(3)(iv).

■ c. Adding paragraph (e)(3)(v).

■ d. Adding paragraph (e)(8).

The revision and additions read as follows:

§ 412.23 Excluded hospitals: Classifications.

* * * * *

(e) * * *

(3) * * *

(iv) If a hospital seeks exclusion from the inpatient prospective payment system as a long-term care hospital and a change of ownership (as described in § 489.18 of this chapter) occurs within the period of at least 5 months of the 6-month period preceding its petition for long-term care hospital status, the hospital may be excluded from the inpatient prospective payment system as a long-term care hospital for the next cost reporting period if, for the period of at least 5 months of the 6 months immediately preceding the start of the cost reporting period for which the hospital is seeking exclusion from the inpatient prospective payment system as a long-term care hospital (including time before the change of ownership), the hospital has met the required average length of stay, has continuously operated as a hospital, and has continuously participated as a hospital in Medicare.

(v) For periods beginning on or after October 1, 2011, a hospital that is excluded from the inpatient prospective payment system as a long-term care hospital that plans to undergo a change of ownership (as described in § 489.18 of this chapter) must notify its fiscal intermediary or MAC within 30 days of the effective date of such change of

[71] Nursing Time—24 hours @ $41.59 per hour = $998.16; $998.16 × 435 LTCHs = $434,200.

Admin Time—36 hours @ $20.57 per hour = $740.52; $740.52 × 435 LTCHs = $322,126.

TOTAL = $434,200 + $322,126 = $756,326.

ownership, as specified in § 424.516(e) of this subchapter. The hospital will continue to be excluded from the inpatient prospective payment system as a long-term care hospital for the cost reporting period following the change of ownership only if, for the period of at least 5 months of the 6 months immediately preceding the change of ownership, the hospital meets the required average length of stay (calculated in accordance with paragraph (e)(3)(i) of this section).

* * * * *

(8) *Application of LTCH moratorium on the increase in beds at section 114(d)(1)(B) of Public Law 110–173 to LTCHs and LTCH satellite facilities established or classified as such under section 114(d)(2) of Public Law 110–173.* Effective for the period beginning October 1, 2011, and ending December 28, 2012, for long-term care hospitals and long-term care hospital satellite facilities established under paragraph (e)(6)(ii) of this section for the period beginning December 29, 2007, and ending September 30, 2011, the moratorium under paragraph (e)(7) of this section applies and the number of Medicare-certified beds must not be increased beyond the number of beds that were certified by Medicare at the long-term care hospital or the long-term care hospital satellite facility as of October 1, 2011.

* * * * *

■ 3. Section 412.64 is amended by—

■ a. Adding paragraph (d)(1)(iv).

■ b. Revising paragraph (h)(4) introductory text.

The addition and revision read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(iv) For fiscal year 2012, the percentage increase in the market basket index less a multifactor productivity adjustment (as determined by CMS) and less 0.1 percentage point for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas.

* * * * *

(h) * * *

(4) For discharges on or after October 1, 2004 and before September 30, 2013, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology:

* * * * *

■ 4. Section 412.105 is amended by revising paragraph (b)(4) to read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(b) * * *

(4) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, ancillary labor/delivery services, or inpatient hospice services;

* * * * *

■ 5. Section 412.106 is amended by revising paragraph (a)(1)(ii)(B) to read as follows:

§ 412.106 Special treatment: Hospitals that service a disproportionate share of low income patients.

(a) * * *

(1) * * *

(ii) * * *

(B) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or inpatient hospice services;

* * * * *

■ 6. Section 412.140 is added to Subpart H to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Review (IQR) Program.

(a) *Participation in the Hospital IQR Program.* In order to participate in the Hospital IQR Program, a section 1886(d) of the hospital must–

(1) Register on QualityNet.org, before it begins to report data;

(2) Identify and register a QualityNet Administrator as part of the registration process under paragraph (a)(1) of this section; and

(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 (CNN).

(i) A hospital that would like to participate in the program for the first time (and to which paragraph (a)(3)(ii) of this section does not apply), or that previously withdrew from the program and would now like to participate again, must submit to CMS a completed Notice of Participation Form by December 31 of the fiscal year preceding the fiscal year in which it wishes to participate.

(ii) A hospital that has received a new CCN and would like to participate in the program must submit a completed Notice of Participation Form to CMS no later than 180 days from the date identified as the open date on the approved CMS Quality Improvement Evaluation System (QIES).

(b) *Withdrawal from the Hospital IQR Program.* CMS will accept Hospital IQR Program withdrawal forms from hospitals on or before August 15 of the fiscal year preceding the fiscal year for which a Hospital IQR payment determination will be made.

(c) *Submission and validation of Hospital IQR Program data.* (1) *General rule.* Except as provided in paragraph (c)(2) of this section, subsection (d) hospitals that participate in the Hospital IQR Program must submit to CMS data on measures selected under section 1886(b)(3)(B)(viii) of the Act in a form and manner, and at a time, specified by CMS. A hospital must begin submitting data on the first day of the quarter following the date that the hospital submits a completed Notice of Participation form under paragraph (a)(3) of this section.

(2) *Exception.* Upon request by a hospital, CMS may grant an extension or waiver of one or more data submission deadlines in the event of extraordinary circumstances beyond the control of the hospital. Specific requirements for submission of a request for an extension or waiver are available onQualityNet.org.

(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.

(2) A hospital meets the validation requirement with respect to a fiscal year if it achieves a 75-percent score, as determined by CMS.

(e) *Reconsiderations and appeals of Hospital IQR Program decisions.* (1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital IQR Program for a particular fiscal year. Except as provided in paragraph (c)(2) of this section, a hospital must submit a reconsideration request to CMS no later than 30 days from the date identified on the Hospital Inpatient Quality Reporting Program Annual

Payment Update Notification Letter provided to the hospital.

(2) A reconsideration request must contain the following information:

(i) The hospital's CMS Certification Number (CCN);

(ii) The name of the hospital;

(iii) Contact information for the hospital's chief executive officer and QualityNet system administrator, including each individual's name, e-mail address, telephone number, and physical mailing address;

(iv) A summary of the reason(s), as set forth in the Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter, that CMS concluded the hospital did not meet the requirements of the Hospital IQR Program;

(v) A detailed explanation of why the hospital believes that it complied with the requirements of the Hospital IQR Program for the applicable fiscal year;

(vi) Any evidence that supports the hospital's reconsideration request, including copies of patient charts, e-mails and other documents; and

(vii) If the hospital has requested reconsideration on the basis that CMS concluded it did not meet the validation requirement set forth in paragraph (d) of this section, the reconsideration request must contain the following additional information:

(A) A copy of each patient chart that the hospital timely submitted to CMS or its contractor in response to a request made under paragraph (d)(1) of this section; and

(B) A detailed explanation identifying which data the hospital believes was improperly validated by CMS and why the hospital believes that such data are correct.

(3) A hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under Part 405, Subpart R of this chapter.

■ 7. Section 412.211 is amended by adding paragraph (c)(4) to read as follows:

§ 412.211 Puerto Rico rates for Federal fiscal year 2004 and subsequent fiscal years.

* * * * *

(c) * * *

(4) For fiscal year 2012 and subsequent fiscal years, the applicable percentage increase specified in § 412.64(d).

* * * * *

■ 8. Section 412.230 is amended by adding paragraph (d)(5) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

* * * * *

(d) * * *

(5) *Single hospital MSA exception.* The requirements of paragraph (d)(1)(iii) of this section do not apply if a hospital is the single hospital in its MSA that is paid under subpart D of this Part.

■ 9. Section 412.523 is amended by adding paragraphs (c)(3)(viii) and (d)(4) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(viii) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2011, and ending September 30, 2012.* The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2011, and ending September 30, 2012, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.8 percent. The standard Federal rate is adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

(d) * * *

(4) *Changes to the adjustment for area wage levels.* Beginning in FY 2012, CMS adjusts the standard Federal rate by a factor that accounts for the estimated effect of any adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments.

* * * * *

■ 10. Section 412.525 is amended by revising paragraph (c) to read as follows:

§ 412.525 Adjustments to the Federal prospective payment.

* * * * *

(c) *Adjustments for area wage levels.* (1) The labor portion of a long-term care hospital's Federal prospective payment is adjusted to account for geographical differences in the area wage levels using an appropriate wage index (established by CMS), which reflects the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined in accordance with the definitions set forth in § 412.503) of the hospital compared to the national average level of hospital wages and wage-related costs. The appropriate wage index that is established by CMS is updated annually. The labor portion of a long-term care hospital's Federal prospective payment is established by CMS and is updated annually.

(2) Beginning in FY 2012, any adjustments or updates to the area wage level adjustment under this paragraph (c) will be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 11. The authority citation for Part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–133 (113 Stat. 1501A–332).

■ 12. Section 413.70 is amended by—

■ a. Revising paragraph (b)(5)(i)(B).

■ b. Adding paragraph (b)(5)(i)(C).

The revision and addition read as follows:

§ 413.70 Payment for services of a CAH.

* * * * *

(b) * * *

(5) * * *

(i) * * *

(B) Effective for cost reporting periods beginning on or after January 1, 2004 and on or before September 30, 2011, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity.

(C) Effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. If there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services

furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH.

* * * * *

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

■ 13. The authority citation for Part 476 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

■ 14. Section 476.78 is amended by—

■ a. In paragraph (a), removing the reference ''§ 466.71'' and adding in its place the reference ''§ 476.71''.

■ b. Revising paragraph (b).

The revision reads as follows:

§ 476.78 Responsibilities of health care facilities.

* * * * *

(b) *Cooperation with QIOs.* Health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO review.

(1) Providers must allocate adequate space to the QIO for its conduct of review at the times the QIO is conducting review.

(2) Providers must provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. QIOs pay providers paid under the prospective payment system for the costs of photocopying records requested by the QIO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first class postage for mailing the records to the QIO. When the QIO does postadmission, preprocedure review, the provider must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis. Providers must—

(i) Photocopy and deliver to the QIO all required information within 30 calendar days of a request;

(ii) Deliver all required medical information to the QIO within 21 calendar days from the date of the request in those situations where a potential ''serious reportable event'' has been identified or where other circumstances as deemed by the QIO warrant earlier receipt of all required medical information. For purposes of this paragraph, a serious reportable event is defined as a preventable, serious, and unambiguous adverse event that should never occur.

(3) Providers must inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to QIO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under § 411.402(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the provider has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the QIO within 3 working days.

(5) Providers must assure, in accordance with the provisions of their agreements with the QIO, that each case subject to preadmission review has been reviewed and approved by the QIO before admission to the hospital or a timely request has been made for QIO review.

(6)(i) Providers must agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the QIO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a provider, in accordance with its agreement with a QIO, makes a timely request for preadmission review and the QIO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Hospitals must agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the QIO.

* * * * *

(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: July 21, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 27, 2011.

Kathleen Sebelius,

Secretary.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, and Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2011

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2012 for acute care hospitals. We also are setting forth the rate-of-increase percentages for updating the target amounts for certain hospitals excluded from the IPPS for FY 2012. 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 finalrule, we are finalizing 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, 2011.

In addition, we are setting forth a description of the methods and data we used to determine the standard Federal rate that will be applicable to Medicare LTCHs for FY 2012.

In general, except for SCHs, MDHs, and hospitals located in Puerto Rico, 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 the FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically have been paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. 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 from the end of FY 2011 to the end of FY 2012, by striking ''October 1, 2011'' and inserting ''October 1, 2012''. Section 3124(b) of the Affordable Care Act also made conforming amendments to sections 1886(b)(3)(D) and 1886(b)(3)(D)(iv)

of the Act. Section 3124(b)(2) of the Affordable Care Act also amended section 13501(e)(2) of OBRA 1993 to extend the provision permitting hospitals to decline reclassification as an MDH through FY 2012. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital-specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor.

For hospitals located in Puerto Rico, the payment per discharge is based on the sum of 25 percent of an updated Puerto Rico-specific rate based on average costs per case of Puerto Rico hospitals for the base year and 75 percent of the Federal national rate. (We refer readers to section II.D.3. of this Addendum for a complete description.)

As discussed below in section II. of this Addendum, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2012. In section III. of this Addendum, we discuss our policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2012. In section IV. of this Addendum, we are setting forth our changes for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2012. In section V. of this Addendum, we are making changes in the determination of the standard Federal rate for LTCHs under the LTCH PPS for FY 2012. The tables to which we refer in the preamble of this final rule are listed in section VI. of this Addendum and are available via the Internet.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2012

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 at § 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 at §§ 412.211 and 412.212. Below we discuss the factors used for determining the prospective payment rates for FY 2012.

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.
- Updates of 1.9 percent for all areas (that is, the FY 2012 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 1.0 percentage point for multifactor productivity and less 0.1 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 update is −0.1 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 1.0 percentage point for multifactor productivity, and less 0.1 percentage point).
- An update of 1.9 percent to the Puerto Rico-specific standardized amount (that is, the FY 2012 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 1.0 percentage point for multifactor productivity and less 0.1 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 in 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 in section 1886(d)(8)(D) of the Act, by removing the FY 2011 budget neutrality factor and applying a revised factor.
- An adjustment to ensure the effects of the rural community hospital demonstration 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 for an additional 5 years are budget neutral, as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment in light of the court's decision in *Cape Cod* v. *Sebelius,* (630 F.3d 203 (DC Cir. 2011)).
- An adjustment to remove the FY 2011 outlier offset and apply an offset for FY 2012, as provided for in section 1886(d)(3)(B) of the Act.
- As discussed below and in section II.D. of the preamble to this final rule, an adjustment to meet the requirements of sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90 to adjust the standardized amounts to offset the estimated amount of the increase in aggregate payments (including interest) due to the effect of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 and FY 2009.

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 2011, for FY 2012, we are continuing to apply the rural floor budget neutrality adjustment to hospital wage indices rather than the standardized amount. Consistent with section 3141 of the Affordable Care Act, instead of applying a State level rural floor budget neutrality adjustment on the wage index, we are applying a uniform, national budget neutrality adjustment to the FY 2012 wage index for the rural floor. We note that, as discussed in section III.F.2. of the preamble of this final rule, we are extending the imputed floor for 2 more years. Therefore, we are continuing to apply the imputed floor budget neutrality adjustment to the wage indices. Thus, the imputed floor is reflected in the final FY 2012 wage index.

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. For Puerto Rico hospitals, the Puerto Rico-specific standardized amount is based on per discharge averages of adjusted target amounts from a base period (section 1886(d)(9)(B)(i) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d)(9) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS. The September 1, 1987 final rule (52 FR 33043 and 33066) contains a detailed explanation of how the target amounts were determined and how they are used in computing the Puerto Rico rates.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

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 2012, we are continuing to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2011, for the national standardized amounts and 62.1 percent for the Puerto Rico-specific standardized amount. Consistent with section 1886(d)(3)(E) of the Act, we are applying 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 applying the wage index to a labor-related share of 68.8 percent of the national standardized amount. For FY 2012, all Puerto Rico hospitals have a wage index less than 1.0. Therefore, the national labor-related share will always be 62 percent because the wage index for all Puerto Rico hospitals is less than 1.0.

For hospitals located in Puerto Rico, we are applying a labor-related share of 62.1 percent if its Puerto Rico-specific wage index is greater than 1.0000. For hospitals located in Puerto Rico whose Puerto-Rico specific wage index values are less than or equal to 1.0000, we are applying a labor share of 62 percent.

The standardized amounts for operating costs appear in Table 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this final rule and are available via 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 calculating the FY 2012 national and Puerto Rico standardized amounts 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. As discussed in section IV.K.3. of the preamble of this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are reducing the FY 2012 applicable percentage increase (which is based on the second quarter 2011 forecast of the FY 2006-based IPPS market basket) by the multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.0 percent, which is calculated based on IHS Global Insight, Inc.'s (IGI's) second quarter 2011 forecast. In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are further updating the standardized amount for FY 2012 by the estimated market basket percentage increase less 0.1 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) 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 2011 second quarter forecast of the hospital market basket increase (as discussed in Appendix B of this final rule), the most recent forecast of the hospital market basket increase for FY 2012 is 3.0 percent. Thus, for FY 2012, the update to the average standardized amount is 1.9 percent for hospitals in all areas (that is, the FY 2012 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 1.0 percentage point for multifactor productivity and less 0.1 percentage point). For hospitals that do not submit quality data pursuant to section 1886(b)(3)(B)(viii), the estimated update to the operating standardized amount is −0.1 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit data under the IQR program, less an adjustment of 1.0 percentage point for multifactor productivity, and less 0.1 percentage point) The standardized amounts in Tables 1A through 1C that are published in section VI. of this Addendum and 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 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 finalizing an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.9 percent.

Although the update factors for FY 2012 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 2012 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our proposed recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this final rule.

4. Other Adjustments to the Average Standardized Amount

As in the past, we are adjusting the FY 2012 standardized amount to remove the effects of the FY 2011 geographic reclassifications and outlier payments before applying the FY 2012 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2012 payment policies.

We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG 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 DRG classifications, recalibration of the DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

Consistent with our methodology established in the FY 2011 IPPS/LTCH 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. In order to account for these Medicare Advantage IME payments in determining the budget neutrality adjustments for this final rule, we identified Medicare Advantage claims from IPPS teaching hospitals in the MedPAR data. Consistent with our methodology established in the FY 2011 IPPS/LTCH final rule (75 FR 50422–50423), we first searched the MedPAR file for all claims with an IME payment greater than zero. We then filtered these claims for a subset of claims with a GHO Paid indicator with a value of ''1'' or if the IME payment field was equal to the DRG payment field. The GHO Paid indicator with a value of ''1'' in the MedPAR file indicates that the claim was paid by a Medicare Advantage plan (other than the IPPS IME payment specified at § 412.105(g)). For these Medicare Advantage claims from IPPS teaching hospitals, we computed a transfer-adjusted CMI by provider based on the FY 2011 MS–DRG GROUPER Version 28.0 assignment and relative weights. We also computed a transfer-adjusted CMI for these Medicare

Advantage claims from IPPS teaching hospitals based on the FY 2012 MS–DRG GROUPER Version 29.0 assignments and relative weights. These transfer-adjusted CMIs (and corresponding case counts) were used to calculate an IME teaching add-on payment in accordance with § 412.105(g). The total Medicare Advantage IME payment amount was then added to the total Federal payment amount for each provider (where applicable) in order to account for the Medicare Advantage IME payment in determining the budget neutrality adjustments. We note that we did not include Medicare Advantage IME claims when estimating outlier payments for providers because Medicare Advantage claims are not eligible for outlier payments under the IPPS.

Also, for this 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).

Additionally, consistent with our methodology established in the FY 2011 IPPS/LTCH final rule (75 FR 50422–50423), we examined the MedPAR and removed pharmacy charges for antihemophilic 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.

Comment: One commenter noted that it is still likely that CMS is including charges for anti-hemophilic blood factor (which are paid separately under the IPPS) for the budget neutrality adjustments. The commenter explained that the majority of patients receiving blood clotting drugs have a pharmacy indicator of ''5,'' which denotes ''general drugs and/or IV therapy and blood clotting drugs.'' The commenter searched the MedPAR file and found 48,494 claims with a pharmacy indicator of ''5'' and 715 claims with a pharmacy indicator of ''3.'' Based on this analysis the commenter concluded that a majority of anti hemophilic blood factor claims contain an indicator of ''5'' rather than ''3.'' The commenter requested that CMS develop a method to identify and separate the charges for blood clothing drugs from other pharmacy charges for blood factor claims with an indicator of ''5.'' The commenter also stated that, alternatively, CMS could remove all pharmacy charges for code ''5'' claims that are projected to qualify as outliers under the FY 2012 proposed rule in situations where no outlier payments for FY 2010 were shown on the claims, but the patients would have qualified as outliers in FY 2010 based on the MedPAR claims for covered charges (which include charges for anti-hemophilic drugs). The commenter explained that anti-hemophilic blood factor are typically included in the covered charges but are excluded by the PRICER program from the charges used to pay the outlier. In many of these cases an outlier payment would have been made if the covered charges were used but once the PRICER program excluded pharmacy charges for blood factor claims with an indicator of ''5'', no outlier payment was made.

Response: We appreciate the commenter's insights and are studying methods to uniquely identify anti-hemophilic blood factor charges in our MedPAR claims database with an indicator of ''5.'' It is possible that a change would be required to the MedPAR file, which could delay implementation, depending on the time needed to adopt the systems change. Additionally, we thank the commenter for providing an alternative methodology to identify anti-hemophilic blood factor charges with an indicator of ''5.'' However, we are not able to determine if the charges the commenter is excluding are only charges related to anti-hemophilic blood factor, and we are concerned that this method could exclude other charges that are not related to these items. Therefore, we prefer to develop a methodology that is more specific so that charges that are not related to antihemophilic blood factor are not excluded.

a. Recalibration of DRG 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. of the preamble of this final rule, we normalized the recalibrated DRG weights by an adjustment factor so that the average case weight after recalibration is equal to the average case weight prior to recalibration. However, equating the average case weight after recalibration to the average case 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 weight. Therefore, as we have done in past years, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0, 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 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 2012, we are adjusting 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.C. of the preamble of this final rule.

For FY 2012, to comply with the requirement that 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 2010 discharge data to simulate payments and compared aggregate payments using the FY 2011 labor-related share percentages, the FY 2011 relative weights, and the FY 2011 pre-reclassified wage data to aggregate payments using the FY 2011 labor-related share percentages, the FY 2012 relative weights, and the FY 2011 pre-reclassified wage data. Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.997903. As discussed in section IV. of this Addendum, we also apply the DRG reclassification and recalibration budget neutrality factor of 0.997903 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2011.

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 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 DRG reclassification and recalibration budget neutrality factor of 0.997903 by using the same methodology described above to determine the DRG reclassification and recalibration budget neutrality factor for the Puerto Rico standardized amount and hospital-specific rates. Secondly, to compute a budget neutrality factor for wage index and labor-related share changes, we used FY 2010 discharge data to simulate payments and compared aggregate payments using FY 2012 relative weights and FY 2011 pre-reclassified wage indices, and applied the FY 2011 labor-related share of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0) to aggregate payments using the FY 2012 relative weights and the FY 2012 pre-reclassified wage indices, and applied the labor-related share for FY 2012 of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0). In addition, we applied the 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 2011 to FY 2012. By applying this methodology, we determined a budget neutrality factor of

1.000558 for changes to the wage index. Finally, we multiplied the DRG reclassification and recalibration budget neutrality factor of 0.997903 (derived in the first step) by the budget neutrality factor of 1.000558 for changes to the wage index (derived in the second step) to determine the DRG reclassification and recalibration and updated wage index budget neutrality factor of 0.99846.

b. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that, effective with discharges occurring on or after October 1, 1988, 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 under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account ''in applying any budget neutrality adjustment with respect to such index'' under section 1886(d)(8)(D) of the Act. To calculate the budget neutrality factor for FY 2012, we used FY 2010 discharge data to simulate payments and compared total IPPS payments with FY 2012 relative weights, FY 2012 labor-related share percentages, and FY 2012 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act to total IPPS payments with FY 2012 relative weights, FY 2012 labor-related share percentages, and FY 2012 wage data after such reclassifications. Based on these simulations, we calculated an adjustment factor of 0.991493 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The FY 2012 budget neutrality adjustment factor is applied to the standardized amount after removing the effects of the FY 2011 budget neutrality adjustment factor. We note that the FY 2012 budget neutrality adjustment reflects FY 2012 wage index reclassifications approved by the MGCRB or the Administrator. We note that, for this final rule, as discussed in section III.B. of the preamble to this final rule, section 3137(c) of the Affordable Care Act resulted in some additional hospitals receiving reclassifications, or some hospitals receiving reclassifications to a different area. These reclassifications are included in the calculation of reclassification budget neutrality.

c. Rural Floor and Imputed Floor Budget Neutrality Adjustment

As noted above, as discussed in section III.F.2. of the preamble of this final rule, we are extending the imputed floor for 2 more years. 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. As discussed in section III.F. of the preamble of this final rule, consistent with section 3141 of the Affordable Care Act, the budget neutrality adjustment for the rural and imputed floors is a national adjustment to the wage index.

As discussed in section III.F.2. of the preamble of this final rule, for the FY 2012 wage index, there is one new hospital in rural Puerto Rico when previously there were none. Therefore, for FY 2012, we are calculating a national rural Puerto Rico wage index (used to adjust the labor-related share of the national standardized amount for hospitals 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 in Puerto Rico that receive 25 percent of the Puerto Rico-specific standardized amount). As the new rural Puerto Rico hospital 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 on the computation of the rural Puerto Rico wage index can be found in section III.G. of the preamble of this final rule. In past fiscal years, when there was no rural Puerto Rico wage index, we applied the national rural floor budget neutrality wage index factor to the national wage indices used to adjust the labor-related share for the national standardized amount (including the national Puerto Rico wage indexes) but did not apply this factor to the Puerto Rico-specific wage indices. We did not apply the national rural floor budget neutrality wage index factor to the Puerto Rico-specific wage indices (nor did we compute a Puerto Rico-specific rural floor budget neutrality wage index factor) because there were no rural hospitals in Puerto Rico. As mentioned above, for FY 2012, there is now one rural Puerto Rico hospital and, therefore, it is necessary to compute and apply a Puerto Rico-specific rural floor budget neutrality wage index factor (in addition to the national factor).

To calculate the national rural floor and imputed floor budget neutrality factor and Puerto Rico-specific rural floor budget neutrality adjustment factor, we used FY 2010 discharge data and FY 2012 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 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 national rural budget neutrality adjustment factor of 0.991007 and the Puerto Rico-specific budget neutrality adjustment factor of 0.989417. The national adjustment was applied to the national wage indices to produce a national rural floor budget neutral wage index and the Puerto Rico-specific adjustment was then applied to the Puerto Rico-specific wage indices to produce a Puerto Rico-specific rural floor budget neutral wage index.

d. Adjustment in Light of Court Decision in *Cape Cod* v. *Sebelius*

In the FY 2012 IPPS/LTCH PPs proposed rule (76 FR 26022), we proposed a 1.1 percent adjustment to the standardized amount in recognition of the decision of *Cape Cod* v. *Sebelius* (630 F.3d 203 (DC Cir. 2011)) (hereafter referred to as ''*Cape Cod*''). However, we emphasized that remand proceedings in that case were not complete at that time and that the proposal reflected the timing of the development of the proposed rule and not a final decision as to how the remand will proceed. In *Cape Cod,* the plaintiff hospitals challenged the rural floor budget neutrality adjustments for FY 2007 and FY 2008. In its opinion, the DC Circuit Court found that section 4410 of the Balanced Budget Act of 1997 (BBA) Public Law 105–33, which authorized both the rural floor and rural floor budget neutrality, would not permit CMS to ignore prior year errors in calculating rural floor budget neutrality adjustments. The case was remanded to CMS for further proceedings consistent with the DC Circuit Court's opinion.

While *Cape Cod* involved only FYs 2007 and 2008, in the FY 2012 proposed rule we stated that the decision may have implications for FY 2012 payment rates, depending on the ultimate result of the remand proceedings. In light of that opinion and the timing of the rulemaking development process, we proposed to restore to the FY 2012 standardized amount the offset for the rural floor and imputed floor on the standardized amount over FY 1998 through 2006. We stated by making this proposal for FY 2012, all affected parties would have an opportunity to consider and comment on the proposed adjustment. Given that the court had remanded the case to the Secretary for FYs 2007 and 2008 and those remand proceedings were not yet completed at the time of issuance of the proposed rule, we indicated that the final rule might adopt a different approach, depending on public comments or developments in the remand proceedings.

For purposes of the proposed rule, to assess the overall impact of applying the rural floor budget neutrality adjustment to the standardized amount for the years between FY 1998 and FY 2006, we remodeled the recalibration/wage index budget neutrality factor for the years at issue (for which data were available), excluding the effect of the rural floor adjustment. For example, to compute the revised recalibration/wage index budget neutrality factor for FY 2000, we compared the FY 1999 pre-reclassified wage data with no rural floor to FY 2000 pre-reclassified wage data with no rural floor. We then compared the revised factor to the wage/recalibration budget neutrality factor derived under the original modeling logic; that is, where the current year's pre-reclassified wage data had a rural floor applied. The percent change in these

two factors was then calculated for each remodeled year.

Remodeled years from FY 1998 to FY 2004 showed an approximate 0.1 percentage point increase between the factors for each year. This increase results in a total of 0.7 percentage point, which we proposed to return to the standardized amount in setting the FY 2012 IPPS rates. Beginning with FY 2005 through FY 2006, the number of States for which a floor wage index was available was extended via the imputed floor policy. With additional States receiving increases in payment due to the application of the imputed floor, we estimated the combined effects of the rural and imputed floor to be approximately 0.2 percentage point per year. This resulted in a total of 0.4 percentage point, which we proposed to return to the standardized amount in setting the FY 2012 IPPS rates. Therefore, to remove the effects of the rural floor from the standardized amount for FY 1998 through FY 2006, we proposed a one-time adjustment of 1.1 percentage points, which increases the standardized amount (0.7 percentage point plus 0.4 percentage point for a factor of 1.011). We noted that, in the FY 2008 IPPS final rule with comment period, we applied a one-time adjustment of 1.002214 to the FY 2008 standardized amount to address a single year transition (from FY 2007 to FY 2008) to a noncumulative system of the rural floor budget neutrality adjustment. The adjustment of 1.002214 to the FY 2008 standardized amount reflected the increase to the rates to remove the effects of the rural floor budget neutrality adjustment from FY 2007. Because this 1.002214 factor remains on the rate, we did not include an adjustment for FY 2007 in our calculation above.

Comment: Commenters supported CMS' proposal to provide a 1.1 percent adjustment in setting FY 2012 IPPS rates in light of the Court's decision in *Cape Cod Hospital* vs. *Sebelius.* Several commenters requested that CMS provide complete explanations of the methodologies and data used in the calculation of the 1.1 and 0.9 percent adjustments to the standardized amount and hospital-specific rate, respectively, for FYs 1998 through 2006. The commenters suggested that such information would allow them to verify the adjustment. These commenters, however, did not propose an adjustment different from the 1.1 percent included in the FY 2012 proposed rule.

Response: In response to these commenters' comments, we are providing more detail on how we calculated the one-time adjustment for purposes of determining the FY 2012 IPPS rates. All of the data files discussed in this response are available to the public for download at *http://www.cms.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage.*

We first estimated the percentage by which the budget neutrality factors for wage and recalibration differed due to applying a cumulative budget rural floor for FYs 1998 through FY 2006. In calculating the original wage and recalibration budget neutrality factors, we simulated payments with the prior year's pre-reclassified wage data that had no rural floor applied and prior year DRG assignments and weights. We then simulated payments with the current year's pre reclassified wage data with a rural floor applied and new DRG assignments and weights. These two simulations were compared against each other. The revised modeling approach, which was instituted and described in the FY 2008 IPPS final rule with comment period, calculates the wage and recalibration budget neutrality factor by simulating payments with the prior year pre reclassified wage data with no rural floor applied and prior year DRG assignments and weights and comparing those to simulated payments with the current year's pre-reclassified wage data with no rural floor applied and new DRG assignments and weights.

To estimate the percentage contribution of the rural floor to the wage and recalibration budget neutrality, we reconstructed payment data and budget neutrality models for the years involved in this case and then applied both the original and revised budget neutrality calculation methodology within the model. Some fiscal years (for example, FY 1998, FY 2001, and FY 2005) were more challenging to model than other fiscal years because multiple statutory changes in those years led to a more complicated payment structure. Each year, impact files are prepared to analyze the payment impact of policies and payment changes put forth in the IPPS final rules and contain the variables needed to simulate payments within each year. These impact files did not hold a wage index variable that reflected the ''new'' pre-reclassified wage data with no floor applied. From FY 2003 forward, we reconstructed pre reclassified wage index values with and without a floor applied using the wage and hour data files. For years prior to FY 2003, the wage and hour data files were not available so we set the wage index from the standardization file as the pre reclassified no floor wage index. Standardization files are prepared each year in conjunction with each final rule and contain pre-reclassified, pre-floor wage index values for use in the process of recalibrating the DRG relative weights. Due to the time constraints with preparing the final rule each year, the wage index values contained in the standardization files are typically prepared as soon as there is wage data available and would reflect a pre-reclassified, pre-floor wage index value. Although they may not reflect all corrections and edits to the wage data that occurred in a particular year, the majority of wage index values contained in these files should match the correct pre-reclassified, pre-floor wage index values. Therefore, we believe these files are sufficient to approximate the payment effects of the rural floor policy. To establish a rural floor for each State, we used the wage index values for providers physically located in the rural area for their States. We then compared each provider's pre-reclassified no floor wage index to the rural floor; if the pre-reclassified no floor wage index was lower, the provider's wage index value was set equal to its State rural floor wage index. This established a pre-reclassified wage index with the rural floor.

For FY 2003, FY 2004, and FY 2006, we reconstructed pre-reclassified wage index values with and without a rural floor using the wage data files. Because the wage data files typically reflect the final wage data for the year and contain the most recent updates (minor wage data updates can occur throughout the year if there were mistakes in the data on the part of the provider and/or CMS), these files produced slightly different national average hourly wage values than the values published in the **Federal Register** for the IPPS final rules. Again, the majority of wage index values contained in these files should match the correct pre-reclassified, pre-floor wage index values. Therefore, we believe these files are sufficient to approximate the payment effects of the rural floor policy. We followed the same steps that we took for fiscal years prior to FY 2003 in building pre-reclassified with floor wage index values using the pre-floor wage index values for the rural providers to set the rural floors. Once the ''with'' and ''without'' rural floor wage index variables were constructed, they were merged into the impact files. Using payment simulation programs and rates from the historical budget neutrality libraries, we were able to estimate the effect of the rural floor policy for FY 1999, FY 2000, FY 2002, FY 2003, FY 2004, and FY 2006. We used these resulting estimates to assume a rural floor effect for the years we were unable to remodel in full because of the complexity of the payment structure in those years as noted above, that is, FY 1998, FY 2001, and FY 2005.

For each separate fiscal year remodeled, we simulated payments with the prior year pre-reclassified wage data with no rural floor applied and prior year DRG assignments and weights. We compared these to simulated payments with the current year's pre-reclassified wage data with no rural floor applied (constructed as described in the preceding paragraph) and new DRG assignments and weights. For example, for FY 2000, we compared the FY 1999 pre-reclassified wage data with no rural floor to FY 2000 pre-reclassified wage data with no rural floor. This produced a wage and recalibration budget neutrality factor that did not carry any rural floor effects. Using the same data set, we then repeated the original calculation methodology that retained prior years' rural floor budget neutrality on the standardized amount; that is, we simulated payments with the prior year pre reclassified wage data with no floor applied and prior year DRG assignments and weights and then compared them to simulated payments with the new year's pre reclassified wage data with floor applied (constructed as described in the preceding paragraph) and new DRG assignments and weights. We then calculated the percent change between the resulting budget neutrality factors to determine the percent contribution of the rural floor to the budget neutrality adjustment. The ''original'' methodology under which the rural floor was included in the wage and recalibration budget neutrality calculation was repeated on the data set(s) used for this estimate rather than using the actual wage and recalibration factors carried on the rates in order to limit the percent change between the two numbers solely to the application of the rural floor and to prevent introducing differences that would be due to data shifts between the original files and the ones used for this estimate.

Remodeled budget neutrality	Original budget neutrality method with rural floor included	Revised budget neutrality method excluding rural floor	Percent change between estimated budget neutrality factors (percent)
FY 1999	0.999053	0.999666	0.10
FY 2000	1.007418	1.008316	0.10
FY 2002	0.996092	0.997134	0.10
FY 2003	0.993478	0.994443	0.10
FY 2004	1.003011	1.003932	0.10
FY 2006	1.001375	1.003103	0.20

We note that there is no difference between applying the cumulative and non-cumulative rural floor budget neutrality methodology in FY 1998 because there are no prior year payments to FY 1998 where the rural floor was applied. The first year in which there is an impact of the cumulative methodology is FY 1999, which carries forward the budget neutrality adjustment made in FY 1998. The only significant change in rural floor wage index policy (during the FYs 1999 through 2006) happened in FY 2005 when the imputed floor policy was established. The imputed floor policy provided a higher wage index to hospitals in States that have no rural areas and increases the impact of the rural floor on the budget neutrality calculation. In all the years we modeled through and including FY 2004, the percentage change in the wage and recalibration budget neutrality showed a 0.1 percent effect for the rural floor within each year. For FY 2006 and FY 2007, the estimate for the rural floor showed a 0.2 percent effect. Therefore, we assume that, similar to FY 2006, FY 2005 would also show a 0.2 percent effect because that was the year the imputed floor was first implemented. We further assume that any year prior to FY 2004 for which budget neutrality was not remodeled (that is, FY 1998 and FY 2001) would show a 0.1 percent effect due to the rural floor. Once the effects within each year were determined, we determined a cumulative effect of 1.1 percentage points.

We note that, in the FY 2008 IPPS final rule with comment period, we applied a one-time adjustment of 1.002214 to the FY 2008 standardized amount to address a single year transition (from FY 2007 to FY 2008) to a noncumulative system of the rural floor budget neutrality adjustment. This adjustment of 1.002214 to the FY 2008 standardized amount reflected the increase to the rates to remove the effects of the rural floor budget neutrality adjustment from FY 2007. Because this 1.002214 factor remains on the rate, we do not include an adjustment for FY 2007 in the calculation described above.

e. Case-Mix Budget Neutrality Adjustment

(1) Adjustment to the FY 2012 IPPS Standardized Amount for the Prospective Adjustment for FY 2010 and Subsequent Years Authorized by Section 7(b)(1)(A) of Public Law 110–90 and Section 1886(d)(3)(A)(vi) of the Act

As stated earlier, beginning in FY 2008, we adopted the MS–DRG patient classification system for the IPPS to better recognize patients' severity of illness in Medicare payment rates. In the FY 2008 IPPS final rule with comment period (73 FR 47175 through 47186), we indicated that we believe 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 changes in documentation and coding. In that final rule, using the Secretary's authority under section 1886(d)(3)(A)(vi) of the Act to maintain budget neutrality by adjusting the national standardized amounts to eliminate the effect of changes in documentation and coding that do not reflect real change in case-mix, 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 (for a total adjustment of −4.8 percent). On September 29, 2007, Public Law 110–90 was enacted. Section 7 of Public Law 110–90 included a provision that reduces the documentation and coding adjustment for 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. To comply with the provision of section 7(a) of Public Law 110–90, in a final rule that appeared in the **Federal Register** on November 27, 2007 (72 FR 66886), we changed the IPPS documentation and coding adjustment for FY 2008 to −0.6 percent, and revised the FY 2008 national standardized amounts (as well as other payment factors and thresholds) accordingly, with these revisions being effective as of October 1, 2007. For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent instead of the −1.8 percent adjustment specified in the FY 2008 IPPS final rule with comment period. As required by statute, we applied a documentation and coding adjustment of −0.9 percent to the FY 2009 IPPS national standardized amounts. The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period are cumulative. As a result, the −0.9 percent documentation and coding adjustment in FY 2009 was in addition to the −0.6 percent adjustment in FY 2008, yielding a combined effect of −1.5 percent.

In the FY 2010 IPPS proposed rule and final rule (74 FR 24092 through 24101 and 43768 through 43772, respectively), we discussed our analysis of FY 2008 claims data and did not apply any additional documentation and coding adjustments to the average standardized amounts under section 1886(d) of the Act. We refer readers to these rules for a detailed description of our analysis, responses to comments, and final policy respectively. 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. 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. Therefore, we determined that 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 on future payments. As we discussed in the FY 2011 IPPS/LTCH PPS final rule, 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 implement the requisite adjustment) were 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90. Our actuaries estimate that this 3.9 percentage point increase will result in an aggregate payment of approximately $4 billion. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a detailed description of our analysis, responses to comments, and final policy (75 FR 50057 through 50073).

In the proposed rule, we stated it was imperative that CMS make a prospective adjustment amount in FY 2012 to prevent the continued accumulation of unrecoverable overpayments. After consideration of the public comments we received, and in keeping with our longstanding policy to mitigate, when possible, the effects of significant downward adjustments on hospitals to avoid what could be widespread, disruptive effects of such adjustments on hospitals, we are finalizing a prospective adjustment of −2.0 percent instead of the −3.15 percent prospective adjustment that was proposed. We refer the reader to section II.D. of the preamble of this final rule for more discussion. In addition, for a complete discussion on our proposed and final documentation and coding adjustment to the hospital-specific rates, we refer readers to section II.D.2.c.of this Addendum.

(2) Adjustment to the FY 2012 IPPS Standardized Amount for the Recoupment or Repayment Adjustment for FY 2010 Authorized by Section 7(b)(1)(B) of Public Law 110–90

As indicated in section II.D.4. in the preamble to this final rule, the change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 and FY 2009 exceeded the −0.6 and −0.9 percent prospective documentation and coding adjustment applied under section 7(a) of Public Law 110–90 for those 2 years respectively by 1.9 percentage points in FY 2008 and 3.9 percentage points in FY 2009. In total, this change exceeded the cumulative prospective adjustments by 5.8 percentage points. Our actuaries estimated that this 5.8 percentage point increase resulted in an increase in aggregate payments of approximately $6.9 billion. In the FY 2011 IPPS/LTCH PPS final rule, we determined that an aggregate adjustment of -5.8 percent in FYs 2011 and 2012, subject to actuarial adjustment to reflect accumulated interest, 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, as we specified in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50425), we made an adjustment in FY 2011 to the standardized amount of −2.9 percent, representing half of the aggregate adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. As we have previously noted, unlike the prospective adjustment to the standardized amounts under section 7(b)(1)(A) of Public Law 110–90 described earlier, the recoupment or repayment adjustment to the standardized amounts under section 7(b)(1)(B) of Public Law 110–90 is not cumulative, but would be removed for subsequent fiscal years once we have offset the increase in aggregate payments for discharges for FY 2008 expenditures and FY 2009 expenditures. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a detailed description of our analysis, responses to comments, and final policy (75 FR 50057 through 50073).

While we stated in the FY 2011 IPPS/LTCH PPS final rule the need to potentially adjust the remaining −2.9 percent estimate to account for accumulated interest, our actuaries have determined that there has been no significant interest accumulation and that no additional adjustment will be required. Therefore, in section II.D. of the preamble to this final rule, we finalized our proposal to complete the recoupment adjustment according to the timeframes set forth by section 7(b)(1)(B) of Public Law 110–90 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 in FY 2011.

Because these adjustments will, in effect, balance out, there will be no year-to-year change in the standardized amount due to this recoupment adjustment. As this adjustment will complete the required recoupment for overpayments due to documentation and coding effects on discharges occurring in FYs 2008 and 2009, we anticipate removing the effect of this adjustment by adding 2.9 percent to the standardized amount in FY 2013. We continue to believe that this is a reasonable and fair approach that satisfies the requirements of the statute while substantially moderating the financial impact on hospitals. We refer the reader to section II.D. of the preamble to this final rule for more discussion.

(3) Adjustment to the FY 2012 Puerto Rico Standardized Amount

As discussed in section II.D.9. of the preamble of this final rule, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), using the same methodology we applied to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals, our best estimate, based on the then most recently available data (FY 2009 claims paid through March 2010), was that for documentation and coding changes that occurred over FY 2008 and FY 2009, a cumulative adjustment of −2.6 percent was required to eliminate the full effect of the documentation and coding changes on future payments from the Puerto Rico-specific rate. In FY 2011, as finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), we applied an adjustment of −2.6 percent to the Puerto Rico-specific rate. Therefore, because the Puerto Rico-specific rate received a full prospective adjustment of −2.6 percent in FY 2011, in section II.D.9. of the preamble of this final rule, we finalized our proposal to make no further adjustment for FY 2012. For a complete discussion on our final policy, we refer readers to section II.D.9. of the preamble of this final rule.

f. Rural Community Hospital Demonstration Program Adjustment

As discussed in section IV.N. of the preamble to this final rule, section 410A of Public Law 108–173 originally required the Secretary to establish a demonstration 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 for an additional 5-year period, and allow 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 2011 IPPS/LTCH PPS final rule (75 FR 50426), 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 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, 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 2012, we proposed the estimated amount for the adjustment to the national IPPS rates for FY 2012 to be $52,642,213. For this final rule, we determined that for the 25 hospitals participating in the demonstration project an estimated amount for the adjustment to the national IPPS rates for FY 2012 is $52,452,060. Accordingly, to account for the estimated costs of the demonstration for the specific time periods as explained in detail in section IV.N. of the preamble of this final rule, for FY 2012, we computed a factor of 0.999487 for the rural community hospital demonstration program budget neutrality adjustment that is applied to the IPPS standardized rate.

We noted that because the settlement process for the demonstration hospitals' third and fourth year cost reports, that is, for cost reporting periods starting in FYs 2007 and 2008, has experienced a delay, for the proposed rule, we were unable to state the costs of the demonstration corresponding to FYs 2007 and 2008 for purposes of determining the amount by which the costs of the demonstration corresponding to FYs 2007 and 2008 exceeded the amount offset by the budget neutrality adjustments for FYs 2007 and 2008. As a result, we were unable to propose the specific numeric adjustment representing this offsetting process that would be a component of the budget neutrality adjustment and that would be applied to the national IPPS rates. Therefore, the estimated budget neutrality adjustment to the national IPPS rate in the proposed rule did not include a component to account for these costs. We indicated in the proposed rule that we anticipated that this information may be available for the FY 2012 IPPS/LTCH PPS final rule, at which time, if data from settled cost reports are available, under our proposal, we would incorporate a component into the budget neutrality adjustment to the national IPPS rates to account for the amount by which the demonstration costs corresponding to FY 2007 and FY 2008 exceeded the amount offset by the budget neutrality adjustments for FYs 2007 and 2008.

Similarly, for this final rule, we are unable to identify the specific numeric amount representing this offsetting process that can be incorporated into the budget neutrality adjustment applied to the national IPPS rates

due to delays in the settlement process for the demonstration hospitals' third and fourth year cost reports. We note that we anticipate that they may be available for the FY 2013 IPPS/LTCH PPS proposed and final rules. Therefore, the estimated adjustment to the national IPPS rates in this final rule cannot include a component to account for these costs.

g. Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2012 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 plus outlier payments. We note that the statute requires outlier payments 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.hhs.gov/AcuteInpatientPPS/04_outlier.asp#TopOfPage.*

(1) FY 2012 Outlier Fixed-Loss Cost Threshold

For FY 2012, we proposed to continue to use the same methodology used for FY 2009 (73 FR 48763 through 48766) to calculate the outlier threshold. Similar to the methodology used in the FY 2009 IPPS final rule, for FY 2012, we proposed to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). As we have done in the past, to calculate the proposed FY 2012 outlier threshold, we simulated payments by applying proposed FY 2012 rates and policies using cases from the FY 2010 MedPAR files. Therefore, in order to determine the proposed FY 2012 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2010 to FY 2012.

We proposed to continue to use a refined methodology that takes into account the lower inflation in hospital charges that are occurring as a result of the outlier final rule (68 FR 34494), which changed our methodology for determining outlier payments by implementing the use of more current CCRs. Our refined methodology uses more recent data that reflect the rate-of-change in hospital charges under the new outlier policy.

Using the most recent data available, we calculated the 1-year average annualized rate-of-change in charges per case from the last quarter of FY 2009 in combination with the first quarter of FY 2010 (July 1, 2009 through December 31, 2009) to the last quarter of FY 2010 in combination with the first quarter of FY 2011 (July 1, 2010 through December 31, 2010). This rate-of-change was 4.43 percent (1.044394) or 9.07 percent (1.090759) over 2 years. As we have done in the past, we established the proposed FY 2012 outlier threshold using hospital CCRs from the December 2010 update to the Provider-Specific File (PSF)—the most recent available data at the time of the proposed rule.

As discussed in the FY 2007 IPPS final rule (71 FR 48150), we worked with the Office of Actuary to derive the methodology described below to develop the CCR adjustment factor. For FY 2012, we proposed to continue to use the same methodology to calculate the CCR adjustment by using the FY 2010 operating cost per discharge increase in combination with the actual FY 2010 operating market basket percentage increase determined by IHS Global Insight, Inc. (IGI), as well as the charge inflation factor described above to estimate the adjustment to the CCRs. (We note that the FY 2010 actual (otherwise referred to as ''final'') operating market basket percentage increase reflects historical data, whereas the published FY 2010 operating market basket update factor was based on IGI's 2009 second quarter forecast with historical data through the first quarter of 2009. We also note that while the FY 2010 published operating market basket update was based on the FY 2002-based IPPS market basket, the actual or ''final'' market basket percentage increase is based on the FY 2006-based IPPS market basket. Similarly, the FY 2010 published capital market basket update factor was based on the FY 2002-based capital market basket and the actual or ''final'' capital market basket percentage increase is based on the FY 2006-based capital market basket.) By using the operating market basket percentage increase and the increase in the average cost per discharge from hospital cost reports, we are using two different measures of cost inflation. For FY 2012, we determined the adjustment by taking the percentage increase in the operating costs per discharge from FY 2008 to FY 2009 (1.0285) from the cost report and dividing it by the final operating market basket percentage increase from FY 2009 (1.026). This operation removes the measure of pure price increase (the market basket) from the percentage increase in operating cost per discharge, leaving the nonprice factors in the cost increase (for example, quantity and changes in the mix of goods and services). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the operating market basket percentage increase and the increase in cost per case from the cost report (the FY 2006 to FY 2007 percentage increase of operating costs per discharge of 1.0465 divided by the FY 2007 final operating market basket percentage increase of 1.036, the FY 2007 to FY 2008 percentage increase of operating costs per discharge of 1.0506 divided by the FY 2008 final operating market basket percentage increase of 1.040). For FY 2012, we averaged the differentials calculated for FY 2007, FY 2008, and FY 2009, which resulted in a mean ratio of 1.0076. We multiplied the 3-year average of 1.0076 by the FY 2010 final operating market basket percentage increase of 1.021, which resulted in an operating cost inflation factor of 2.87 percent or 1.028747. We then divided the operating cost inflation factor by the 1-year average change in charges (1.044394) and applied an adjustment factor of 0.985018 to the operating CCRs from the PSF (calculation performed on unrounded numbers).

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.

We used the same methodology for the capital CCRs and determined the adjustment by taking the percentage increase in the capital costs per discharge from FY 2008 to FY 2009 (1.0508) from the cost report and dividing it by the final capital market basket percentage increase from FY 2009 (1.015). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the capital market basket percentage increase and the increase in cost per case from the cost report (the FY 2006 to FY 2007 percentage increase of capital costs per discharge of 1.0507 divided by the FY 2007 final capital market basket percentage increase of 1.013, the FY 2007 to FY 2008 percentage increase of capital costs per discharge of 1.0811 divided by the FY 2008 final capital market basket percentage increase of 1.015). For FY 2012, we averaged the differentials calculated for

FY 2007, FY 2008, and FY 2009, which resulted in a mean ratio of 1.0459. We multiplied the 3-year average of 1.0459 by the FY 2010 final capital market basket percentage increase of 1.010, which resulted in a capital cost inflation factor of 5.63 percent or 1.056329. We then divided the capital cost inflation factor by the 1-year average change in charges (1.044394) and applied an adjustment factor of 1.011428 to the capital CCRs from the PSF (calculation performed on unrounded numbers). We proposed to use the same charge inflation factor for the capital CCRs that was used for the operating CCRs. The charge inflation factor is based on the overall billed charges. Therefore, we believe it is appropriate to apply the charge factor to both the operating and capital CCRs.

As stated above, for FY 2012, we applied the proposed FY 2012 rates and policies using cases from the FY 2010 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.F. of this final 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 2012, 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 2012. If we did not take into account this provision, our estimate of total FY 2012 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.

In the proposed rule, we stated that our estimate of the cumulative effect of changes in documentation and coding due to the adoption of the MS–DRGs through FY 2010 of 5.4 percent is already included within the claims data (FY 2010 MedPAR files) used to calculate the FY 2012 outlier threshold. We also stated in the proposed rule that we estimated that there would be no continued changes in documentation and coding in FYs 2011 and 2012. Therefore, the cumulative effect of documentation and coding that has occurred is already reflected within the FY 2010 MedPAR claims data, and we did not believe there was any need to inflate FY 2010 claims data for any additional case-mix growth projected to have occurred since FY 2010.

Using this methodology, we proposed an outlier fixed-loss cost threshold for FY 2012 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $23,375.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2012 outlier payments, we did not propose to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We indicated that we continue to believe that, due to the policy implemented in the June 9, 2003 outlier final rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We also note 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 proposed not to make any assumptions about the effects of reconciliation on the outlier threshold calculation.

Comment: Commenters, including major hospital associations, stated that CMS currently estimates outlier payments in FY 2010 at 4.7 percent of total payments. The commenters commended CMS for making refinements such as applying an adjustment factor to CCRs when computing the outlier threshold but noted that, because CMS is still not reaching the 5.1 percent target for outlier payments, there is still room for improvement. The commenters further stated that although CMS currently projects outlier payments in FY 2011 to be estimated at 4.9 percent of total payments, which is lower the 5.1 percent target, this estimate is based on discharges from a prior year and, in their view, will likely not reflect the actual result. The commenters noted that in prior years when CMS provided its projected estimate of outlier payments for a given fiscal year, once the actual claims were available to determine the actual outlier payment (in the following fiscal year), their analysis showed that the estimate declined between 0.2 percent and 0.3 percent from the projection.

One commenter suggested that the methodology to develop the adjustment factor to the CCRs is unnecessarily complicated and does not lead to a more accurate result. The commenter requested clarification if CMS applies the same CCR throughout the fiscal year within the outlier model. The commenter also urged CMS to adopt a methodology that uses recent historical industry wide average rate of change, similar to the methodology used to develop the charge inflation factor. Specifically, the commenter recommended that CMS measure the rate of change in CCRs to develop the adjustment factor to the CCRs. Further, in addition to recommending an adjustment to the CCRs based on historical data, the commenter opposed CMS's methodology of applying the adjustment factor over one year and suggested that the CCRs should be projected over different periods of time, some less or more than one year, based on variations in hospital fiscal year ends. The commenter also opposed CMS' use of the December 2010 update of the PSF and assert that CMS's methodology is oversimplified. The commenter believed that its methodology would more accurately project the decline in CCRs.

The commenter also suggested that, if CMS did not incorporate the changes described above to its methodology for estimating outlier payments, it would recommend incorporating an ''estimate adjustment factor'' into the outlier projections. The commenter explained that outlier payments have been underpaid in every year since 2004. Based on actual payments determined by the commenter using data analysis, the commenter asserted that the underpayment has exceeded 0.5 percent in all years except one. The commenter recommended that CMS maintain the outlier threshold at 5.1 percent but apply an estimate adjustment factor when projecting the outlier threshold. The commenter provided an example and computed this factor for FY 2009 and FY 2010 by taking the average variance in the actual payment for FY 2008 and FY 2009 which was 0.491 percent. Based on this factor, CMS would model the threshold to a level of 5.591 percent (5.1 plus .491 percent). If CMS were to overpay outliers, then the adjustment would be become negative. The commenter stated that this would fulfill the statutory requirement in section 1886 (d)(5)(A) of the Act that requires that CMS establish thresholds such that outlier payments will be projected to achieve at least 5.1 percent of DRG payments and would more closely achieve a result that is fully consistent with the statute.

The commenter responded to CMS's concerns expressed in last year's final rule (75 FR 50429) that an ''estimate adjustment factor'' to the outlier threshold or standardized amount in a given year to account for ''overpayments'' or ''underpayments'' of outliers in other years would not result in the agency making outlier payments that were not directly related to the actual cost of furnishing care in extraordinarily costly cases. The commenter believed that an ''estimate adjustment factor'' represents a prospective adjustment factor based on historical data and would not constitute a retroactive adjustment to prior outlier payments because the adjustment would have no impact on past outlier payments. Moreover, the commenter further opined that the estimate adjustment factor would be based on historical outlier cases so payments would be directly related to the actual cost of furnishing care to outlier patients.

Response: Commenters to previous rules have raised similar concerns regarding our estimates of outlier payments. We refer readers to a similar discussion in the FY 2008 final rule with comment period (72 FR 47418). In response to the comment that CCRs should be projected over different periods of time, it is possible that some of the

CCRs in the March PSF will be used in FY 2009 for actual outlier payments, while other CCRs may be one year old. Therefore, we apply a 1-year adjustment to the CCRs. The adjusted CCR is applied throughout the fiscal year within the outlier model. With respect to the comment on our methodology used to adjust the CCRs, as we stated in the FY 2008 IPPS final rule with comment period (72 FR 47418), we continue to believe this calculation of an adjustment to the CCRs is more accurate and stable than the commenter's methodology because it takes into account the costs per discharge and the market basket percentage increase when determining a cost adjustment factor. There are times where the market basket and the cost per discharge will be constant, while other times these values will differ from each other, depending on the fiscal year. Therefore, as mentioned above, using the market basket in conjunction with the cost per discharge takes into account two sources that measure potential cost inflation and ensures a more accurate and stable cost adjustment factor.

With respect to the comment of computing an ''estimate adjustment factor,'' we thank the commenter for further explaining their position on this adjustment. Further analysis by CMS is necessary to determine if the commenter's approach to applying an ''estimate adjustment factor'' is appropriate. We will consider the commenter's suggestion of applying an ''estimate adjustment factor'' in future rulemaking if, based on our analysis, we determine that application of an ''estimate adjustment factor'' is appropriate and consistent with the statute.

Comment: One commenter was concerned that CMS did not include outlier reconciliations in developing the outlier threshold. The commenter requested that CMS disclose in the final rule and future proposed and final IPPS rules the amount of money it has recovered through reconciliation. The commenter explained that this information will allow others to comment specifically on how this provision would impact the threshold.

Response: We received a similar comment to last year's rule, and we thank the commenter for again informing us of its concern regarding not including outlier reconciliation within the development of the outlier threshold. However, as stated above, 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 proposed and are finalizing our policy not to make any assumptions about the effects of reconciliation on the outlier threshold calculation.

Additionally, we published a 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. The instructions in Change Request 7192 regarding outlier reconciliation were effective on April 1, 2011. Medicare contractors record the outlier reconciliation amount on each provider's cost report (and are not required to report these data to CMS outside of the cost report settlement process). Therefore, the outlier reconciliation data that the commenter is requesting will be publicly available once the cost report data are posted on our Web site at *http://www.cms.gov/CostReports/02_HospitalCostReport.asp#TopOfPage.* Since April 1, 2011, we have approved some provider's outlier payments to be reconciled. Other providers that were flagged for outlier reconciliation are still under review for approval. Some providers flagged for outlier reconciliation may experience a delay in reconciling their outlier payments due to circumstances that prevent the Medicare contractor from finalizing the hospital's cost report (such as other payments that may need to be reconciled aside from outlier payments). As instructed in Change Request 7192, barring an exception from CMS, Medicare contractors were given until October 1, 2011, to complete the reconciliation process for those providers flagged for outlier reconciliation prior to April 1, 2011. 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.*

Because we are not making any changes to our methodology for this final rule, for FY 2012, we are using the same methodology we proposed to calculate the outlier threshold.

Using the most recent data available, we calculated the 1-year average annualized rate-of-change in charges per case from the first quarter of FY 2010 in combination with the second quarter of FY 2010 (October 1, 2009 through March 31, 2010) to the first quarter of FY 2011 in combination with the second quarter of FY 2011 (October 1, 2010 through March 31, 2010). This rate-of-change was 3.89 percent (1.038944) or 7.94 percent (1.079405) over 2 years. As we have done in the past, we established the final FY 2012 outlier threshold using hospital CCRs from the March 2011 update to the Provider-Specific File (PSF)—the most recent available data at the time of this final rule.

For FY 2012, we calculated the CCR adjustment by using the FY 2010 operating cost per discharge increase in combination with the actual FY 2010 operating market basket percentage increase determined by IHS Global Insight, Inc. (IGI), as well as the charge inflation factor described above to estimate the adjustment to the CCRs. (We note that the FY 2010 actual (otherwise referred to as ''final'') operating market basket percentage increase reflects historical data, whereas the published FY 2010 operating market basket update factor was based on IGI's 2009 second quarter forecast with historical data through the first quarter of 2009. We also note that while the FY 2010 published operating market basket update was based on the FY 2002-based IPPS market basket, the actual or ''final'' market basket percentage increase is based on the FY 2006-based IPPS market basket. Similarly, the FY 2010 published capital market basket update factor was based on the FY 2002-based capital market basket and the actual or ''final'' capital market basket percentage increase is based on the FY 2006-based capital market basket.) By using the operating market basket percentage increase and the increase in the average cost per discharge from hospital cost reports, we are using two different measures of cost inflation. For FY 2012, we determined the adjustment by taking the percentage increase in the operating costs per discharge from FY 2008 to FY 2009 (1.0290) from the cost report and divided it by the final operating market basket percentage increase from FY 2009 (1.026). This operation removes the measure of pure price increase (the market basket) from the percentage increase in operating cost per discharge, leaving the nonprice factors in the cost increase (for example, quantity and changes in the mix of goods and services). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the operating market basket percentage increase and the increase in cost per case from the cost report (the FY 2006 to FY 2007 percentage increase of operating costs per discharge of 1.0464 divided by the FY 2007 final operating market basket percentage increase of 1.036, the FY 2007 to FY 2008 percentage increase of operating costs per discharge of 1.0507 divided by FY 2008 final operating market basket percentage increase of 1.040). For FY 2012, we averaged the differentials calculated for FY 2007, FY 2008, and FY 2009, which resulted in a mean ratio of 1.0078. We multiplied the 3-year average of 1.0078 by the FY 2010 final operating market basket percentage increase of 1.021, which resulted in an operating cost inflation factor of 2.87 percent or 1.028913. We then divided the operating cost inflation factor by the 1-year average change in charges (1.038994) and applied an adjustment factor of 0.990297 to the operating CCRs from the PSF (calculation performed on unrounded numbers).

We used the same methodology for the capital CCRs and determined the adjustment by taking the percentage increase in the capital costs per discharge from FY 2008 to FY 2009 (1.0494) from the cost report and dividing it by the final capital market basket percentage increase from FY 2009 (1.015). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the capital market basket percentage increase and the increase in cost per case from the cost report (the FY 2006 to FY 2007 percentage increase of capital costs per discharge of 1.0508 divided by the FY 2007 final capital market basket percentage increase of 1.013, the FY 2007 to FY 2008 percentage increase of capital costs per discharge of 1.0813 divided by the FY 2008 final capital market basket percentage increase of 1.015). For FY 2012,

we averaged the differentials calculated for FY 2007, FY 2008, and FY 2009, which resulted in a mean ratio of 1.0455. We multiplied the 3-year average of 1.0455 by the FY 2010 final capital market basket percentage increase of 1.010, which resulted in a capital cost inflation factor of 5.6 percent or 1.055964. We then divided the capital cost inflation factor by the 1-year average change in charges (1.038994) and applied an adjustment factor of 1.011428 to the capital CCRs from the PSF (calculation performed on unrounded numbers). We are using the same charge inflation factor for the capital CCRs that was used for the operating CCRs. The charge inflation factor is based on the overall billed charges.

As stated above, for FY 2012, we applied the FY 2012 rates and policies using cases from the FY 2010 MedPAR files in calculating the 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.F. of this final 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 final outlier threshold for FY 2012, 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 2012. If we did not take into account this provision, our estimate of total FY 2012 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.

Also, for this final rule, our estimate of the cumulative effect of changes in documentation and coding due to the adoption of the MS–DRGs through FY 2010 of 5.4 percent is already included within the claims data (FY 2010 MedPAR files) used to calculate the FY 2012 outlier threshold. Also, we estimate that there will be no continued changes in documentation and coding in FYs 2011 and 2012. Therefore, the cumulative effect of documentation and coding that has occurred is already reflected within the FY 2010 MedPAR claims data, and we did not believe there was any need to inflate FY 2010 claims data for any additional case-mix growth projected to have occurred since FY 2010.

Using this methodology, we calculated a final outlier fixed-loss cost threshold for FY 2012 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $22,385.

We note that our final threshold is less than the proposed threshold. We believe this is due to the increase in the standardized amount from the proposed rule to the final rule. (Some examples that caused the standardized amount to increase from the proposed rule to this final rule include, but are not limited to, the increase in the market basket update and the decreases in the multifactor productivity adjustment and our prospective documentation and coding adjustment). As payments increase, fewer cases will qualify for outlier payments thus requiring us to lower the threshold from the proposed rule to this final rule.

(2) Other Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2012 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 6.18 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, as we proposed, we are reducing the FY 2012 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that are applied to the standardized amount based on the FY 2012 outlier threshold are as follows:

	Operating standardized amounts	Capital federal rate
National	0.948990	0.938207
Puerto Rico	0.953549	0.926153

We are applying the outlier adjustment factors to the FY 2012 rates after removing the effects of the FY 2011 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 0.159, or hospitals for which the fiscal intermediary or MAC is unable to calculate a CCR (as described at § 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 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, 2011, these statewide average ratios will replace the ratios published in the IPPS final rule for FY 2011 (75 FR 50390–50392). Table 8B listed in section VI. of this Addendum (and available via the Internet) contains the comparable statewide average capital CCRs. Again, the CCRs in Tables 8A and 8B will be used during FY 2012 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 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. Additionally, 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 2010 and FY 2011 Outlier Payments

In the FY 2011 IPPS final rule (75 FR 50431), we stated that, based on available data, we estimated that actual FY 2010 outlier payments would be approximately 4.7 percent of actual total DRG payments. This estimate was computed based on simulations using the FY 2009 MedPAR file (discharge data for FY 2009 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2010 claims, but instead reflected the application of FY 2010 rates and policies to available FY 2009 claims.

Our current estimate, using available FY 2010 claims data, is that actual outlier

payments for FY 2010 were approximately 4.7 percent of actual total DRG payments. Thus, the data indicate that, for FY 2010, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 2010. 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 2010 are equal to 5.1 percent of total DRG payments.

We currently estimate that actual outlier payments for FY 2011 will be approximately 4.8 percent of actual total DRG payments, approximately 0.3 percentage points lower than the 5.1 percent we projected when setting the outlier policies for FY 2011. This estimate of 4.8 percent is based on simulations using the FY 2010 MedPAR file (discharge data for FY 2010 claims).

Comment: Commenters disagreed with CMS' use of modeled data versus actual payment data to compute the outlier payment percentage for FY 2010. The commenters stated that they performed their own analysis using actual payment information in the MedPAR file which resulted in outlier payments being 4.36 percent of actual DRG payments for FY 2010. The commenters recommended that CMS determine the FY 2010 outlier payment percentage using actual payments rather than modeled payments.

The commenters disagreed with CMS' reasons in the FY 2011 final rule (75 FR 50431) for using modeled data instead of actual data. In last year's final rule, CMS supported its decision to use modeled data in part because ''while accurate at the time the MedPAR file is constructed, claims can be cancelled, edited and resubmitted to NCH after the MedPAR file is built, and therefore the payment field shown on MedPAR is subject to change and does not necessarily represent the final payment on that claim.'' The commenters stated that while this is true, the argument applies equally to modeling payments from the MedPAR data. The commenters explained that if a claim is cancelled after the MedPAR file is built, the modeled payment for that claim will be included in overall estimates.

The commenters further noted that, in last year's final rule, CMS expressed concern that SCHs and MDHs complicates the use of the payment field shown on the MedPAR file (75 FR 50431). The commenter disagreed with CMS and stated that CMS' argument is valid for determining the DRG-based operating payments needed to calculate outlier payment levels; however, the SCH/MDH argument does not apply to outlier payments. The commenters claimed that ''the PRICER program determines outlier payments for all hospitals, including SCH/MDHs, based on the Federal rate only.'' The commenters added that ''the outlier payments are recorded in the ''OUTLIER AMOUNT'' field (and not included in the DRG PRICE).'' Therefore, the commenters asserted that ''obtaining the outlier payments directly from the MedPAR file does not introduce complications related to the SCH/MDH status.'' Moreover, the commenters noted ''that SCH/MDH hospitals represent a small percent of hospitals overall.''

The commenters also requested further clarification regarding how CMS conducted its analysis that showed an outlier payment percentage of 4.7 percent for FY 2010. The commenters specifically requested that CMS disclose what CCRs were used to develop the FY 2010 estimate payment set forth in the proposed rule, and state whether the same CCRs or different CCRs were used to determine the FY 2010 payments as set forth in the FY 2011 proposed and final rules.

Response: We continue to believe that modeling FY 2010 outlier payments is a reasonable approach to compute the outlier payment percentage for that year. Similar to our response in the FY 2011 final rule, to determine the FY 2010 outlier estimate, we used the FY 2010 PRICER and the latest update of the FY 2010 MedPAR file to model actual outlier payments for FY 2009. Although the MedPAR does contain the actual payment amounts to hospitals, we still believe that modeling actual outlier payments for FY 2010 produces an enhanced accuracy of actual outlier payments. For example, we model which SCHs would have greater hospital-specific payment amounts versus their Federal payments, (similar to what is currently done at cost report settlement) and exclude those providers from our determination of FY 2010 actual outlier payments. Also, we believe modeling actual outlier payments for FY 2010 is consistent with our approach of using modeling for the rate setting for FY 2011 (which also models the FY 2010 payments for use in the FY 2011 rate setting).

The commenters noted that that if a claim is cancelled after the MedPAR file is built, the modeled payment for that claim will also be included in overall estimates. While the commenter is correct, this concern is relevant regardless of whether we use actual data or modeled data to compute the outlier payment percentage. Therefore, we do not believe that this argument supports the use of actual payment data instead of modeled data. As stated above, we continue to believe that modeling that outlier payment percentage presents more accuracy.

We disagree with the commenter that obtaining the outlier payments directly from the MedPAR file does not introduce complications related to the SCH/MDH status. Specifically, if an SCH or MDH is paid at the end of its cost reporting year based on its target amount, then including the payment in the ''Outlier Amount'' field in the outlier payment percentage would distort the computation of the outlier payment percentage because the hospital's actual payment was based on its target amount and not the federal standardized amount. Therefore, as mentioned above, we model which SCHs would have greater hospital-specific payment amounts versus payments based on the standardized amount (similar to what is currently done at cost report settlement), and we then exclude those providers from our determination of FY 2010 outlier percentage payout. Because we are modeling which SCHs would have greater hospital-specific payment amounts versus their Federal payments, we believe it is appropriate to model the outlier percentage payout.

Without further detail from the commenters, we are unable to determine why the commenters were unable to duplicate our estimate of the FY 2010 outlier percentage payout. However, to provide further clarification of the CCRs used to model the FY 2010 outlier percentage payout, we used CCRs from the March 2010 update of the PSF. This is the same file that was used to compute the FY 2010 outlier percentage payout in the FY 2011 proposed and final rules.

5. FY 2012 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 national standardized amounts that we are applying to all hospitals, except hospitals located in Puerto Rico, for FY 2012. The Puerto Rico-specific amounts are shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is the labor-related share of 68.8 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 applying 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 (other than those in Puerto Rico) whose wage indices are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the standardized amounts reflecting the applicable percentage increase of 1.9 percent for FY 2012, and an update of -0.1 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 labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2012 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 Puerto Rico standardized amounts. The labor-related share applied to the Puerto Rico specific standardized amount is the labor-related share of 62.1 percent, or 62 percent, depending on which provides higher payments to the hospital. (Section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.)

The following table illustrates the changes from the FY 2011 national standardized amount. The second column shows the changes from the FY 2011 standardized amounts for hospitals that satisfy the quality

data submission requirement and therefore receive the full update of 1.9 percent. The third column shows the changes for hospitals receiving the reduced update of -0.1 percent. The first row of the table shows the updated (through FY 2011) average standardized amount after restoring the FY 2011 offsets for outlier payments, demonstration budget neutrality and the geographic reclassification budget neutrality. The DRG reclassification and recalibration wage index budget neutrality factors are cumulative. Therefore, the FY 2011 factor is not removed from this table.

COMPARISON OF FY 2011 STANDARDIZED AMOUNTS TO THE FY 2012 STANDARDIZED AMOUNT WITH FULL AND REDUCED UPDATE

	Full Update (1.9 percent); Wage index is greater than 1.0000	Full Update (1.5 percent); Wage index is less than or equal to 1.0000	Reduced Update (−0.1 percent); Wage index is greater than 1.0000	Reduced Update (−0.1 percent); Wage index is less than or equal to 1.0000
FY 2011 Base Rate, after removing geographic reclassification budget neutrality, demonstration budget neutrality, cumulative FY 2008 and FY 2009 documentation and coding adjustment, FY 2011 documentation and coding recoupment, and outlier offset (based on the labor–related share percentage for FY 2011)	Labor: $3,947.65 Nonlabor: $1,790.21	Labor: $3,557.48 Nonlabor: $2,180.39	Labor: $3,947.65 Nonlabor: $1,790.21	Labor: $3,557.48 Nonlabor: $2,180.39
FY 2012 Update Factor	1.019	1.019	0.999	0.999
Adjustment for Restoring Rural Floor Budget Neutrality	1.011	1.011	1.011	1.011
FY 2012 DRG Recalibration and Wage Index Budget Neutrality Factor	0.99846	0.99846	0.99846	0.99846
FY 2012 Reclassification Budget Neutrality Factor	0.991493	0.991493	0.991493	0.991493
FY 2012 Rural Demonstration Budget Neutrality Factor	0.999487	0.999487	0.999487	0.999487
FY 2012 Outlier Factor	0.948990	0.948990	0.948990	0.948990
Documentation and coding adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90	0.9386	0.9386	0.9386	0.9386
Final Rate for FY 2012	Labor: $3,584.30 Nonlabor: $1,625.44	Labor: $3,230.04 Nonlabor: $1,979.70	Labor: $3,513.95 Nonlabor: $1,593.54	Labor: $3,166.64 Nonlabor: $1,940.85

B. Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the Internet), contain the labor-related and nonlabor-related shares that we used to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2012. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national and Puerto Rico prospective payment rates, respectively, to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. In section III. of the preamble of this final rule, we discuss the data and methodology for the FY 2012 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act authorizes the Secretary to make an adjustment 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. For FY 2011 and in prior fiscal years, we used the most recent updated 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.* We multiply the nonlabor-related portion of the standardized amount by the applicable adjustment factor.

Sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009) transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Public Law 111–84, locality pay is being phased in over a 3-year period beginning in January 2010 with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay.

In the proposed rule, we stated that we did not believe it was appropriate to use either the 2010 or 2011 reduced factors for adjusting the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii for Medicare payment purposes. Therefore, for FY 2012, we proposed to continue to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which are based on OPMs 2009 COLA factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. We stated that we believe using these COLAs will appropriately adjust the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii consistent with section 1886(d)(5)(H) of the Act.

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal to use the same factors currently in use under the IPPS for FY 2011 for FY 2012. Below is a table of factors obtained from OPM that we are using for FY 2012.

TABLE OF COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Cost of living adjustment factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.18
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

(The above factors are based on data obtained from the U.S. Office of Personnel Management Web site at: *http://www.opm.gov/oca/cola/rates.asp.*)

C. MS–DRG Relative Weights

As discussed in section II.H. of the preamble of this final rule, we have developed relative weights for each MS–DRG that reflect the resource utilization of cases in each MS–DRG relative to Medicare cases in other MS–DRGs. Table 5 listed in section VI. of this Addendum (and available via the Internet) contains the relative weights that we are applying to discharges occurring in FY 2012. These factors have been recalibrated as explained in section II. of the preamble of this final rule.

D. Calculation of the Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2012

In general, the operating prospective payment rate for all hospitals paid under the IPPS located outside of Puerto Rico, except SCHs and MDHs, for FY 2012 equals the Federal rate.

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 the FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2012 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for MDHs for FY 2012 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described below. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987 or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

The prospective payment rate for hospitals located in Puerto Rico for FY 2012 equals 25 percent of the Puerto Rico 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 IV.E. of the preamble of this final rule.

2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that 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 the FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As discussed previously, currently MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the greater of the updated hospital-specific rates based on either FY 1982, FY 1987 or FY 2002 costs per discharge.

Hospital-specific rates have been determined for each of these hospitals based on the FY 1982 costs per discharge, the FY 1987 costs per discharge, or, for SCHs, the FY 1996 costs per discharge or the FY 2006 costs per discharge, and for MDHs, the FY 2002 cost per discharge. For a more detailed discussion of the calculation of the hospital-specific rates, we refer the reader to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002, and FY 2006 Hospital-Specific Rates for FY 2012

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the applicable percentage increase to the hospital-specific rates applicable to SCHs and MDHs is 1.9 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 1.0 percentage point for multifactor productivity and less 0.1 percentage point) for hospitals that submit quality data or −0.1 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 1.0 percentage point for multifactor productivity, and less 0.1 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 and MDHs, we refer readers to section IV.H. of the preamble of this final rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the DRG classifications and the recalibration of the DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, for both SCHs and MDHs, the hospital-specific rate is adjusted by the DRG reclassification and recalibration budget neutrality factor of 0.997903, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate an SCH or MDH will receive for its discharges beginning on or after October 1, 2011.

c. Documentation and Coding Adjustment to the FY 2012 Hospital-Specific Rates for SCHs and MDHs

As discussed in section II.D. of the preamble of this final rule, because hospitals (SCHs and MDHs) paid based in whole or in part on the hospital-specific rate use the same MS–DRG system as other hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patients' severity of illness. Under section 1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid based on the standardized amount should not receive additional payments based on the effect of documentation and coding changes that do not reflect real changes in case-mix. Similarly, we believe that hospitals paid based on the hospital-specific rate should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patients' severity of illness. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50426) and in section II.D. of the preamble of this final rule, we believe they should be equally subject to a prospective budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. While we continue to believe that section 1886(d)(3)(A)(vi) of the Act does not provide explicit authority for application of the documentation and coding adjustment to the hospital-specific rates, we believe that we have the authority to apply the documentation and coding adjustment to the hospital-specific rates using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act.

As we discuss in section II.D. of the preamble of this final rule, our best estimate, based on the most recently available data, is that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of the documentation and coding changes on future payments to SCHs and MDHs. Unlike the case of standardized amounts paid to IPPS hospitals, prior to FY 2011 we had not made any previous adjustments to the hospital specific rates paid to SCHs and MDHs to account for documentation and coding changes. Consequently, in order to maintain consistency as far as possible with the adjustments applied to IPPS hospitals, we made an adjustment of −2.9 percent in FY 2011 to the hospital-specific rates paid to SCHs and MDHs.

As discussed above, we are making a −2.0 percent documentation and coding adjustment for IPPS hospitals in FY 2012 (−2.0 percent prospective adjustment plus a −2.9 percent recoupment adjustment in FY 2012, offset by the removal of the −2.9 percent recoupment adjustment for FY 2011). We believe that any adjustment to the hospital-specific rate due to documentation and coding effect should be as similar as possible to adjustments to the IPPS rate. Accordingly, we are making a −2.0 percent payment adjustment to the hospital-specific rate. We believe that a prospective adjustment of −2.0 percent allows CMS to maintain, to the extent possible, similarity and consistency in payment rates for different IPPS hospitals paid using the MS–DRG.

d. Adjustment To Restore Prior Rural Floor Budget Neutrality Offsets

As discussed in section II.A.4.d. of this Addendum, in light of the *Cape Cod* decision, we are adjusting hospital-specific amounts by 0.9 percent to restore to these amounts the offset for the rural floor and imputed floor in prior years. Our rationale and methodology for such adjustment are explained in section II.A.4.d of this Addendum. As with the standardized amount, we are returning 0.7 percentage point for FYs 1998 through 2004, and 0.2 percentage point for FY 2005 to the hospital-specific rates. We note that, in the FY 2006 IPPS final rule (70 FR 47429 and 47430), beginning in FY 2006, we changed our methodology and began applying only the DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates. Because the rural floor budget neutrality adjustment was not applied to the hospital-specific rates in FYs 2006 and 2007, we are not including FY 2006 and FY 2007 in our assessment. Therefore, to remove the effects of the rural floor from the hospital-specific rates for FYs 1998 through 2005, we are applying a one-time permanent adjustment of 0.9 percent to the hospital-specific rates (that is, a factor of 1.009). We received comments requesting complete explanations of the methodologies and data used in the calculation of the 1.1 and 0.9 percent adjustments to the standardized amount and hospital-specific rate. A complete summary and response to this comment can be found above in section II.A.4.d. of this Addendum.

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning on or After October 1, 2011, and Before October 1, 2012

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 Rate

The Puerto Rico prospective payment rate is determined as follows:

Step 1—Select the applicable average standardized amount considering the applicable wage index (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 (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 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 (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 rate and the national 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.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2012

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, hospitals were paid during a 10-year transition period (which extended through FY 2001) to change the payment methodology for Medicare acute care hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. Below we discuss the factors that we used to determine the capital Federal rate for FY 2012, which is effective for discharges occurring on or after October 1, 2011.

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 (regular and special) exceptions under § 412.348. 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.

For FYs 1992 through 1995, § 412.352 required that the capital Federal rate also be adjusted by a budget neutrality factor so that aggregate payments for inpatient hospital capital costs were projected to equal 90 percent of the payments that would have been made for capital-related costs on a reasonable cost basis during the respective fiscal year. That provision expired in FY 1996. Section 412.308(b)(2) describes the 7.4 percent reduction to the capital Federal rate that was made in FY 1994, and § 412.308(b)(3) describes the 0.28 percent reduction to the capital Federal rate made in FY 1996 as a result of the revised policy for paying for transfers. In FY 1998, we implemented section 4402 of Public Law 105–33, which required that, for discharges occurring on or after October 1, 1997, the budget neutrality adjustment factor in effect as of September 30, 1995, be applied to the unadjusted capital standard Federal rate and the unadjusted hospital-specific rate. That factor was 0.8432, which was equivalent to a 15.68 percent reduction to the unadjusted capital payment rates. An additional 2.1 percent reduction to the rates was effective from October 1, 1997 through September 30, 2002, making the total reduction 17.78 percent. As we discussed in the FY 2003 IPPS final rule (67 FR 50102) and implemented in § 412.308(b)(6), the 2.1 percent reduction was restored to the unadjusted capital payment rates effective October 1, 2002.

To determine the appropriate budget neutrality adjustment factor and the regular exceptions payment adjustment during the 10-year transition period, we developed a dynamic model of Medicare inpatient capital-related costs; that is, a model that projected changes in Medicare inpatient capital-related costs over time. With the expiration of the budget neutrality provision, the capital cost model was only used to estimate the regular exceptions payment adjustment and other factors during the transition period. As we explained in the FY 2002 IPPS final rule (66 FR 39911), beginning in FY 2002, an adjustment for regular exception payments is no longer necessary because regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991, and before October 1, 2001 (we refer readers to § 412.348(b) of our regulations). Because payments are no longer made under the regular exception policy effective with cost reporting periods beginning in FY 2002, we discontinued use of the capital cost model. The capital cost model and its application during the transition period are described in Appendix B of the FY 2002 IPPS final rule (66 FR 40099).

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. Prior to FY 1998, hospitals located in Puerto Rico were paid a blended operating rate that consisted of 75 percent of the applicable standardized amount specific to Puerto Rico hospitals and 25 percent of the applicable national average standardized amount. Similarly, prior to FY 1998, hospitals located in Puerto Rico were paid a blended capital rate that consisted of 75 percent of the applicable capital Puerto Rico-specific rate and 25 percent of the applicable capital Federal rate. However, effective October 1, 1997, in accordance with section 4406 of Public Law 105–33, 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 50 percent of the applicable standardized amount specific to Puerto Rico hospitals and 50 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, 1997, we also revised the methodology for computing capital payments to hospitals located in Puerto Rico to be based on a blend of 50 percent of the Puerto Rico capital rate and 50 percent of the national capital Federal rate.

As we discussed in the FY 2005 IPPS final rule (69 FR 49185), section 504 of Public Law 108–173 increased the national portion of the operating IPPS payments for hospitals located in Puerto Rico from 50 percent to 62.5 percent and decreased the Puerto Rico portion of the operating IPPS payments from 50 percent to 37.5 percent for discharges occurring on or after April 1, 2004 through September 30, 2004 (refer to the March 26, 2004 One-Time Notification (Change Request 3158)). In addition, section 504 of Public Law 108–173 provided that the national portion of operating IPPS payments for hospitals located in Puerto Rico is equal to 75 percent and the Puerto Rico-specific portion of operating IPPS payments is equal to 25 percent for discharges occurring on or after October 1, 2004. Consistent with that change in operating IPPS payments to hospitals located in Puerto Rico, for FY 2005 we revised the methodology for computing capital payments to hospitals located in Puerto Rico to be based on a blend of 25 percent of the Puerto Rico-specific capital rate and 75 percent of the national capital Federal rate for discharges occurring on or after October 1, 2004 (69 FR 49185).

A. Determination of Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2012. In particular, we explain why the FY 2012 capital Federal rate increases approximately 0.3 percent, compared to the FY 2011 capital Federal rate. As discussed in the impact analysis in Appendix A of this final rule, we estimate that capital payments per discharge will increase 1.8 percent during that same period. Because capital payments constitute about 10 percent of hospital payments, a percent change in the capital Federal rate yields only about a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate-of-increase as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The update factor for FY 2012 under that framework is 1.5 percent based on the best data available at this time. The update factor under that framework is based on a projected 1.5 percent increase in the CIPI, a 0.0 percent adjustment for intensity, a 0.0 percent adjustment for case-mix, a 0.0 percent adjustment for the FY 2010 DRG reclassification and recalibration, and a forecast error correction of 0.0 percent. 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 2012 CIPI projection in that same section of this Addendum. We note, as discussed in section VI.E.1. of the preamble of this final rule, we are applying a -1.0 percent adjustment to the capital rate in FY 2012 to account for the effect of changes in documentation and coding under the MS–DRGs that do not correspond to changes in real increases in patients' severity of illness. Below we describe the policy adjustments that we are applying in the update framework for FY 2012.

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

weight 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 in the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2012, we are projecting a 1.0 percent total increase in the case-mix index. We estimated that the real case-mix increase will also equal 1.0 percent for FY 2012. The net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, as we proposed, the net adjustment for case-mix change in FY 2012 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. 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 2010 DRG reclassification and recalibration as part of our update for FY 2012. To adjust for reclassification and recalibration effects, under our historical methodology, we would run the FY 2010 cases through the FY 2009 GROUPER and through the FY 2010 GROUPER. If the resulting ratio of the case-mix indices did not equate to 1.0, in the update framework for FY 2012, we would make an adjustment to account for the reclassification and recalibration effects in FY 2010. In the update framework for FY 2011 (the FY 2011 IPPS final rule (75 FR 50435)), we did not adjust for reclassification and recalibration effects from FY 2009 because it was accounted for in the documentation and coding adjustment to the capital Federal rates for FY 2011. For FY 2012, we are not performing an analysis of changes in case-mix in FY 2010 due to the effect of documentation and coding, as this would be most consistent with our approach under the operating IPPS. Therefore, at this time, under our broad authority in section 1886(g) of the Act, as we proposed, we are making a 0.0 percent adjustment for reclassification and recalibration in the update framework. We may evaluate the effect of FY 2010 reclassification and recalibration if we perform an analysis of the documentation and coding effect in FY 2010 in future rulemaking.

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 -0.2 percentage point was calculated for the FY 2012 update. That is, current historical data indicate that the forecasted FY 2010 CIPI (1.2 percent) used in calculating the FY 2010 update factor was 0.2 percentage point higher than the actual realized price increases (1.0 percent). The two primary contributing factors for the FY 2010 CIPI forecast being slightly higher than the actual FY 2010 increase in the CIPI were that the prices for the nonprofit and government interest cost category grew slower than what had been forecasted, and the prices for the other capital expenses cost category also grew slower than what had been forecasted. Because the estimation of the FY 2010 forecast error for the CIPI is not greater than 0.25 percentage point, as we proposed, we are making a 0.0 percent adjustment for forecast error in the update for FY 2012.

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 non-cost-effective services. Our intensity measure is based on a 5-year average.

Historically, we calculated case-mix constant intensity as the change in total charges per admission, 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.

We developed a Medicare-specific intensity measure based on a 5-year average. Past studies of case-mix change by the RAND Corporation (*Has DRG Creep Crept Up? Decomposing the Case Mix Index Change Between 1987 and 1988* by G. M. Carter, J. P. Newhouse, and D. A. Relles, R–4098–HCFA/ProPAC (1991)) suggest that real case-mix change was not dependent on total change, but was usually a fairly steady increase of 1.0 to 1.5 percent per year. However, we used 1.4 percent as the upper bound because the RAND study did not take into account that hospitals may have induced doctors to document medical records more completely in order to improve payment.

In accordance with § 412.308(c)(1)(ii), we began updating the capital standard Federal rate in FY 1996 using an update framework that takes into account, among other things, allowable changes in the intensity of hospital services, as noted above. For much of the last decade, we found that the charge data appeared to be skewed as a result of hospitals attempting to maximize outlier payments, while lessening costs, and we established a 0.0 percent adjustment for intensity in each of those years. Therefore, for FY 2011, in an effort to further refine the intensity adjustment and more accurately reflect allowable changes in hospital intensity, we revised our intensity measure to use changes in hospital *costs* per discharge over a 5-year average rather than changes in hospital charges, which had been the basis of the intensity adjustment in prior years. The unique nature of capital—how and when it is purchased, its longevity, and how it is financed—creates a greater degree of variance in capital cost among hospitals than does operating cost. As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436), we believe that using changes in capital costs per discharge as the basis for the intensity adjustment in lieu of changes in charges will decrease some of the variability of this adjustment. In this final rule, for FY 2012, as we proposed, we are using an intensity measure that is based on a 5-year adjusted average of cost per discharge, as we did for FY 2011. Therefore, the intensity measure for FY 2012 is based on an average of cost per discharge data from the 5-year period beginning with FY 2005 and extending through FY 2009. Based on these data, we estimated that case-mix constant intensity declined during FYs 2005 through 2009. In the past, when we found intensity to be declining, we believed a zero (rather than negative) intensity adjustment was appropriate. Consistent with this approach, because we estimate that intensity declined during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2012. Therefore, as we proposed, we are making a 0.0 percent adjustment for intensity in the update for FY 2012.

Above, we described the basis of the components used to develop the 1.5 percent capital update factor under the capital update framework for FY 2012 as shown in the table below.

CMS FY 2012 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index	1.5
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	−1.0
Projected Case-Mix Change	1.0
Subtotal	1.5
Effect of FY 2010 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.5

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2011 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2012. (MedPAC's Report to the Congress: Medicare Payment Policy, March 2011, 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 2011, we estimated that outlier payments for capital would equal 5.96 percent of inpatient capital-related payments based on the capital Federal rate in FY 2011. Based on the thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs will equal 6.18 percent for inpatient capital-related payments based on the capital Federal rate in FY 2012. Therefore, we are applying an outlier adjustment factor of 0.9382 in determining the capital Federal rate. Thus, we estimate that the percentage of capital outlier payments to total capital standard payments for FY 2012 will be slightly higher than the percentage for FY 2011. This slight increase in estimated capital outlier payments is primarily due to the decrease 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 is lower, cases will receive higher outlier payments and more cases will 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 FY 2012 outlier adjustment of 0.9382 is a −0.23 percent change from the FY 2011 outlier adjustment of 0.9404. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2012 is 0.9977 (0.9382/0.9404). Thus, the outlier adjustment will decrease the FY 2012 capital Federal rate by 0.23 percent compared with the FY 2011 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. Because we implemented a separate GAF for Puerto Rico, we apply separate budget neutrality adjustments for the national GAF and the Puerto Rico GAF. We apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. Separate adjustments were unnecessary for FY 1998 and earlier because the GAF for Puerto Rico was implemented in FY 1998.

In the past, we used the actuarial capital cost model (described in Appendix B of the FY 2002 IPPS final rule (66 FR 40099)) to estimate the aggregate payments that would have been made on the basis of the capital Federal rate with and without changes in the DRG classifications and weights and in the GAF to compute the adjustment required to maintain budget neutrality for changes in DRG weights and in the GAF. During the transition period, the capital cost model was also used to estimate the regular exception payment adjustment factor. As we explained in section III.A. of this Addendum, beginning in FY 2002, an adjustment for regular exception payments was no longer necessary. Therefore, we no longer use the capital cost model. Furthermore, as discussed below, special exceptions payments will no longer be made in FY 2012, and an exceptions payment adjustment factor will no longer be necessary, as there are no remaining hospitals eligible to receive special exceptions payments.

To determine the proposed factors for FY 2012, we compared (separately for the national capital rate and the Puerto Rico capital rate) estimated aggregate capital Federal rate payments based on the FY 2011 MS–DRG classifications and relative weights and the FY 2011 GAF to estimated aggregate capital Federal rate payments based on the FY 2011 MS–DRG classifications and relative weights and the FY 2012 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we are applying an incremental budget neutrality adjustment of 1.0010 for FY 2012 to the previous cumulative FY 2011 adjustment of 0.9902, yielding an adjustment of 0.9912, through FY 2012. For the Puerto Rico GAFs, we are applying an incremental budget neutrality adjustment of 1.0085 for FY 2012 to the previous cumulative FY 2011 adjustment of 0.9965, yielding a cumulative adjustment of 1.0049 through FY 2012.

We then compared estimated aggregate capital Federal rate payments based on the FY 2011 DRG relative weights and the FY 2012 GAFs to estimate aggregate capital Federal rate payments based on the cumulative effects of the FY 2012 MS–DRG classifications and relative weights and the FY 2012 GAFs. The incremental adjustment for DRG classifications and changes in relative weights is 0.9994 both nationally and for Puerto Rico. The cumulative adjustments for MS–DRG classifications and changes in relative weights and for changes in the GAFs through FY 2012 are 0.9905 nationally and 1.0043 for Puerto Rico. We note that all the values are calculated with unrounded numbers. The following table summarizes the adjustment factors for each fiscal year:

BUDGET NEUTRALITY ADJUSTMENT FOR DRG RECLASSIFICATIONS AND RECALIBRATION AND THE GEOGRAPHIC ADJUSTMENT FACTORS

Fiscal year	National				Puerto Rico			
	Incremental adjustment			Cumulative	Incremental adjustmant			Cumulative
	Geographic adjustment factor	DRG Reclassifications and recalibration	Combined		Geographic adjustment factor	DRG Reclassifications and recalibration	Combined	
1992	.....	.....	.....	1.00000	.....	.....	.....	.....
1993	.....	.....	0.99800	0.99800	.....	.....	.....	.....
1994	.....	.....	1.00531	1.00330	.....	.....	.....	.....
1995	.....	.....	0.99980	1.00310	.....	.....	.....	.....
1996	.....	.....	0.99940	1.00250	.....	.....	.....	.....
1997	.....	.....	0.99873	1.00123	.....	.....	.....	.....
1998	.....	.....	0.99892	1.00015	.....	.....	.....	1.00000
1999	0.99944	1.00335	1.00279	1.00294	0.99898	1.00335	1.00233	1.00233
2000	0.99857	0.99991	0.99848	1.00142	0.99910	0.99991	0.99901	1.00134
2001 [1]	0.99782	1.00009	0.99791	0.99933	1.00365	1.00009	1.00374	1.00508
2001 [2]	0.99771 [3]	1.00009 [3]	0.99780 [3]	0.99922	1.00365 [3]	1.00009 [3]	1.00374 [3]	1.00508
2002	0.99666 [4]	0.99668 [4]	0.99335 [4]	0.99268	0.98991 [4]	0.99668 [4]	0.99662 [4]	0.99164
2003 [5]	0.99915	0.99662	0.99577	0.98848	1.00809	0.99662	1.00468	0.99628
2003 [6]	0.99896 [7]	0.99662 [7]	0.99558 [7]	0.98830	1.00809	0.99662	1.00468	0.99628
2004 [8]	1.00175 [9]	1.00081 [9]	1.00256 [9]	0.99083	1.00028	1.00081	1.00109	0.99736
2004 [10]	1.00164 [9]	1.00081 [9]	1.00245 [9]	0.99072	1.00028	1.00081	1.00109	0.99736
2005 [11]	0.99967 [12]	1.00094	1.00061 [12]	0.99137	0.99115	1.00094	0.99208	0.98946
2005 [13]	0.99946 [12]	1.00094	1.00040 [12]	0.99117	0.99115	1.00094	0.99208	0.98946
2006	1.00185 [14]	0.99892	1.00076 [14]	0.99198	1.00762	0.99892	1.00653	0.99592
2007	1.00000	0.99858	0.99858	0.99057	1.00234	0.99858	1.00092	0.99683
2008	1.00172	0.99792	0.99963	0.99021	1.00079	0.99792	0.99870	0.99554
2009 [15]	1.00206	0.99945	1.00150	0.99170	1.00097	0.99945	1.00041	0.99595
2010 [16]	0.99989	0.99945	0.99941	0.99112	1.00141	0.99953	1.00094	0.99688
2011 [17]	0.99989	0.99914	0.99903	0.99016	1.00050	0.99914	0.999564	0.99652
2012 [18]	1.00104	0.99935	1.00039	0.99054	1.00845	0.99935	1.00780	1.00429

[1] Factors effective for the first half of FY 2001 (October 2000 through March 2001).
[2] Factors effective for the second half of FY 2001 (April 2001 through September 2001).
[3] Incremental factors are applied to FY 2000 cumulative factors.
[4] Incremental factors are applied to the cumulative factors for the first half of FY 2001.
[5] Factors effective for the first half of FY 2003 (October 2002 through March 2003).
[6] Factors effective for the second half of FY 2003 (April 2003 through September 2003).
[7] Incremental factors are applied to FY 2002 cumulative factors.
[8] Factors effective for the first half of FY 2004 (October 2003 through March 2004).
[9] Incremental factors are applied to the cumulative factors for the second half of FY 2003.
[10] Factors effective for the second half of FY 2004 (April 2004 through September 2004).
[11] Factors effective for the first quarter of FY 2005 (September 2004 through December 2004).
[12] Incremental factors are applied to average of the cumulative factors for the first half (October 1, 2003 through March 31, 2004) and second half (April 1, 2004 through September 30, 2004) of FY 2004.
[13] Factors effective for the last three quarters of FY 2005 (January 2005 through September 2005).
[14] Incremental factors are applied to average of the cumulative factors for 2005.
[15] Final factors for FY 2009, including the implementation of section 124 of Public Law 110–275, which affects wage indices and GAFs for FY 2009.
[16] Final revised factors for FY 2010 which reflect the effect of the provisions of the Affordable Care Act.
[17] Final factors for FY 2011.
[18] Final factors for FY 2012.

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 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 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.

For FY 2011, we established a GAF/DRG budget neutrality factor of 0.9990 (75 FR 50437). For FY 2012, we are establishing a GAF/DRG budget neutrality factor of 1.0004. The GAF/DRG budget neutrality factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement 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 incremental change in the adjustment from FY 2011 to FY 2012 is 1.0004. The cumulative change in the capital Federal rate due to this adjustment is 0.9905 (the product of the incremental factors for FYs 1995 through 2011 and the incremental factor of 1.0004 for FY 2012). (We note that averages of the incremental factors that were in effect during FYs 2005 and 2006, respectively, were used in the calculation of the cumulative adjustment of 0.9905 for FY 2012.)

The factor accounts for the MS–DRG reclassifications and recalibration and for changes in the GAFs. It also incorporates the effects on the GAFs of FY 2012 geographic reclassification decisions made by the MGCRB compared to FY 2011 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Exceptions Payment Adjustment Factor

Section 412.308(c)(3) of our regulations requires that the capital standard Federal rate be reduced by an adjustment factor equal to the estimated proportion of additional payments for both regular exceptions and special exceptions under § 412.348 relative to total capital PPS payments. In estimating the proportion of regular exception payments to total capital PPS payments during the transition period, we used the actuarial capital cost model originally developed for determining budget neutrality (described in Appendix B of the FY 2002 IPPS final rule (66 FR 40099)) to determine the exceptions payment adjustment factor, which was applied to both the Federal and hospital-specific capital rates.

Since FY 2002, an adjustment for regular exception payments was no longer necessary in determining the capital Federal rate because, in accordance with § 412.348(b), regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001. Accordingly, in FY 2002 and subsequent fiscal years, no payments are made under the regular exceptions provision (66 FR 39949). Furthermore, there are no longer any remaining hospitals eligible to receive a special exceptions payment under § 412.348(g) because they have reached the limitation on the period for exception payments under § 412.348(g)(7). A hospital qualifying for a special exceptions payment could receive exceptions payments for up to 10 years from the year in which it completed a project that met the applicable criteria under § 412.348(g). However, the project had to be completed no later than the end of the hospital's last cost reporting period beginning before October 1, 2001. Therefore, FY 2012 will be the final year any hospital could have received a special exceptions payment. However, as we indicated above, based on the date the projects were completed, there are no remaining hospitals eligible to receive a special exceptions payment in FY 2012, which negates the need for a special exceptions adjustment for FY 2012. Furthermore, we note that special exceptions adjustments will no longer be made in subsequent years because FY 2012 is the final year payments could have been made to eligible hospitals in accordance with § 412.348(g)(7).

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50439), we estimated that total (special) exceptions payments for FY 2011 would equal 0.04 percent of aggregate payments based on the capital Federal rate. Therefore, we applied an exceptions adjustment factor of 0.9996 (1 − 0.0004) to determine the FY 2011 capital Federal rate. As we stated above, because there are no special exceptions payments in FY 2012, we are no longer applying an exceptions payment adjustment factor to the capital Federal rate for FY 2012. However, the exceptions reduction factors were not built permanently into the capital rates; that is, the factors were not applied cumulatively in determining the capital Federal rate. Therefore, we are applying a permanent factor of 1.0004 (1/0.9996) in determining the FY 2012 capital Federal rate to restore the reduction that resulted from the 0.9996 exceptions adjustment factor that was applied in determining the FY 2011 capital Federal rate.

5. Capital Standard Federal Rate for FY 2012

For FY 2011, we established a capital Federal rate of $420.01 (75 FR 50439). We are establishing an update of 1.5 percent in determining the FY 2012 capital Federal rate for all hospitals. However, as discussed in greater detail in section V.E. of the preamble of this final rule, under the statutory authority at section 1886(g) of the Act, consistent with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, we are making an additional 1.0 percent reduction to the national capital Federal payment rate in FY 2012 to account for the effect of changes in case-mix resulting from documentation and coding changes that do not reflect real changes in the case-mix in light of the adoption of MS–DRGs. Accordingly, we are applying a cumulative documentation and coding adjustment factor of 0.9479 in determining the FY 2012 capital Federal rate (that is, the existing −0.6 percent adjustment in FY 2008 plus the −0.9 percent adjustment in FY 2009, plus the −2.9 percent adjustment for FY 2011, plus the −1.0 percent adjustment for FY 2012, computed as 1 divided by (1.006 × 1.009 × 1.029 × 1.010). (We note that we did not apply a documentation and coding adjustment to the capital Federal rate in FY 2010 (74 FR 43927).) As a result of the 1.5 percent update and other budget neutrality factors discussed above, we are establishing a national capital Federal rate of $421.42 for FY 2012. The national capital Federal rate for FY 2012 was calculated as follows:

- The FY 2012 update factor is 1.015, that is, the update is 1.5 percent.
- The FY 2012 budget neutrality adjustment factor that is applied to the capital standard Federal payment rate for changes in the MS–DRG classifications and relative weights and changes in the GAFs is 1.004.
- The FY 2012 outlier adjustment factor is 0.9382.
- The FY 2012 (special) exceptions payment adjustment factor is 1.0000 because we project that there will be no exceptions payments made in FY 2012 as discussed above in section III.A. of this Addendum. However, we are applying a permanent factor of 1.0004 (1/0.9996) in determining the FY 2012 capital Federal rate to restore the reduction that resulted from the 0.9996 exceptions adjustment factor applied in determining the FY 2011 capital Federal rate.
- The cumulative adjustment factor for FY 2012 applied to the national capital Federal rate for changes in documentation and coding under the MS–DRGs is 0.9479.

Because the capital Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, indirect medical education costs, and payments to hospitals serving a disproportionate share of low-income patients, we are not making additional adjustments in the capital standard Federal rate for these factors, other than the budget neutrality factor for changes in the MS–DRG classifications and relative weights and for changes in the GAFs.

We are providing the following chart that shows how each of the factors and adjustments for FY 2012 affects the computation of the FY 2012 national capital Federal rate in comparison to the FY 2011 national capital Federal rate. The FY 2012 update factor has the effect of increasing the capital Federal rate by 1.5 percent compared to the FY 2011 capital Federal rate. The GAF/DRG budget neutrality factor of 1.0004 has the effect of increasing the capital Federal rate by 0.04 percent. The FY 2012 outlier adjustment factor has the effect of decreasing the capital Federal rate by 0.23 percent compared to the FY 2011 capital Federal rate. The FY 2012 special exceptions payment adjustment factor to restore the FY 2011 exceptions adjustment factor of 0.9996 has the net effect of increasing the FY 2012 national capital Federal rate by 0.04 percent as compared to the FY 2011 national capital Federal rate. The combined effect of all the changes will increase the national capital Federal rate by approximately 0.34 percent compared to the FY 2011 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2011 CAPITAL FEDERAL RATE AND FY 2012 CAPITAL FEDERAL RATE

	FY 2011	FY 2012	Change	Percent change
Update Factor [1]	1.0150	1.0150	1.0150	1.50
GAF/DRG Adjustment Factor [1]	0.9990	1.0004	1.0004	0.04
Outlier Adjustment Factor [2]	0.9404	0.9382	0.9977	−0.23
Exceptions Adjustment Factor [3]	0.9996	1.0000	1.0004	0.04
MS–DRG Documentation and Coding Adjustment Factor	0.9574 [4]	0.9479 [5]	0.9901 [6]	−0.99
Capital Federal Rate [7]	$420.01	$421.42	1.0034	0.34

[1] The update factor and the GAF/DRG budget neutrality factors are built permanently into the capital rates. Thus, for example, the incremental change from FY 2011 to FY 2012 resulting from the application of the 1.0004 GAF/DRG budget neutrality factor for FY 2012 is a net change of 1.0004.

[2] The outlier reduction factor is not built permanently into the capital rate; that is, the factor is not applied cumulatively in determining the capital rate. Thus, for example, the net change resulting from the application of the FY 2012 outlier adjustment factor is 0.9382/0.9404, or 0.9977.

[3] There are no longer any hospitals eligible to receive special exception adjustments in FY 2012, but since the exceptions payment adjustment is not cumulative, we are restoring the 0.9996 special exceptions adjustment applied to the FY 2011 capital rate.

[4] The documentation and coding adjustment factor includes the −0.6 percent in FY 2008, −0.9 percent in FY 2009, no additional reduction in FY 2010, and the −2.9 percent in FY 2011.

[5] The documentation and coding adjustment factor includes the −0.6 percent in FY 2008, −0.9 percent in FY 2009, no additional reduction in FY 2010, the −2.9 percent in FY 2011, and the proposed −1.0 percent in FY 2012.

[6] The change is measured from the FY 2011 cumulative factor of 0.9574.

[7] Sum of percent change may not sum due to rounding.

In this final rule, we also are providing the following chart that shows how the final FY 2012 capital Federal rate differs from the proposed FY 2012 capital Federal rate as presented in the FY 2012 IPPS/LTCH PPS proposed rule.

COMPARISON OF FACTORS AND ADJUSTMENTS: PROPOSED FY 2012 CAPITAL FEDERAL RATE AND FINAL FY 2012 CAPITAL FEDERAL RATE

	Proposed FY 2012	Final FY 2012	Percent change
Update Factor	1.0150	1.0150	0.00
GAF/DRG Adjustment Factor	1.0005	1.0004	−0.01
Outlier Adjustment Factor	0.9406	0.9382	−0.26
Exceptions Adjustment Factor	1.0000	1.0000	0.00
MS–DRG Documentation and Coding Adjustment Factor	0.9479	0.9479	0.00
Capital Federal Rate	$422.54	$421.42	−0.27

6. Special Capital Rate for Puerto Rico Hospitals

Section 412.374 provides for the use of a blended payment system for payments 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, as discussed in section V. of the preamble of this final rule, beginning with discharges occurring on or after October 1, 2004, capital payments 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 adjustments for the national GAF and for the Puerto Rico GAF. However, we apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. The budget neutrality adjustments for the national GAF and for the Puerto Rico GAF, and the budget neutrality factor for MS–DRG reclassifications and recalibration (which is the same nationally and for Puerto Rico) 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). In FY 1998, we implemented a 17.78 percent reduction to the Puerto Rico capital rate as a result of Public Law 105–33. In FY 2003, a small part of that reduction was restored.

For FY 2011, the special capital rate for hospitals located in Puerto Rico was $197.66 (75 FR 50441). Consistent with our adjustment to the FY 2011 Puerto Rico-specific standardized amount, under the Secretary's broad authority under section 1886(g) of the Act, we established an adjustment to the Puerto Rico-specific capital rate of −2.6 percent in FY 2011 for the cumulative increase in case-mix due to changes in documentation and coding under the MS–DRGs for FYs 2008 and 2009. The −2.6 percent adjustment to the capital Puerto Rico-specific rate that we made in FY 2011 reflects the entire amount of our current estimate of the effects of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico. Consequently, in this final rule, we are not making any additional adjustments for the effect of documentation and coding that did not reflect real changes in case-mix to the capital Puerto Rico-specific rate for FY 2012. Therefore, with the changes we are making to the other factors used to determine the capital rate, the FY 2012 special capital rate for hospitals in Puerto Rico is $203.86.

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2012

Because the 10-year capital PPS transition period ended in FY 2001, all hospitals (except ''new'' hospitals under § 412.324(b) and under § 412.304(c)(2)) are paid based on 100 percent of the capital Federal rate in FY 2012.

For purposes of calculating payments for each discharge during FY 2012, the capital standard Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The outlier thresholds for FY 2012 are in section II.A. of this Addendum. For FY 2012, 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 fixed-loss amount of $22,385.

Currently, as provided in § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price

changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021), we rebased and revised the CIPI to a FY 2006 base year to reflect the more current structure of capital costs in hospitals. A complete discussion of this rebasing is provided in section IV. of the preamble of that final rule.

2. Forecast of the CIPI for FY 2012

Based on the latest forecast by IHS Global Insight, Inc. (second quarter of 2011), we are forecasting the FY 2006-based CIPI to increase 1.5 percent in FY 2012. This reflects a projected 1.9 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.0 percent increase in other capital expense prices in FY 2012, partially offset by a projected 1.3 percent decline in vintage-weighted interest expenses in FY 2012. The weighted average of these three factors produces the 1.5 percent increase for the FY 2006-based CIPI as a whole in FY 2012.

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages

Historically, 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 all categories of excluded providers (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.)

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26037), we proposed that the FY 2012 rate-of-increase percentage for updating the target amounts for cancer and children's hospitals and RNHCIs be the estimated percentage increase in the FY 2012 IPPS operating market basket, estimated to be 2.8 percent, in accordance with applicable regulations at § 413.40. We also proposed to use the most recent data available to determine the estimated percentage increase for the FY 2012 IPPS operating market basket. For this final rule, we are using the most recent data available to determine the FY 2012 IPPS operating market basket update. Based on IHS Global Insight, Inc.'s second quarter 2011 forecast, with historical data through the 2011 first quarter, the IPPS operating market basket update is 3.0 percent for FY 2012. Therefore, for cancer and children's hospitals and RNHCIs, the FY 2012 rate-of-increase percentage that is applied to the FY 2011 target amounts in order to determine the FY 2012 target amount is 3.0 percent.

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 is based on cost-based reimbursement rules under 42 CFR Part 413 (certain providers do not receive a transitioning 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 VII. of the preamble and section V. of the Addendum to this final rule for the update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2012. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

We did not receive any public comments on our proposals under this section.

V. Changes to the Payment Rate for the LTCH PPS for FY 2012

A. LTCH PPS Standard Federal Rate for FY 2012

1. Background

In section VII. of the preamble of this final rule, we discuss our changes to the payment rates, factors, and specific policies under the LTCH PPS for FY 2012.

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 considered 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).

Several provisions of the Affordable Care Act revised the annual update to the standard Federal rate, beginning in RY 2010. Specifically, section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as ''the multifactor productivity (MFP) adjustment'') as discussed in section VII.E.2.d. of the preamble of this final rule.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.E.2.d. of the preamble of this final rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we employ ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For FY 2011, 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 2.5 percent, the 0.50 percentage point reduction required by sections 1886(m)(3)(A)(i) and (m)(4)(B) of the Act, and an adjustment to account for the increase in case-mix in prior periods (FYs 2008 and 2009) that resulted from the effect of documentation and coding practices of −2.5 percent. Accordingly, at § 412.523(c)(vii) of the regulations, we established an annual update of −0.49 percent to the standard Federal rate for FY 2011 (75 FR 50443 through 50444).

In this final rule, for FY 2012, as discussed in greater detail in section VII.E.2. of the preamble of this final rule, we are establishing an annual update to the LTCH PPS standard Federal rate of 1.8 percent based on the full estimated increase in the LTCH PPS market basket of 2.9 percent less the MFP adjustment of 1.0 percentage point required under 1886(m)(3)(A)(ii) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(i) and (m)(4)(C) of the Act. As discussed in greater detail below, for FY 2012, we are not making an adjustment to account for the increase in case-mix in a prior period (FY 2010) resulting from the effect of documentation and coding.

2. Development of the FY 2012 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. We also continue to believe it is appropriate that the standard Federal rate be offset by an adjustment to account for any effect of documentation and coding practices that does not reflect increased severity of illness. Such an adjustment protects the integrity of the Medicare Trust Funds by ensuring that the LTCH PPS payment rates better reflect the true costs of treating LTCH patients.

Consistent with past LTCH payment policy, we have continued to monitor the most recent available LTCH data. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26038), we stated that, based on an analysis of FY 2010 LTCH claims from the December 2010 update of the MedPAR files, it did not appear that an adjustment for the effect of documentation and coding in FY 2010 was warranted. Therefore, we did not propose to make an adjustment for the effect of documentation and coding during FY 2010 in our proposed annual update to the LTCH PPS standard Federal rate for FY 2012. Furthermore, we proposed that, consistent with our historical practice of using the best available data, if more recent data subsequently became available, we would examine such data for the final rule to determine if an adjustment for the effect of documentation and coding during FY 2010 is warranted.

For this final rule, based on an analysis of the most recent available data, that is FY 2010 LTCH claims from the March 2011 update of the MedPAR file, it does not appear that an adjustment for the effect of documentation and coding in FY 2010 is warranted. Therefore, in this final rule, as we proposed, we are not making an adjustment for the effect of documentation and coding during FY 2010 in our annual update to the LTCH PPS standard Federal rate for FY 2012.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444), we established an annual update to the LTCH PPS standard Federal rate for FY 2011 based on the full estimated LTCH PPS market basket increase of 2.5 percent, the 0.50 percentage point reduction required by sections 1886(m)(3)(A)(i), (m)(3)(A)(ii), and (m)(4)(B) of the Act, and an adjustment to account for the increase in case-mix in prior periods (FYs 2008 and 2009) that resulted from the effect of documentation and coding practices of −2.5 percent. Accordingly, at § 412.523(c)(vii), we established an annual update to the standard Federal rate for FY 2011 of −0.49 percent. That is, we applied an update factor of 0.9951 (calculated as 1.020 × 1 divided by 1.025 = 0.9951 or −0.49 percent) to the RY 2010 Federal rate of $39,794.95 (as established in the June 2, 2010 FY 2010 IPPS/RY 2010 LTCH PPS notice (75 FR 31128 through 31129)) to determine the FY 2011 standard Federal rate. Consequently, we established a standard Federal rate for FY 2011 of $39,599.95, which is applicable to LTCH PPS discharges occurring on or after October 1, 2010, through September 30, 2011.

In the FY 2012 IPPS/LTCH PPS proposed rule, for FY 2012, as noted above and as discussed in greater detail in section VII.E.2. of the preamble of the proposed rule, consistent with our historical practice, we proposed to establish an annual update to the LTCH PPS standard Federal rate of 1.5 percent, based on the full estimated increase in the proposed LTCH PPS market basket of 2.8 percent less the proposed MFP adjustment of 1.2 percentage points required under 1886(m)(3)(A)(ii) and less the 0.1 percentage point required by sections 1886(m)(3)(A)(i) and(m)(4)(C) of the Act. Accordingly, we proposed an update factor to the standard Federal rate for FY 2012 of 1.5 percent. That is, under proposed § 412.523(c)(viii), we proposed to apply a factor of 1.015 to the FY 2011 standard Federal rate of $39,599.95 (as established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50444)) to determine the FY 2012 standard Federal rate. Furthermore, as discussed in greater detail in section VII.E.3. of the preamble of the proposed rule, for FY 2012, we proposed to apply an area wage level budget neutrality factor of 0.99723 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 proposed to establish a standard Federal rate for FY 2012 of $40,082.61 (calculated as $39,599.95 × 1.015 × 0.99723), which would be applicable to LTCH PPS discharges occurring on or after October 1, 2011, through September 30, 2012.

Comment: Several commenters expressed general support for the development of the proposed standard Federal rate. In particular, commenters agreed that an adjustment for the effect of documentation and coding during FY 2010 was not warranted.

Response: We appreciate the commenters' support for the development of the proposed standard Federal rate. We are finalizing our proposed approach for the development of the standard Federal rate for FY 2012 (based on the latest available data) without modification in this final rule.

In this final rule, for FY 2012, as noted above and as discussed in greater detail in section VII.E.2. of the preamble of the final rule, consistent with our historical practice, we are establishing an annual update to the LTCH PPS standard Federal rate of 1.8 percent, based on the full estimated increase in the LTCH PPS market basket of 2.9 percent less the MFP adjustment of 1.0 percentage point required under section 1886(m)(3)(A)(ii) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(i) and(m)(4)(C) of the Act. Accordingly, the update factor to the standard Federal rate for FY 2012 is 1.8 percent. That is, under § 412.523(c)(viii), we apply a factor of 1.018 to the FY 2011 standard Federal rate of $39,599.95 (as established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50444)) to determine the FY 2012 standard Federal rate. Furthermore, as discussed in greater detail in section VII.E.3. of the preamble of this final rule, for FY 2012, we are applying an area wage level budget neutrality factor of 0.99775 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) will not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Consequently, we are establishing a standard Federal rate for FY 2012 of $40,222.05 (calculated as $39,599.95 x 1.018 x 0.99775), which will be applicable to LTCH PPS discharges occurring on or after October 1, 2011, through September 30, 2012.

B. Adjustment for Area Wage Levels Under the LTCH PPS for FY 2012

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.

As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56015), 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 56017 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. 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), effective October 1, 2004 (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 updated the LTCH PPS CBSA-based labor market area definitions annually since they were adopted for RY 2006 (73 FR 26812 through 26814, 74 FR 44023 through 44204, and 75 FR 50444 through 50445).

As we discussed in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26039), 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 they are also reflected in this FY 2012 final rule. In 2013, OMB plans to announce new area delineations based on its 2010 standards (75 FR 37246) and the 2010 Census data.

The OMB bulletin is available on the OMB Web site at *http://www.whitehouse.gov/OMB-go* to ''Agency Information'' and click on ''Bulletins''.

3. 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, and all other labor-intensive services) and a labor-related portion of capital costs using the applicable LTCH PPS market basket. Currently, as established in the RY 2007 LTCH PPS final rule (71 FR 27829 through 27830), the LTCH PPS labor-related share is based on the relative importance of the labor-related share of operating costs and capital costs of the rehabilitation, psychiatric, and long-term care hospital (RPL) market basket based on FY 2002 data, as those were the best available data at that time that reflected the cost structure of LTCHs. For the past 4 years (RY 2008, RY 2009, RY 2010, and FY 2011), we updated the LTCH PPS labor-related share annually based on the latest available data for the FY 2002-based RPL market basket. For FY 2011, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 20445), we established a labor-related share of 75.271 percent based on the best available data at that time for the FY 2002-based RPL market basket for FY 2011. (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).)

As discussed in section VII.D. of the preamble of this final rule, we are finalizing our proposal to revise and rebase the market basket used under the LTCH PPS beginning in FY 2012 by adopting the newly created FY 2008-based RPL market basket. We also are finalizing our proposal to determine the labor-related share for FY 2012 as the sum of the FY 2012 relative importance of each labor-related cost category of the FY 2008-based RPL market basket. (The summary of comments we received on the proposed LTCH PPS labor-related share for FY 2012 and our responses can be found in section VII.D.3.f. of the preamble of this final rule.)

As we discuss in section VII.D.3.f. of the preamble of this final rule, we are establishing a labor-related share under the LTCH PPS for FY 2012 based on IHS Global Insight, Inc.'s second quarter 2011 forecast of the FY 2008-based RPL market basket for FY 2012, as these are the most recent available data that reflect the cost structure of LTCHs. Consistent with our proposal, the labor-related share for FY 2012 is the sum of the FY 2012 relative importance of each labor-related cost category of the FY 2008-based RPL market basket, and reflects the different rates of price change for these cost categories between the base year (FY 2008) and FY 2012. As discussed in greater detail in section VII.D.3.f. of this preamble, the sum of the relative importance for FY 2012 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All-Other: Labor-related Services) is 66.564 percent and the proposed labor-related share of capital costs is 3.635 percent. Therefore, in this final rule, under the authority set forth in section 123 of the BBRA as amended by section 307(b) of the BIPA, we are establishing a labor-related share of 70.199 percent (66.564 percent plus 3.635 percent) under the LTCH PPS for the FY 2012, which will be effective for discharges occurring on or after October 1, 2011, and through September 30, 2012. (For additional details on the development of the LTCH PPS labor-related share for FY 2012, we refer readers to section VII.D.3.f. of the preamble of this final rule.)

4. LTCH PPS Wage Index for FY 2012

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 2011 LTCH PPS final rule (75 FR 50445 through 50446), we calculated the FY 2011 LTCH PPS wage index values using the same data used for the FY 2011 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2007), 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 2011 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). 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 2012, 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 proposed to use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2008, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act. We proposed to use FY 2008 data because these data are the most recent complete data available. These are the same data used to compute the FY 2012 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final 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 FY 2012 LTCH PPS wage index values we are presenting in this final rule are computed consistent with the urban and rural geographic classifications (labor market areas) discussed above in section V.B.2. of the Addendum to this final 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.F. of the preamble of this final rule). Furthermore, in determining the FY 2012 LTCH PPS wage index values in this final rule, we are continuing to use our existing policy for determining wage index values in areas where there are no IPPS wage data.

As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50446), 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 as we proposed, we are continuing to use this methodology for FY 2012. As was the case in FY 2011, there are currently no LTCHs located in labor areas without IPPS hospital wage data (or IPPS hospitals) for FY 2012. 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. (We refer readers to 73 FR 26817 through 26818 for an explanation of and rationale for our policy.)

Comment: One commenter pointed out that it is not necessary to use our methodology for determining a LTCH PPS wage index value for areas with no IPPS wage data to determine a LTCH PPS wage index value for the rural area of Massachusetts for FY 2012, as we proposed, because there are, in fact, data for rural Massachusetts (CBSA code 22) in the FY 2008 IPPS wage data that we proposed to use to determine the FY 2012 LTCH PPS wage index values in the proposed rule.

Response: We appreciate the commenter pointing out that we mistakenly stated in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26040) that there was no IPPS wage data for the rural area of Massachusetts in the FY 2008 IPPS wage data that we proposed to use to determine the FY 2012 LTCH PPS wage index values. We note that, although our proposal incorrectly stated that we would use our established methodology for rural areas with no IPPS wage data to compute the FY 2012 LTCH PPS wage index for the rural area of Massachusetts, the proposed FY 2012 LTCH PPS wage index for the rural area of Massachusetts (CBSA code 22, as shown in Table 12B of that same proposed rule) was computed based on the proposed FY 2008 IPPS wage data (and was not computed using our policy for rural areas with no IPPS wage data as our proposal indicated). Accordingly, in this final rule, we determined the FY 2012 LTCH PPS wage index value for the rural area of Massachusetts (CBSA code 22) using the FY 2008 IPPS wage data that we are generally using to determine all of the FY 2012 LTCH PPS wage index values in this final rule.

Based on the FY 2008 IPPS wage data that we used to determine the FY 2012 LTCH PPS wage index values in this final rule, there are no IPPS wage data for the urban area Hinesville-Fort Stewart, GA (CBSA 25980). Consistent with the methodology discussed above and as we proposed, we calculated the FY 2012 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this final rule and available via the Internet). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

The FY 2012 LTCH wage index values that will be applicable for LTCH discharges occurring on or after October 1, 2011, through September 30, 2012, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum of this final rule and available via the Internet.

e. 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. However, there are currently no statutory or regulatory requirements that the annual update to the LTCH PPS area wage level adjustment at existing § 412.525(c) (that is, the wage index and the labor-related share) be budget neutral such that estimated aggregate LTCH PPS payments would be unaffected (that is, would be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes). In section VII.E.3. of the preamble of this final rule, as we proposed, under new § 412.525(c)(2), we are providing that, beginning in FY 2012, any changes to the wage index values or labor-related share will be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected, that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, as we proposed, we have also determined an area wage level adjustment budget neutrality factor that is 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. Therefore, under § 412.523(d)(4), we are applying an area wage level adjustment budget neutrality factor of 0.99775 (determined under the methodology described in section VII.E.3. of the preamble of this final rule) to determine the FY 2012 LTCH PPS standard Federal rate. (The development of the LTCH PPS standard Federal rate for FY 2012 is discussed in section V.A.2. of this Addendum.)

C. LTCH PPS Cost-of-Living Adjustment for LTCHs Located in Alaska and Hawaii

In the August 30, 2002 final rule (67 FR 56022), we established, under § 412.525(b), a cost-of-living adjustment (COLA) 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.

For FY 2011 and in prior years, 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 payments for LTCHs in Alaska and Hawaii. Sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111 – 84, October 28, 2009) transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Public Law 111–84, locality pay is being phased in over a 3-year period beginning in January 2010 with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality.

As we discussed in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26040), we do not believe it is appropriate to use either the 2010 or 2011 reduced factors for adjusting the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska or Hawaii. Therefore, for FY 2012, we proposed to continue to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which are based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii, and we invited public comment on this proposal. We believe using these COLA factors would appropriately adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii consistent with § 412.525(b). We did not receive any public comments on this proposal.

In this final rule, for FY 2012, 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, as we proposed, we will continue to use the same COLA factors (published by OPM)

that we use to adjust LTCH PPS payments in FY 2011. We believe using these COLA factors will appropriately adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii consistent with § 412.525(b). (We note that this policy is consistent with the proposed adjustment for cost-of-living in Alaska and Hawaii for IPPS hospitals discussed in section II.B.2. of this Addendum). Therefore, consistent with our current policy, under § 412.525(b), for FY 2012 we are applying 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 factors listed in the chart below because they are the most recent available data at this time. As discussed above, these factors were obtained from the OPM and are also used under the IPPS for FY 2012.

COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS FOR THE LTCH PPS FOR FY 2012

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	1.18
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

(The above factors are based on data obtained from the U.S. Office of Personnel Management Web site at: *http://www.opm.gov/oca/cola/rates.asp.*)

D. 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 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 to 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 the proposed rule, using our established methodology for determining the LTCH total CCR ceiling (described above), based on IPPS total CCR data from the December 2010 update of the PSF, we proposed to establish

a total CCR ceiling of 1.210 under the LTCH PPS that would be effective for discharges occurring on or after October 1, 2011, through September 30, 2012. Consistent with our historical policy of using the best available data, we also proposed that if more recent data became available, we would use such data to establish a total CCR ceiling for FY 2012 in the final rule. Consistent with that proposal, in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCOs and § 412.529(f)(4)(iii)(B) for SSOs, in this final rule, using our established methodology for determining the LTCH total CCR ceiling (described above), based on IPPS total CCR data from the March 2011 update of the PSF, we are establishing a total CCR ceiling of 1.215 under the LTCH PPS that will be effective for discharges occurring on or after October 1, 2011, through September 30, 2012.

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.)

In the 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 2010 update of the PSF, we proposed LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2011, through September 30, 2012, in Table 8C which is listed in section VI. of the Addendum to that proposed rule and available via the Internet. Consistent with our historical practice of using the best available data, in this final rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS total CCR data from the March 2011 update of the PSF, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2011, through September 30, 2012, in Table 8C which is listed in section VI. of the Addendum to this final rule and available via the Internet.

As we explained in the proposed rule (76 FR 26042), 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 listed in section VI. of the Addendum to this final rule and available via the Internet. 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 North Dakota 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 2011. Therefore, there is no rural statewide average total CCR listed for rural North Dakota in Table 8C listed in section VI. of the Addendum to this final rule and available via the Internet.

In addition, consistent with our existing methodology and as we proposed, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, in this final rule, we used, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We used this proxy because we believe that the CCR data on 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 LTCH PPS Fixed-Loss Amount for FY 2012

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 2012 IPPS/LTCH PPS proposed rule (76 FR 26042), we proposed to continue to use our existing methodology to calculate the fixed-loss amount for FY 2012 (based on data and the rates and policies presented in that 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 2012, we used the most recent available LTCH claims data and CCR data at this time. Specifically, for the proposed rule, we used LTCH claims data from the December 2010 update of the FY 2010 MedPAR file and CCRs from the December 2010 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 2012 because these data were the most recent complete LTCH data available at that time. We also proposed to determine the FY 2012 fixed-loss amount based on the proposed MS–LTC–DRG classifications and proposed relative weights from the version of the GROUPER that would be in effect as of the beginning of FY 2012, that is, Version 29.0 of the GROUPER. In that same proposed rule, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of BIPA, we proposed to establish a fixed-loss amount of $19,270 for FY 2012. Thus, we proposed to make an additional payment to an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the proposed outlier threshold (the sum of the adjusted proposed Federal LTCH payment for the proposed MS–LTC–DRG and the proposed fixed-loss amount of $19.270).

In this final rule, as we proposed, we are continuing to use our existing methodology to calculate the fixed-loss amount for FY 2012 (based on updated data and the rates and policies presented in this final rule) in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments. (For an explanation of our rationale for establishing an HCO payment ''target'' of 8 percent of total estimated LTCH payments, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024).) Consistent with our historical practice of using the best data available, in determining the fixed-loss amount for FY 2012, we used the most recent available LTCH claims data and CCR data at this time. Specifically, for this final rule, we used LTCH claims data from the March 2011 update of the FY 2010 MedPAR file and

CCRs from the March 2011 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 2012 because these data are the most recent complete LTCH data currently available. Furthermore, we determined the FY 2012 fixed-loss amount based on the MS–LTC–DRG classifications and relative weights from the version of the GROUPER that is in effect as of the beginning of FY 2012, that is, Version 29.0 of the GROUPER.

Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of BIPA, we are establishing a fixed-loss amount of $17,931 for FY 2012. Thus, we will make an additional payment to 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 $17.931). We also note that the fixed-loss amount of $17,931 for FY 2012 is lower than the FY 2011 fixed-loss amount of $18,785, and is also somewhat lower than the proposed FY 2012 fixed-loss amount of $19,270 (which was determined using LTCH claims data from the December 2010 update of the FY 2010 MedPAR file and CCRs from the December 2010 update of the PSF because these data were the most recent complete data available at that time). Based on our payment simulations using the most recent available data at this time, the decrease in the fixed-loss amount for FY 2012 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, as noted above, 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 a SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as a 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 a HCO. Thus, for a SSO case in FY 2012, 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 fixed-loss amount of $17,931 and the amount paid under the SSO policy as specified in § 412.529).

E. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2012

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 appropriate LTCH PPS wage index (as shown in Tables 12A and 12B listed in section VI. of the Addendum of this final rule and available via the Internet). The standard Federal rate is also adjusted to account for the higher costs of hospitals in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal rate by the appropriate cost-of-living factor (shown in the chart in section V.C.5. of the Addendum of this final rule) in accordance with § 412.525(b). In this final rule, we are establishing a standard Federal rate for FY 2012 of $40,222.05, as discussed above in section V.A.2. of the Addendum of this final rule. We illustrate the methodology to adjust the LTCH PPS Federal rate for FY 2012 in the following example:

Example:

During FY 2012, a Medicare patient is in a LTCH located in Chicago, Illinois (CBSA 16974). The FY 2012 LTCH PPS wage index value for CBSA 16974 is 1.0600 (Table 12A listed in section VI. of the Addendum of this final rule and available via the Internet). The Medicare patient is classified into proposed MS–LTC–DRG 28 (Spinal Procedures with MCC), which has a relative weight for FY 2012 of 1.7420 (Table 11 listed in section VI. of the Addendum of this final rule and available via the Internet).

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient in FY 2012, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted standard Federal rate ($40,222.05) by the labor-related share (70.199 percent) and the wage index value (1.0600). This wage-adjusted amount is then added to the nonlabor-related portion of the unadjusted standard Federal rate (29.801 percent; adjusted for cost of living, if applicable) to determine the adjusted Federal rate, which is then multiplied by the MS–LTC–DRG relative weight (1.7420) to calculate the total adjusted Federal LTCH PPS prospective payment for FY 2012 ($73,017.99). The table below illustrates the components of the calculations in this example.

Unadjusted Standard Federal Prospective Payment Rate	$40,222.05
Labor-Related Share	× 0.70199
Labor-Related Portion of the Federal Rate	= $28,235.48
Wage Index (CBSA 16974)	× 1.0600
Wage-Adjusted Labor Share of Federal Rate	= $29,929.61
Nonlabor-Related Portion of the Federal Rate ($40,222.08 × 0.29801)	+ $11,986.57
Adjusted Federal Rate Amount	= $41,916.18
MS–LTC–DRG 28 Relative Weight	× 1.7420
Total Adjusted Federal Prospective Payment	= $73,017.99

VI. Tables Referenced in This Final Rule and Available Only Through the Internet on the CMS Web Site

This section lists the tables referred to throughout the preamble of this final rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, IPPS tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 5, 6A, 6B, 6C, 6D, 6E, 6F, 7A, 7B, 8A, 8B, 9A, 9C, and 10, and LTCH PPS tables 8C, 11, 12A, and 12B will no longer be published as part of the annual IPPS/LTCH PPS proposed and final rulemakings. Instead, these tables, along with new LTCH PPS tables 13A and 13B, and new IPPS table 14 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. We note that previously tables 6G, 6H, 6I, 6I.1, 6I.2, 6J, 6J.1, 6J.2, and 6K were already made available only through the Internet. We will continue to post these tables through the Internet.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified below should contact Ing Jye Cheng at (410) 786–4548.

The following IPPS tables for this FY 2012 final rule are available only through the

Internet 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 2012 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download''.

Table 2.—Acute Care Hospitals Case-Mix Indexes for Discharges Occurring in Federal Fiscal Year 2010; Hospital Wage Indexes for Federal Fiscal Year 2012; Hospital Average Hourly Wages for Federal Fiscal Years 2010 (2006 Wage Data), 2011 (2007 Wage Data), and 2012 (2008 Wage Data); and 3–Year Average of Hospital Average Hourly Wages

Table 3A.—FY 2012 and 3-Year Average Hourly Wage for Acute Care Hospitals in Urban Areas by CBSA

Table 3B.—FY 2012 and 3-Year Average Hourly Wage for Acute Care Hospitals in Rural Areas by CBSA

Table 4A.—Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Urban Areas by CBSA and by State—FY 2012

Table 4B.—Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Rural Areas by CBSA and by State—FY 2012

Table 4C.—Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals That Are Reclassified by CBSA and by State—FY 2012

Table 4D.—States Designated as Frontier, with Acute Care Hospitals Receiving at a Minimum the Frontier State Floor Wage Index[1]; Urban Areas with Acute Care Hospitals Receiving the Statewide Rural Floor Wage Index—FY 2012

Table 4E.—Urban CBSAs and Constituent Counties for Acute Care Hospitals—FY 2012

Table 4F.—Puerto Rico Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals by CBSA—FY 2012

Table 4J.—Out-Migration Adjustment for Acute Care Hospitals—FY 2012

Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2012

Table 6A.—New Diagnosis Codes—FY 2012

Table 6B.—New Procedure Codes—FY 2012

Table 6C.—Invalid Diagnosis Codes—FY 2012

Table 6D.—Invalid Procedure Codes—FY 2012

Table 6E.—Revised Diagnosis Code Titles—FY 2012

Table 6F.—Revised Procedure Code Titles—FY 2012

Table 6G.—Additions to the CC Exclusions List—FY 2012

Table 6H.—Deletions from the CC Exclusions List—FY 2012

Table 6I.—Complete MCC List—FY 2012

Table 6I.1.—Additions to the MCC List—FY 2012

Table 6I.2.—Deletions to the MCC List—FY 2012

Table 6J.—Complete CC List—FY 2012

Table 6J.1.—Additions to the CC List—FY 2012

Table 6J.2.—Deletions to the CC List—FY 2012

Table 6K.—Complete List of CC Exclusions—FY 2012

Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2010 MedPAR Update—March 2011 GROUPER V28.0 MS–DRGs

Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2010 MedPAR Update—March 2011 GROUPER V29.0 MS–DRGs

Table 8A.—FY 2012 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—FY 2012 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 9A.—Hospital Reclassifications and Redesignations—FY 2012

Table 9C.—Hospitals Redesignated as Rural under Section 1886(d)(8)(E) of the Act—FY 2012

Table 10.—Geometric Mean Plus the Lesser of .75 of the National Adjusted Operating Standardized Payment Amount (Increased to Reflect the Difference Between Costs and Charges) or .75 of One Standard Deviation of Mean Charges by Medicare Severity Diagnosis-Related Groups (MS–DRGs)

Table 14.—List of Hospitals with Fewer than 1,600 Medicare Discharges Based on the March 2011 Update of the FY 2010 MedPAR File and Their FY 2012 Low-Volume Payment Adjustment

The following LTCH PPS tables for this FY 2012 final rule are available only through the Internet on the CMS Web site at *http://www.cms.gov/LongTermCareHospitalPPS/LTCHPPSRN/list.asp* under the list item for Regulation Number CMS–1518–P.

Table 8C.—FY 2012 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for Discharges Occurring from October 1, 2011 through September 30, 2012 under the LTCH PPS

Table 12A.—LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2011 through September 30, 2012

Table 12B.—LTCH PPS Wage Index for Rural Areas for Discharges Occurring From October 1, 2011 through September 20, 2012

Table 13A.—Composition of Low-Volume Quintiles for MS–LTC–DRGs—FY 2012

Table 13B.—No-Volume MS–LTC–DRG Crosswalk for FY 2012

TABLE 1A—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (68.8 PERCENT LABOR SHARE/31.2 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2012

Full update (1.90 percent)		Reduced update (−0.10 percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
$3,584.30	$1,625.44	$3,513.95	$1,593.54

TABLE 1B—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2012

Full update (1.90 percent)		Reduced update (−0.10 percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
$3,230.04	$1,979.70	$3,166.64	$1,940.85

TABLE 1C—ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR—FY 2012

	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National	$3,584.30	$1,625.44	$3,230.04	$1,979.70
Puerto Rico	1,553.29	947.98	1,550.79	950.48

TABLE 1D—CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2012

	Rate
National	$421.42
Puerto Rico	203.86

TABLE 1E—LTCH STANDARD FEDERAL PROSPECTIVE PAYMENT RATE—FY 2012

	Rate
Standard Federal Rate	$40,222.05

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011) the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We have determined that this final rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the changes for FY 2012 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million among different types of inpatient cases. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, will result in an estimated $1.13 billion increase in FY 2012 operating payments (or 1.1 percent change) and an estimated $151 million increase in FY 2012 capital payments (or 1.8 percent change). The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience a change in payments by $126 million (or 2.5 percent).

Our operating impact estimate includes the −2.0 percent documentation and coding adjustment applied to the hospital-specific rates and to the IPPS standardized amounts. In addition, our operating impact estimate includes the 1.9 percent hospital update to the standardized amount (which includes the 3.0 percent market basket update with the reduction of 1.0 percentage point for the multifactor productivity adjustment and the 0.1 percentage point reduction required under the Affordable Care Act). Finally, our operating impact estimate includes the 1.1 percent update to the standardized amount and the 0.9 percent update to the hospital-specific rates in light of DC Circuit's decision in *Cape Cod* v. *Sebelius* (630 F.3d 203 (DC Cir. 2011)). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which would also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. The final rule will affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant.

B. Need

This final rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This final rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS payment system.

C. Objectives of the IPPS

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe the changes in this final rule will further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2012, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but, generally, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 32 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, only the 46 such hospitals in Maryland remain excluded from the IPPS pursuant to the waiver under section 1814(b)(3) of the Act.

As of July 2011, there are 3,423 IPPS acute care hospitals to be included in our analysis. This represents about 64 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,346 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. (We refer readers to section I.H.15. of this Appendix for a further description of the impact of CAH-related policy changes.) There are also 1,290 IPPS-excluded hospitals and 2,119 IPPS-excluded hospital units. These IPPS-excluded hospitals and units include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, and 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 final rule. The impact of the update and policy changes to the LTCH PPS for FY 2012 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of July 2011, there were 3,409 hospitals and hospital units excluded from the IPPS. Of these, 78 children's hospitals, 11 cancer hospitals, and 17 RNHCIs are being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. The remaining providers, 235 rehabilitation hospitals and 940 rehabilitation units, and 437 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 512 psychiatric hospitals and 1,179 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 final rule. The impacts of the changes to LTCHs are discussed in section I.J. of this Appendix.

In the past, certain hospitals and units excluded from the IPPS have been paid based on their reasonable costs subject to limits as established by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Cancer and children's hospitals continue to be paid on a reasonable cost basis subject to TEFRA limits for FY 2012. For these hospitals (cancer and children's hospitals), consistent with the authority provided in section 1886(b)(3)(B)(ii) of the Act, the update is the FY 2012 percentage increase in the IPPS

operating market basket. In compliance with section 404 of the MMA, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43930), we replaced the FY 2002-based IPPS operating and capital market baskets with the revised and rebased FY 2006-based IPPS operating and capital market baskets. Therefore, consistent with current law, based on IHS Global Insight, Inc.'s 2011 second quarter forecast, with historical data through the 2011 first quarter, we are estimating that the FY 2012 update based on the IPPS operating market basket is 3.0 percent (that is, the current estimate of the market basket rate-of-increase). However, the Affordable Care Act requires an adjustment for multifactor productivity (currently estimated to be 1.0 percentage point) and a 0.1 percentage point reduction to the market basket update resulting in a 1.9 percent applicable percentage increase for IPPS hospitals. RNCHIs, children's hospitals and cancer hospitals are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under § 413.40. Therefore, for RNHCIs, the update is the same as for children's and cancer hospitals, which is the percentage increase in the FY 2012 IPPS operating market basket, estimated at 3.0 percent, without the reductions required under the Affordable Care Act.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with per-case 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 reimbursed.

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 50 percent of the difference between its reasonable costs and 110 percent of the limit, not to exceed 110 percent of its limit. In addition, under the various provisions set forth in § 413.40, cancer and children's hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this final rule, we are announcing policy changes and payment rate updates for the IPPS for FY 2012 for operating costs of acute care hospitals. FY 2012 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2012 operating payments will increase by 1.1 percent compared to FY 2011, largely due to the documentation and coding adjustments and the applicable percentage increase applied to the IPPS rates. In addition to the applicable percentage increase, this amount reflects the FY 2012 adjustments for documentation and coding and recoupment described in section II.D. of the preamble of this final rule: − 2.0 percent for the IPPS national standardized amounts and the IPPS hospital-specific rates. The impacts do not illustrate changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

We have prepared separate impact analyses of the changes to each system. This section deals with changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available data to enable us to estimate the impacts on payments per case of certain changes in this final rule. However, there are other changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented below are taken from the FY 2010 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2010 MedPAR file, we simulated payments under the operating IPPS given various combinations of payment parameters. As described above, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, or the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2012 are discussed in section I.I. of this Appendix.

We discuss the following changes below:

- Effects of the application of the documentation and coding adjustment and 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.
- Effects of the increase to the standardized amount and hospital-specific rates in light of D.C. Circuit's decision in *Cape Cod* v. *Sebelius,* 630 F.3d 203 (DC Cir. 2011).
- The effects of the annual reclassification of diagnoses and procedures, full implementation of the MS–DRG system and 100 percent cost-based MS–DRG relative weights.
- The effects of the changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2008, compared to the FY 2007 wage data.
- The effects of the recalibration of the MS–DRG relative weights as required by section 1886(d)(4)(C) of the Act, including the wage and recalibration budget neutrality factors.
- The effects of the geographic reclassifications by the MGCRB that will be effective in FY 2012.
- The effects of the rural floor and imputed floor with the application of the national budget neutrality factor applied to the wage index, as required by the Affordable Care Act.
- The effects of the frontier State wage index 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 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 total estimated change in payments based on the FY 2012 policies relative to payments based on FY 2011 policies that include the applicable percentage increase of 1.9 percent (or 3.0 percent market basket update with a reduction of 1.0 percentage point for the multifactor productivity adjustment, and a 0.1 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the FY 2012 changes, our analysis begins with a FY 2011 baseline simulation model using: The FY 2012 applicable percentage increase of 1.9 percent and the documentation and coding adjustment of −2.0 percent; the FY 2011 MS–DRG GROUPER (Version 28.0); the most current CBSA designations for hospitals based on OMB's MSA definitions; the FY 2011 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 through FY 2014, the update factor will include a reduction of 2.0 percentage points for any hospital that does not submit quality data 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, 57 hospitals did not receive the full market basket rate-of-increase for FY 2011 because they failed the quality data submission process or did not choose to participate. For purposes of the simulations shown below, we modeled the payment changes for FY 2012 using a reduced update for these 57 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update factor for FY 2012.

Each policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2012 model incorporating all of the changes. This simulation allows us to isolate the effects of each change.

Our final comparison illustrates the percent change in payments per case from FY 2011 to FY 2012. Three factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are updating the standardized amounts for FY 2012 using an applicable percentage increase of 1.9 percent. This includes our forecasted IPPS operating hospital market basket increase of 3.0 percent with a reduction of 1.0 percentage point for the multifactor productivity adjustment and a 0.1 percentage point reduction as required under the Affordable Care Act. (Hospitals that fail to comply with the quality data submission requirements will receive an update of −0.1 percent (this 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 and for MDHs are also equal to the applicable percentage increase, or 1.9 percent. In addition, we are updating the Puerto Rico-specific amount by an applicable percentage increase of 1.9 percent.

A second significant factor that affects the changes in hospitals' payments per case from FY 2011 to FY 2012 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 2011 that are no longer reclassified in FY 2012. Conversely, payments may increase for hospitals not reclassified in FY 2011 that are reclassified in FY 2012.

A third significant factor is that we currently estimate that actual outlier payments during FY 2011 will be 4.8 percent of total MS–DRG payments. Our updated FY 2011 outlier estimate accounts for changes to the FY 2011 IPPS payments required under the Affordable Care Act. When the FY 2011 final rule was published, we projected FY 2011 outlier payments would be 5.1 percent of total MS–DRG plus outlier payments; the average standardized amounts were offset correspondingly. The effects of the lower than expected outlier payments during FY 2011 (as discussed in the Addendum to this final rule) are reflected in the analyses below comparing our current estimates of FY 2011 payments per case to estimated FY 2012 payments per case (with outlier payments projected to equal 5.1 percent of total MS–DRG payments).

Comment: One commenter noted that in examining the IPPS Impact File associated with the FY 2012 IPPS/LTCH PPS proposed rule posted on the CMS Web site, it found that approximately 27,000 claims were included in the calculation of the case-mix index and case counts (fields such as BILLS, TACMIV29, and CASETA29) which may be Medicare Advantage (MA) patient claims submitted by teaching hospitals in order to receive their IME payments. These claims only had an IME payments listed. The commenter stated that if these claims are MA claims, they are not eligible for outlier payments under the IPPS and, as agreed by CMS, must not be included as part of the calculation of the outlier thresholds or be included in the statistics posted in the IPPS Impact File. Accordingly, the commenter requested that CMS review these 27,000 ''IME only'' claims to determine whether they represent MA claims.

Response: We have reviewed our MedPAR claims file used to calculate outlier thresholds and used to report hospital case counts and case-mix values and have determined that there are MA claims that may be submitted by teaching hospitals that do not have a GHO Paid indicator with a value of 1,'' which is the indicator for MA claims. However, we can identify those claims as likely to be MA claims because the IME payment field is equal to the DRG payment field. We agree with the commenter that MA claims submitted by teaching hospitals for the purpose of the IME payment should not be included in the calculation of the outlier threshold and have excluded those claims from the outlier calculation that have a GHO Paid indicator with a value of ''1'' or do not have a GHO Paid indicator with a value of ''1'' but do have an IMEPAY field equal to the DRGPAY field because these are probably MA claims that are likely not paid under the IPPS and therefore would not incur an outlier payment. Claims that are trimmed using the criteria discussed above are not part of the calculation of the outlier threshold, hospital case count or fee-for-service case mix values reported on the IPPS Impact File in this final rule.

Comment: One commenter requested that CMS provide a table indicating the State-by-State impact of the rural floor provision for providers in each State, including a schedule of what the area wage indexes would be if the rural floor was not applied. The commenter also suggested that CMS publish this information annually.

Response: In this final rule, we are including in this impact section a table indicating State level impacts of the rural floor and imputed floor provision. Also, we are revising Table 4D of the Addendum, which specifies the wage index for States or urban areas receiving the frontier State wage index or rural and imputed floors, to include a column indicating the pre-floor area wage index.

2. Analysis of Table I

Table I displays the results of our analysis of the changes for FY 2012. 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 3,423 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 2,498 hospitals located in urban areas included in our analysis. Among these, there are 1,371 hospitals located in large urban areas (populations over 1 million), and 1,127 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 925 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 2012 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 2,519; 1,384; 1,135; and 904, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive DSH payments, or some combination of these two adjustments. There are 2,391 nonteaching hospitals in our analysis, 792 teaching hospitals with fewer than 100 residents, and 240 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 changes on rural hospitals by special payment groups (SCHs, RRCs, and MDHs). There were 175 RRCs, 320 SCHs, 193 MDHs, and 120 hospitals that are both SCHs and RRCs, and 18 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total patient days. These data were taken from the FY 2008 or FY 2007 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 2012. The second grouping shows the MGCRB rural reclassifications. The final category shows the impact of the policy changes on the 19 cardiac hospitals.

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TABLE I.--IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2012

	Number of Hospitals[1] (1)	Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	Cape Cod Adjustment[3] (3)	FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	FY 2012 Wage Data with Application of Wage Budget Neutrality [5] (5)	FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Application of the Frontier Wage Index[9] (9)	FY 2012 Out-Migration Adjustment[10] (10)	Expiration of Section 508[11] (11)	All FY 2012 Changes [12] (12)
All Hospitals	3423	-0.1	1.1	0	0	0	0	0	0	0	-0.2	1.1
By Geographic Location:												
Urban hospitals	2498	-0.1	1.1	0	0	0	-0.2	0.1	0	0	-0.2	1.2
Large urban areas	1371	-0.1	1.1	0.1	0	0.1	-0.3	0	0	0	-0.2	1.2
Other urban areas	1127	-0.1	1.1	0	0	0	-0.1	0.1	0.1	0	-0.2	1.1
Rural hospitals	925	-0.1	1	-0.2	-0.1	-0.3	1.8	-0.3	0	0.1	0	0.2
Bed Size (Urban):												
0-99 beds	632	-0.1	1.1	-0.1	-0.1	-0.2	-0.5	0.2	0.1	0	-0.1	1.1
100-199 beds	782	-0.1	1.1	0	0	0	0	0.3	0.1	0.1	-0.2	1.2
200-299 beds	449	-0.1	1.1	0	0.1	0.1	-0.2	0	0.1	0.1	-0.1	1.1
300-499 beds	430	-0.1	1.1	0	-0.1	-0.1	-0.2	0	0.1	0	-0.1	1
500 or more beds	205	-0.1	1.1	0.1	0	0.1	-0.2	0	0	0	-0.2	1.3
Bed Size (Rural):												
0-49 beds	320	-0.1	1	-0.3	0	-0.2	0.6	-0.3	0.1	0.2	0	-0.3
50-99 beds	348	-0.1	1	-0.3	-0.1	-0.3	0.9	-0.3	0	0.1	0	-0.1
100-149 beds	152	-0.1	1	-0.2	-0.1	-0.3	2.4	-0.3	0	0	0	0.3
150-199 beds	58	-0.1	1	-0.2	0	-0.2	2.4	-0.3	0.1	0	0	0.5
200 or more beds	47	-0.1	1	-0.1	-0.1	-0.2	2.6	-0.3	0	0	0	0.7
Urban by Region:												
New England	120	-0.1	1.1	0	0.1	0.2	0.7	5.3	0	0.3	-0.2	5.6
Middle Atlantic	320	-0.1	1.1	0	0.2	0.2	0.3	-0.1	0	0	-0.4	0.9

	Number of Hospitals[1] (1)	Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Cape Cod Adjustment[3] (3)	FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5)	FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Application of the Frontier Wage Index[9] (9)	FY 2012 Out-Migration Adjustment[10] (10)	Expiration of Section 508[11] (11)	All FY 2012 Changes[12] (12)
South Atlantic	380	-0.1	1.1	0	-0.1	-0.1	-0.4	-0.4	0	0	0	0.8
East North Central	401	-0.1	1.1	0	-0.5	-0.4	-0.3	-0.5	0	0	-0.5	0.2
East South Central	153	-0.1	1.1	0	-0.3	-0.2	-0.4	-0.4	0	0	0	0.5
West North Central	169	-0.1	1.1	0	0.2	0.2	-0.6	-0.4	0.6	0	0	1.2
West South Central	366	-0.1	1.1	0	0.3	0.3	-0.6	-0.5	0	0	0	1.3
Mountain	159	-0.1	1.1	0	-0.1	-0.1	-0.4	-0.3	0.2	0	0	0.8
Pacific	380	-0.1	1.1	0	0.3	0.3	-0.3	0.1	0	0	-0.1	1.6
Puerto Rico	50	0.3	0.9	-0.2	0.2	-0.1	-0.8	0.1	0	0	0	1.2
Rural by Region:												
New England	23	-0.1	1	-0.3	0.7	0.4	1.5	-0.3	0	0	0	0.3
Middle Atlantic	69	-0.1	1	-0.2	-0.1	-0.3	1.4	-0.2	0	0	-0.1	0.7
South Atlantic	165	-0.1	1.1	-0.2	-0.2	-0.4	2.4	-0.4	0	0.1	0	0.5
East North Central	120	-0.1	1	-0.2	-0.2	-0.4	1.1	-0.2	0	0.1	0	0.4
East South Central	170	-0.1	1.1	-0.1	-0.5	-0.6	2.6	-0.4	0	0.2	-0.1	-0.5
West North Central	99	-0.1	0.9	-0.3	0	-0.2	0.7	-0.1	0.1	0	-0.1	0.6
West South Central	183	-0.1	1.1	-0.2	0.3	0.1	2.4	-0.4	0	0.1	0	-0.3
Mountain	66	-0.1	1	-0.2	0.1	-0.2	0.5	-0.2	0.6	0	0	0.3
Pacific	29	-0.1	1	-0.3	0.3	0	1.2	-0.2	0	0	0	0.7
Puerto Rico	1	0.3	0.9	-0.8	0.7	-0.3	-0.9	-0.4	0	0	0	0.8
By Payment Classification:												
Urban hospitals	2519	-0.1	1.1	0	0	0	-0.2	0.1	0	0	-0.2	1.2
Large urban areas	1384	-0.1	1.1	0	0	0.1	-0.3	0	0	0	-0.2	1.2
Other urban areas	1135	-0.1	1.1	0	0	0	0	0.1	0.1	0	-0.2	1.1

	Number of Hospitals[1] (1)	Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Cape Cod Adjustment[3] (3)	FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5)	FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Application of the Frontier Wage Index[9] (9)	FY 2012 Out-Migration Adjustment[10] (10)	Expiration of Section 508[11] (11)	All FY 2012 Changes[12] (12)
Rural areas	904	-0.1	1	-0.2	-0.1	-0.3	1.6	-0.3	0	0.1	0	0.2
Teaching Status:												
Nonteaching	2391	-0.1	1.1	-0.1	0	-0.1	0.2	0	0	0.1	-0.1	1
Fewer than 100 residents	792	-0.1	1.1	0	0	0	-0.2	0	0.1	0	-0.1	1
100 or more residents	240	-0.1	1.1	0.1	0.1	0.2	-0.2	0.1	0	0	-0.3	1.4
Urban DSH:												
Non-DSH	739	-0.1	1.1	-0.1	-0.1	-0.2	-0.1	0.2	0	0.1	-0.2	0.8
100 or more beds	1547	-0.1	1.1	0	0	0.1	-0.2	0	0	0	-0.2	1.2
Less than 100 beds	337	-0.1	1.1	-0.1	-0.2	-0.2	-0.1	0.1	0.2	0	-0.1	0.9
Rural DSH:												
SCH	417	-0.1	1	-0.3	-0.1	-0.4	0.2	-0.1	0	0.1	0	-0.7
RRC	222	-0.1	1	-0.2	-0.1	-0.3	2.6	-0.3	0	0	0	0.7
100 or more beds	27	-0.1	1.1	-0.1	-0.3	-0.4	0.9	-0.5	0	0.3	-0.3	0.2
Less than 100 beds	134	-0.1	1.1	-0.1	-0.1	-0.2	1.3	-0.5	0	0.5	-0.2	0.4
Urban teaching and DSH:												
Both teaching and DSH	827	-0.1	1.1	0.1	0	0.1	-0.3	0	0.1	0	-0.2	1.2
Teaching and no DSH	144	-0.1	1.1	-0.1	-0.1	-0.2	0.2	0.4	0	0.1	-0.4	0.9
No teaching and DSH	1057	-0.1	1.1	0	0.1	0.1	0	0.1	0	0	0	1.3
No teaching and no DSH	491	-0.1	1.1	-0.1	-0.1	-0.2	-0.3	0	0	0.1	-0.2	0.8
Special Hospital Types:												
RRC	175	-0.1	1.1	-0.1	-0.2	-0.2	3.3	-0.4	0.1	0.1	-0.1	0.6
SCH	320	-0.1	0.9	-0.3	0	-0.3	0.2	-0.1	0	0	0	-0.7
MDH	193	-0.1	1	-0.3	0	-0.3	0.1	-0.2	0	0.2	0	0.5

	Number of Hospitals[1] (1)	Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Cape Cod Adjustment[3] (3)	FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5)	FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Application of the Frontier Wage Index[9] (9)	FY 2012 Out-Migration Adjustment[10] (10)	Expiration of Section 508[11] (11)	All FY 2012 Changes[12] (12)
SCH and RRC	120	-0.1	0.9	-0.2	0	-0.3	0.9	-0.1	0.1	0	0	0.6
MDH and RRC	18	-0.1	1	-0.3	0	-0.3	0.5	-0.1	0	0	0	0.5
Type of Ownership:												
Voluntary	1985	-0.1	1.1	0	0	0	0	0.1	0.1	0	-0.2	1.1
Proprietary	870	-0.1	1.1	0	0.1	0.1	-0.1	-0.3	0	0.1	-0.1	0.9
Government	566	-0.1	1.1	0.1	0	0	-0.1	-0.2	0	0	0	0.9
Medicare Utilization as a Percent of Inpatient Days:												
0-25	358	-0.1	1.1	0.1	0	0.1	-0.4	-0.3	0	0	0	1.3
25-50	1695	-0.1	1.1	0	0	0	-0.3	0	0.1	0	-0.2	1.2
50-65	1081	-0.1	1.1	-0.1	-0.1	-0.2	0.7	0.1	0	0.1	-0.2	0.7
Over 65	198	-0.1	1.1	0	-0.1	-0.1	0.7	0.2	0	0.1	-0.2	0.9
FY 2012 Reclassifications by the Medicare Geographic Classification Review Board:												
All Reclassified Hospitals	655	-0.1	1.1	0	-0.2	-0.2	2.7	0.1	0	0	-0.5	0.9
Non-Reclassified Hospitals	2768	-0.1	1.1	0	0	0.1	-0.7	0	0.1	0	-0.1	1.1
Urban Hospitals Reclassified	323	-0.1	1.1	0	-0.2	-0.2	2.6	0.3	0	0	-0.7	1.1
Urban Nonreclassified Hospitals, FY 2012:	2142	-0.1	1.1	0	0	0.1	-0.7	0	0.1	0	-0.1	1.2

	Number of Hospitals[1] (1)	Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	Cape Cod Adjustment[3] (3)	FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	FY 2012 Wage Data with Application of Wage Budget Neutrality [5] (5)	FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Application of the Frontier Wage Index[9] (9)	FY 2012 Out-Migration Adjustment[10] (10)	Expiration of Section 508[11] (11)	All FY 2012 Changes [12] (12)
All Rural Hospitals Reclassified FY 2012:	332	-0.1	1	-0.2	-0.1	-0.3	2.8	-0.3	0	0	0	0.5
Rural Nonreclassified Hospitals FY 2012:	532	-0.1	1	-0.3	0	-0.3	-0.2	-0.3	0.1	0.2	-0.1	-0.3
All Section 401 Reclassified Hospitals:	40	-0.1	0.9	-0.3	-0.1	-0.3	-0.7	0.2	0	0	0	0.2
Other Reclassified Hospitals (Section 1886(d)(8)(B))	62	-0.1	1	-0.2	-0.1	-0.3	3	-0.4	0	0.1	0	0.3
Specialty Hospitals												
Cardiac specialty Hospitals	19	-0.1	1.1	0.3	-0.1	0.2	-0.8	-0.5	0.3	0	0	1.2

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2010, and hospital cost report data are from reporting periods beginning in FY 2009 and FY 2008.

[2] This column displays the payment impact of the hospital rate update and documentation and coding adjustment including the 1.9 percent adjustment to the national standardized amount (the 3.0 percent market basket update reduced by the 1.0 percentage point for the multifactor productivity adjustment and the 0.1 percentage point reduction under the Affordable Care Act) and the --2.0 percent documentation and coding adjustment to the national standardized amount and the hospital-specific rate.

[3] This column displays the payment impact of the 1.1 percent adjustment to the national standardized amount and the 0.9 percent adjustment to the hospital-specific rate in light of the decision in Cape Cod v. Sebelius.

[4] This column displays the payment impact of the changes to the Version 29.0 GROUPER and the recalibration of the MS-DRG weights based on FY 2010 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.997903, in accordance with section 1886(d)(4)(C)(iii) of the Act.

[5.] This column displays the payment impact of the update to wage index data using FY 2008 cost report data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000558.

[6] This column displays the combined payment impact of the changes in Columns 4 through 5 and the cumulative budget neutrality factor for MS-DRG and wage changes in accordance with section 1886(d)(4)(C)(iii) of the Act and section 1886(d)(3)(E) of the Act. The cumulative wage and recalibration budget neutrality factor of 0.998460 is the product of the wage budget neutrality factor and the recalibration budget neutrality factor.

[7.] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2012 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2012. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.991493.

[8] This column displays the effects of the rural floor and imputed floor, including the Affordable Care Act requirement that the floor budget neutrality is at a 100 percent national level adjustment. The rural floor and imputed floor budget neutrality factor is 0.991007.
[9.] 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.
[10.] This column displays the impact of 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.
[11.] This column displays the impact of the expiration of section 508 of the MMA as extended by the MMEA, a non-budget neutral reclassification provision.
[12.] This column shows the changes in payments from FY 2011 to FY 2012. It reflects the impact of the FY 2012 hospital update, the reductions due to the documentation and coding effect and the adjustment in light of the decision in Cape Cod v. Sebelius. The FY 2012 documentation and coding adjustment is -2.0 percent to the IPPS standardized amounts and the hospital-specific rates. It also reflects changes in hospitals' reclassification status in FY 2012 compared to FY 2011. It incorporates all of the changes displayed in Columns 2, 3, 6, 7, 8, 9, 10 and 11 (the changes displayed in Columns 4 and 5 are included in Column 6). The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.

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a. Effects of the Hospital Update and Documentation and Coding Adjustment (Column 2)

As discussed in section II.D. of the preamble of this final rule, this column includes the hospital update, including the 3.0 percent market basket update, the reduction of 1.0 percentage point for the multifactor productivity adjustment, and the 0.1 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the FY 2012 documentation and coding adjustment of −2.0 percent on the national standardized amount and the hospital-specific rates. As a result, we are applying a −0.1 percent adjustment to the national standardized amount and the hospital specific rate. Overall, hospitals will experience a −0.1 percent decrease in payments due to the effects of the hospital update and documentation and coding adjustment on the national standardized amount. Puerto Rico hospitals will experience a 0.3 percent increase in payments because we are not making any documentation and coding adjustment to the Puerto Rico-specific rate, which is 25 percent of Puerto Rico's payment rate.

b. Effects of the Adjustment to the Standardized Amount for *Cape Cod Hospital* v. *Sebelius* (Column 3)

Column 3 shows the impact of the 1.1 percent adjustment to the national standardized amount and the 0.9 percent adjustment to the hospital-specific rate in light of the decision in *Cape Cod Hospital* v. *Sebelius,* as discussed in section II. of the Addendum to this final rule.

Overall, hospitals will experience a 1.1 percent increase in payments due to the effects of the adjustment on the national standardized amount. Hospital categories that experience less than a 1.1 percent increase in payments include hospitals that are paid under the hospital-specific rate, which we are increasing by 0.9 percent. Rural hospitals will experience a 1.0 percent increase in payments because many rural hospitals are paid under the hospital-specific rate, which we are increasing by 0.9 percent.

c. Effects of the Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 4)

Column 4 shows the effects of the changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are calculating a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this rule, the FY 2012 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2012, the MS–DRGs are calculated using the FY 2010 MedPAR data grouped to the Version 29.0 (FY 2012) MS–DRGs. The methods of calculating the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.H. of the preamble of this final rule.

The ''All Hospitals'' line in Column 4 indicates that changes due to MS–DRGs and relative weights will result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 0.997903 on to the standardized amount. Due to changes to the MS–DRG GROUPER in this final rule, there were some shifts in payments due to changes in the relative weights with rural hospitals experiencing a 0.2 percent decrease in payments and large urban hospitals experiencing a 0.1 percent increase in payments.

d. Effects of Wage Index Changes (Column 5)

Column 5 shows the impact of updated wage data with the application of the 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 wage index for acute care hospitals for FY 2012 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2007 and before October 1, 2008. The estimated impact of the updated wage data and labor share on hospital payments is isolated in Column 5 by holding the other payment parameters constant in this simulation. That is, Column 5 shows the percentage change in payments when going from a model using the FY 2011 wage index, based on FY 2007 wage data, the current labor-related share and having a 100-percent occupational mix adjustment applied, to a model using the FY 2012 pre-reclassification wage index with the labor-related share, also having a 100-percent occupational mix adjustment applied, based on FY 2008 wage data (while holding other payment parameters such as use of the Version 29.0 MS–DRG GROUPER constant). The occupational mix adjustment is based on the 2007–2008 occupational mix survey.

In addition, the column shows the impact of the application of wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage 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 2012, we are calculating the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share 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. 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 wage budget neutrality factor is 1.000558, and the overall payment change is 0 percent.

Column 5 shows the impacts of updating the wage data using FY 2008 cost reports. Overall, the new wage data will lead to a 0.0 percent change for all hospitals before being combined with the wage budget neutrality adjustment shown in Column 5. Among the regions, the largest increase is in the rural New England region, which experiences a 0.7 percent increase due to increases in the wage index among rural Connecticut and rural Massachusetts hospitals. The largest decline from updating the wage data is seen in the rural East South Central region (–0.5 percent decrease).

In looking at the wage data itself, the national average hourly wage increased 3.7 percent compared to FY 2011. Therefore, the

only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 3.7 percent increase in average hourly wage. Of the 3,428 hospitals with wage data for both FYs 2011 and 2012, 1,729, or 50.4 percent, experienced an average hourly wage increase of 3.4 percent or more.

The following chart compares the shifts in wage index values for hospitals for FY 2012 relative to FY 2011. Among urban hospitals, 32 will experience an increase of more than 5 percent and less than 10 percent and 4 will experience an increase of more than 10 percent. Among rural hospitals, 1 will experience an increase of more than 5 percent and less than 10 percent, and none will experience an increase of more than 10 percent. However, 924 rural hospitals will experience increases or decreases of less than 5 percent, while 2,448 urban hospitals will experience increases or decreases of less than 5 percent. Sixteen urban hospitals will experience decreases in their wage index values of more than 5 percent and less than 10 percent. Three urban hospitals will experience decreases in their wage index values of greater than 10 percent. No rural hospitals will experience a decrease of more than 10 percent. No rural hospitals will experience decreases in their wage index values of greater than 5 percent but less than 10 percent. These figures reflect changes in the wage index which is an adjustment to either 68.8 percent or 62 percent of the labor-related share of a hospital's standardized amount, depending upon whether its wage index is greater than 1.0 or less than or equal to 1.0. Therefore, these figures illustrate a somewhat larger change in the wage index than will occur to the hospital's total payment.

The following chart shows the projected impact for urban and rural hospitals.

Percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Increase more than 10 percent	4	0
Increase more than 5 percent and less than 10 percent	32	0
Increase or decrease less than 5 percent	2,448	924
Decrease more than 5 percent and less than 10 percent	16	0
Decrease more than 10 percent	3	0

e. Combined Effects of the MS–DRG and Wage Index Changes (Column 6)

Section 1886(d)(4)(C)(iii) of the Act requires that changes to MS–DRG reclassifications and the relative weights cannot increase or decrease aggregate payments. In addition, section 1886(d)(3)(E) of the Act specifies that any updates or adjustments to the wage index are to be budget neutral. We computed a wage budget neutrality factor of 1.000558, and a recalibration budget neutrality factor of 0.997903 (which is applied to the Puerto Rico-specific standardized amount and the hospital-specific rates). The product of the two budget neutrality factors is the cumulative wage and recalibration budget neutrality factor. The cumulative wage and recalibration budget neutrality adjustment is 0.998460, or approximately –0.15 percent, which is applied to the national standardized amounts. Because the wage budget neutrality and the recalibration budget neutrality are calculated under different methodologies according to the statute, when the two budget neutralities are combined and applied to the standardized amount, the overall payment impact is not necessarily budget neutral. However, in this final rule, we are estimating that the changes in the MS–DRG relative weights and updated wage data with wage and budget neutrality applied will result in a 0.0 change in payments.

We estimate that the combined impact of the changes to the relative weights and MS–DRGs and the updated wage data with budget neutrality applied will result in no change in payments for urban hospitals and 0.1 percent decrease in payments for rural hospitals. Urban Pacific hospitals will experience a 0.3 percent increase in payments due to increases in their wages compared to the national average, while the urban East North Central area will experience a –0.4 decrease in payments because of below average increases in wages. Among the rural hospital categories, rural New England hospitals will experience the greatest increase in payment (0.4 percent) primarily due to above average increases in the wage data, while the rural East North Central area will experience a 0.6 percent decrease in payments due to decreases in the wage data.

f. Effects of MGCRB Reclassifications (Column 7)

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 changes in Column 7 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2012 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 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 the purposes of this impact analysis, we are applying an adjustment of 0.991943 to ensure that the effects of the section 1886(d)(10) reclassifications are budget neutral (section II.A. of the Addendum to this final rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that geographic reclassification will increase payments to rural hospitals by an average of 1.8 percent. By region, all the rural hospital categories, with the exception of the one rural Puerto Rico hospital, will experience increases in payments due to MGCRB reclassification. Rural hospitals in the East South Central region will experience a 2.6 percent increase in payments and rural hospitals in the Mountain region will experience a 0.5 percent increase in payments. Urban hospitals in New England and the Middle Atlantic will 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 final rule and available via the Internet reflects the approved reclassifications for FY 2012.

g. Effects of the Rural and Imputed Floor, Including Application of National Budget Neutrality (Column 8)

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 FY 2011 IPPS/LTCH PPS final rule and this final rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. Beginning with FY 2008, we apply a uniform budget neutrality adjustment is applied to the wage index. In addition, as discussed in section III.F.2. of the preamble of this final rule, the imputed floor, which is budget neutral, was set to expire with the FY 2011 wage index but we are finalizing to extend the imputed floor for 2 additional years. The imputed floor only benefits hospitals located in New Jersey. For FY 2012 (and in FY 2011), 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. The FY 2012 rural floor budget neutrality factor applied to the wage index is 0.991007, which will reduce wage indexes by −0.9 percent.

Column 8 shows the projected impact of the rural floor and imputed floor with the national rural floor budget neutrality factor applied to the wage index. The column compares the post-reclassification FY 2012

wage index of providers before the rural floor and imputed floor adjustment and the post-reclassification FY 2012 wage index of providers with the rural floor and imputed floor adjustment. Only urban hospitals can benefit from the rural floor provision. 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) experience a decrease in payments due to the budget neutrality adjustment applied nationally to their wage index.

We project that, in the aggregate, rural hospitals will experience a −0.3 percent decrease in payments as a result of the application of 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) will 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 5.3 percent increase in payments primarily due to the application of the rural floor in Massachusetts and the applicable national rural floor budget neutrality as required by the Affordable Care Act. All 60 urban providers in Massachusetts are expected to receive the rural floor wage index value, including rural floor budget neutrality, of 1.3452. 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. Massachusetts hospitals can expect approximately an 8.7 percent increase in IPPS payments due to the application of the rural floor.

Urban Puerto Rico hospitals are expected to experience a 0.1 percent increase in payments as a result of the application of a Puerto Rico rural floor. Similar to Massachusetts, this is the first year in which urban Puerto Rico hospitals will receive a rural floor as a result of a new IPPS hospital located in rural Puerto Rico setting a rural floor. We are applying a rural floor budget neutrality factor to the Puerto Rico-specific wage index of 0.989417 or 1.1 percent. The Puerto Rico-specific wage index adjusts the Puerto Rico-specific standardized amount, which represents 25 percent of payments to Puerto Rico hospitals.

There are 39 hospitals in New Jersey that benefit from the extension of the imputed floor and receive the imputed floor wage index value, including rural floor budget neutrality of 1.1264. Urban Middle Atlantic hospitals will experience a −0.1 percent decrease in payments which reflects the increase in payments for New Jersey hospitals receiving the imputed floor and a decrease for all other urban hospitals in the Middle Atlantic region.

In response to a public comment, we are providing the payment impact of the rural floor and imputed floor with budget neutrality at the State level. Column 1 of the table displays the number of IPPS hospitals located in each State. Column 2 displays the number of hospitals in each State that will be receiving the rural floor or imputed floor wage index for FY 2012. Column 3 displays the percentage of total payments each State receives or contributes to fund the rural floor and imputed floor with national budget neutrality. The column compares the post-reclassification FY 2012 wage index of providers before the rural floor and imputed floor adjustment and the post-reclassification FY 2012 wage index of providers with the rural floor and imputed floor adjustment. Column 4 displays an estimated payment amount that each State will gain or lose due to the application of the rural floor and imputed floor with national budget neutrality.

FY 2012 IPPS Estimated Payments due to Rural Floor and Imputed Floor With National Budget Neutrality

State	Number of hospitals	Number of hospitals receiving rural floor or imputed floor	Percent change in payments due to application of rural floor and imputed floor with budget neutrality	Difference (in millions)
Alabama	95	3	−0.4	−$7.5
Alaska	6	4	1.7	2.3
Arizona	57	0	−0.5	−8.8
Arkansas	47	0	−0.4	−5.0
California	308	100	0.2	20.3
Colorado	46	7	0.4	4.3
Connecticut	32	12	1.9	30.0
Delaware	5	0	−0.5	−2.0
Florida	168	5	−0.4	−29.1
Georgia	108	0	−0.5	−13.0
Hawaii	14	0	−0.4	−1.1
Idaho	15	0	−0.4	−1.0
Illinois	130	0	−0.5	−26.3
Indiana	89	1	−0.5	−11.1
Iowa	34	5	−0.3	−3.0
Kansas	55	1	−0.4	−3.5
Kentucky	65	1	−0.4	−8.5
Louisiana	97	10	−0.5	−7.2
Maine	20	0	−0.4	−2.1
Massachusetts	61	60	8.7	274.8
Michigan	100	0	−0.5	−21.4
Minnesota	51	0	−0.5	−8.1
Mississippi	64	0	−0.5	−5.6
Missouri	80	4	−0.4	−10.5
Montana	12	1	−0.3	−0.8
Nebraska	23	0	−0.4	−2.4
Nevada	24	0	−0.5	−3.7
New Hampshire	13	9	1.5	6.3
New Jersey	67	39	1.4	54.2
New Mexico	28	0	−0.3	−1.6
New York	170	2	−0.5	−47.5
North Carolina	89	4	−0.4	−15.5
North Dakota	6	0	−0.3	−0.8

FY 2012 IPPS ESTIMATED PAYMENTS DUE TO RURAL FLOOR AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY—Continued

State	Number of hospitals	Number of hospitals receiving rural floor or imputed floor	Percent change in payments due to application of rural floor and imputed floor with budget neutrality	Difference (in millions)
Ohio	138	9	−0.4	−15.8
Oklahoma	85	2	−0.4	−5.7
Oregon	33	3	−0.4	−3.5
Pennsylvania	152	16	−0.4	−17.3
Puerto Rico	51	12	0.1	0.1
Rhode Island	11	0	−0.6	−2.2
South Carolina	55	0	−0.4	−7.2
South Dakota	19	0	−0.3	−0.9
Tennessee	99	11	−0.3	−7.7
Texas	320	4	−0.5	−34.0
Utah	32	2	−0.4	−1.7
Vermont	6	0	−0.3	−0.6
Virginia	81	2	−0.4	−10.8
Washington	48	2	−0.4	−7.3
Washington, D.C.	7	0	−0.5	−2.5
West Virginia	32	3	−0.3	−2.2
Wisconsin	64	2	−0.4	−6.4
Wyoming	11	0	0	0.0

h. Effects of the Application of the Frontier State Wage Index (Column 9)

Section 10324(a) of the 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, five States (Montana, North Dakota, Nevada, South Dakota, and Wyoming) are considered frontier States and 48 hospitals located in those States will receive a frontier wage index of 1.0. This provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $50 million.

Urban hospitals located in the West North Central region and urban hospitals located in the Mountain region will experience an increase in payments by 0.6 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 will experience an increase in payments by 0.6 percent and 0.1 percent, respectively.

i. Effects of the Wage Index Adjustment for Out-Migration (Column 10)

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 will experience a 0.1 percent increase in payments as a result of the outmigration adjustment. Rural DSH providers will experience a 0.5 percent increase in payments. There are 255 providers that will receive the out-migration adjustment in FY 2012. This out-migration wage adjustment is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase to be approximately $15 million.

j. Effects of the Expiration of Section 508 (Column 11)

Column 11 shows our estimate of the changes in payments due to the expiration of section 508, a non-budget neutral reclassification provision, applied under the MMEA. Because this provision is not budget neutral, the expiration of this reclassification provision results in a −0.2 percent decrease in payments, overall. There are 88 section 508 hospitals in this payment analysis. Section 508 hospitals are generally urban hospitals, resulting in a −0.2 percent decrease in payments among the urban hospital category and a 0.0 percent change in payments among rural hospitals. Urban Middle Atlantic and East North Central regions will experience a decrease in payments of −0.4 percent and −0.5 percent respectively because many section 508 hospitals are located in those regions. Urban teaching hospitals that do not receive DSH will experience a −0.4 percent decrease in payments due to the expiration of section 508.

k. Effects of All FY 2012 Changes (Column 12)

Column 12 shows our estimate of the changes in payments per discharge from FY 2011 and FY 2012, resulting from all changes reflected in this final rule for FY 2012. It includes combined effects of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 1.1 percent for FY 2012 relative to FY 2011. As discussed in section II.D. of the preamble of this final rule, this column includes the FY 2012 documentation and coding adjustment of −2.0 percent on the national standardized amount and on the hospital-specific rates. In addition, this column includes the annual hospital update of 1.9 percent to the national standardized amount. This annual hospital update includes the 3.0 percent market basket update, the reduction of 1.0 percentage point for the multifactor productivity adjustment, and the 0.1 percentage point reduction under section 3401 of the Affordable Care Act. As described in Column 2, the annual hospital update, combined with the documentation and coding adjustment, results in a −0.1 percent decrease in payments in FY 2012 relative to FY 2011. As described in Column 3, the 1.1 percent adjustment to the national standardized amount and the 0.9 percent adjustment to the hospital specific rate in light of a recent court decision related to rural floor budget neutrality results in a 1.1 percent increase in payments in FY 2012 relative to FY 2011. In addition, Column 11 describes a −0.2 percent decrease in payments due to the expiration of section 508 reclassifications that had been extended for FY 2011 under the MMEA. Section 508 was not a budget-neutral provision. The impact of moving from our estimate of FY 2011 outlier payments, 4.8 percent, to the estimate of FY 2012 outlier payments, 5.1 percent, results in an increase of 0.3 percent in FY 2012 payments relative to FY 2011. There might also 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 12 may not equal the sum of the percentage changes described above.

The overall change in payments per discharge for hospitals paid under the IPPS in FY 2012 is estimated to increase by 1.1 percent. The payment increase among the hospital categories is largely attributed to the updates to the rate including the hospital update and the increase to the rate associated with a recent court decision related to rural floor budget neutrality. Hospitals in urban areas will experience an estimated 1.2 percent increase in payments per discharge in FY 2012 compared to FY 2011. Hospital payments per discharge in rural areas are estimated to increase by 0.2 percent in FY 2012 as compared to FY 2011.

Among urban census divisions, the smallest estimated payment increase will be 0.2 percent in the East North Central region because many of the urban providers in this region had benefited from section 508 reclassifications in FY 2011 that have expired for FY 2012. Urban hospitals in New England will see the largest payment increases (5.6 percent) because the Massachusetts hospitals are benefitting from the rural floor in their State. Furthermore, urban Puerto Rico hospitals will experience a 1.2 percent increase in payments due to the application of the rural floor.

Among the rural regions, the providers in the East South Central and West South Central regions will experience decreases in payments of −0.5 percent and 0.3 percent respectively, due to decreases in wage data and the downward adjustment applied to their wage index for rural floor budget neutrality. Rural hospitals in the Pacific region will experience an increase in payments of 0.7 percent because the rural providers in this region benefit from higher than average wage data and MGCRB reclassification.

Among special categories of hospitals, MDHs will receive an estimated payment increase of 0.5 percent. MDHs are paid the higher of the IPPS rate based on the national standardized amount, that is, the Federal rate, or, if the hospital-specific rate exceeds the Federal rate, the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate. SCHs are paid the higher of their Federal rate and the hospital-specific rate. Overall, SCHs will experience an estimated decrease in payments by 0.7 percent.

Rural hospitals reclassified for FY 2012 are anticipated to receive a 0.5 percent payment increase. Rural hospitals that are not reclassifying are estimated to receive a payment decrease of 0.3 percent due to lower wage data, changes to the relative weights and application of rural floor budget neutrality. Urban reclassified hospitals will experience the average payment increase at 1.1 percent due to the benefits under MGCRB reclassification and the rural floor. Urban nonreclassified hospitals will experience a payment increase of 1.2 percent.

Cardiac hospitals are expected to experience a payment decrease of 1.2 percent in FY 2012 relative to FY 2011.

3. Impact Analysis of Table II

Table II presents the projected impact of the changes for FY 2012 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 2011 with the average payments per discharge for FY 2012, as calculated under our models. Thus, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 12 of Table I.

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2012 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per discharge]

	Number of hospitals	Average FY 2011 payment per discharge (2)	Average FY 2012 payment per discharge (3)	All FY 2012 changes (4)
All hospitals	3,423	$10,249	$10,359	1.1
By Geographic Location:				
Urban hospitals	2,498	10,658	10,783	1.2
Large urban areas (populations over 1 million)	1,371	11,239	11,378	1.2
Other urban areas (populations of 1 million or fewer)	1,127	9,944	10,051	1.1
Rural hospitals	925	7,657	7,675	0.2
Bed Size (Urban):				
0–99 beds	632	8,202	8,289	1.1
100–199 beds	782	8,989	9,101	1.2
200–299 beds	449	9,738	9,847	1.1
300–499 beds	430	10,952	11,062	1
500 or more beds	205	13,141	13,316	1.3
Bed Size (Rural):				
0–49 beds	320	6,174	6,157	−0.3
50–99 beds	348	7,169	7,162	−0.1
100–149 beds	152	7,424	7,449	0.3
150–199 beds	58	8,416	8,458	0.5
200 or more beds	47	9,438	9,501	0.7
Urban by Region:				
New England	120	11,136	11,761	5.6
Middle Atlantic	320	11,772	11,877	0.9
South Atlantic	380	9,809	9,891	0.8
East North Central	401	10,043	10,060	0.2
East South Central	153	9,492	9,535	0.5
West North Central	169	10,256	10,379	1.2
West South Central	366	9,995	10,123	1.3
Mountain	159	10,803	10,892	0.8
Pacific	380	13,112	13,316	1.6
Puerto Rico	50	5,299	5,362	1.2
Rural by Region:				
New England	23	10,175	10,210	0.3
Middle Atlantic	69	8,037	8,096	0.7
South Atlantic	165	7,362	7,400	0.5
East North Central	120	7,966	7,997	0.4
East South Central	170	7,027	6,992	−0.5
West North Central	99	8,145	8,196	0.6

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2012 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals	Average FY 2011 payment per discharge (2)	Average FY 2012 payment per discharge (3)	All FY 2012 changes (4)
West South Central	183	6,737	6,720	−0.3
Mountain	66	8,509	8,533	0.3
Pacific	29	10,235	10,307	0.7
Puerto Rico	1	2,280	2,299	0.8
By Payment Classification:				
Urban hospitals	2,519	10,643	10,768	1.2
Large urban areas (populations over 1 million)	1,384	11,224	11,362	1.2
Other urban areas (populations of 1 million or fewer)	1,135	9,925	10,032	1.1
Rural areas	904	7,733	7,751	0.2
Teaching Status:				
Non-teaching	2391	8,592	8,676	1
Fewer than 100 Residents	792	10,136	10,233	1
100 or more Residents	240	15,078	15,289	1.4
Urban DSH:				
Non-DSH	739	8,951	9,026	0.8
100 or more beds	1547	11,137	11,275	1.2
Less than 100 beds	337	7,627	7,696	0.9
Rural DSH:				
SCH	417	7,117	7,069	−0.7
RRC	222	8,471	8,526	0.7
100 or more beds	27	6,372	6,384	0.2
Less than 100 beds	134	5,928	5,952	0.4
Urban teaching and DSH:				
Both teaching and DSH	827	12,180	12,327	1.2
Teaching and no DSH	144	9,858	9,946	0.9
No teaching and DSH	1057	9,120	9,237	1.3
No teaching and no DSH	491	8,529	8,600	0.8
Rural Hospital Types:				
RRC	175	8,561	8,616	0.6
SCH	320	8,149	8,090	−0.7
MDH	193	6,397	6,432	0.5
SCH and RRC	120	9,420	9,479	0.6
MDH and RRC	18	8,467	8,513	0.5
Type of Ownership:				
Voluntary	1,985	10,394	10,512	1.1
Proprietary	870	9,115	9,195	0.9
Government	566	10,869	10,967	0.9
Medicare Utilization as a Percent of Inpatient Days:.				
0–25	358	14,311	14,494	1.3
25–50	1,695	10,897	11,025	1.2
50–65	1,081	8,505	8,567	0.7
Over 65	198	7,456	7,522	0.9
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY 2012 Reclassifications:				
All Reclassified Hospitals FY 2012	655	9,793	9,881	0.9
All Non-Reclassified Hospitals FY 2012	2768	10,371	10,487	1.1
Urban Reclassified Hospitals FY 2012:	323	10,668	10,780	1.1
Urban Non-reclassified Hospitals FY 2012	2142	10,673	10,800	1.2
Rural Reclassified Hospitals FY 2012	332	8,260	8,305	0.5
Rural Nonreclassified Hospitals FY 2012:	532	6,825	6,803	−0.3
All Section 401 Reclassified Hospitals:	40	8,598	8,615	0.2
Other Reclassified Hospitals (Section 1886(d)(8)(B))	62	7,263	7,283	0.3
Specialty Hospitals:				
Cardiac Hospitals	19	11,158	11,288	1.2

H. Effects of Other Policy Changes

In addition to those policy changes discussed above that we are able to model using our IPPS payment simulation model, we are making various other changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes. Our estimates of the likely impacts associated with these other changes are discussed below.

1. Effects of Proposed Policy on HACs, Including Infections

In section II.F. of the preamble of this final rule, we discuss our implementation of section 1886(d)(4)(D) of the Act, which requires the Secretary to identify conditions that are: (1) High cost, high volume, or both; (2) result in the assignment of a case to an MS–DRG that has a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented

through application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission, unless, based on data and clinical judgment, it cannot be determined at the time of admission whether a condition is present. That is, the case will be paid as though the secondary diagnosis were not present. However, the statute also requires the Secretary to continue counting the condition as a secondary diagnosis that results in a higher IPPS payment when doing the budget neutrality calculations for MS–DRG reclassifications and recalibration. Therefore, we will perform our budget neutrality calculations as though the payment provision did not apply, but Medicare will make a lower payment to the hospital for the specific case that includes the secondary diagnosis. Thus, the provision results in cost savings to the Medicare program.

We note that the provision will only apply when one or more of the selected conditions are the only secondary diagnosis or diagnoses present on the claim that will lead to higher payment. Medicare beneficiaries will generally have multiple secondary diagnoses during a hospital stay, such that beneficiaries having one MCC or CC will frequently have additional conditions that also will generate higher payment. Only a small percentage of the cases will have only one secondary diagnosis that would lead to a higher payment. Therefore, if at least one nonselected secondary diagnosis that leads to higher payment is on the claim, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case. In addition, as discussed in section II.F.3.e. of the preamble of this final rule, it is possible to have two severity levels where the HAC does not affect the MS–DRG assignment or for an MS–DRG not to have severity levels. In either of these circumstances, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case.

In section II.F. of the preamble of this final rule, we discuss our decision not to add one HAC for FY 2012: Contrast-Induced Acute Kidney Injury. Therefore, we have deleted the cost estimates for this proposed HAC from the proposed savings estimates for the next 5 fiscal years.

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 2012	$21
FY 2013	22
FY 2014	23
FY 2015	25
FY 2016	27

2. Effects of Policy Relating to New Medical Service and Technology Add-On Payments

In section II.I. of the preamble to this final rule, we discuss two applications for add-on payments for new medical services and technologies for FY 2012, as well as the status of the new technology that was approved to receive new technology add-on payments in FY 2011. 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 final rule, we are not approving either of the two applications for new technology add-on payments for FY 2012. However, we are finalizing our proposal to continue to make new technology add-on payments in FY 2012 for the AutoLITT™ (because the technology is still within the 3-year anniversary of the product's entry onto the market). We note that new technology add-on payments per case are limited to the lesser of (1) 50 percent of the costs of the new technology or (2) 50 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case. Because it is difficult to predict the actual new technology add-on payment for each case, our estimate below is based on the increase in add-on payments for FY 2012 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. For FY 2011, the applicant estimates that approximately 170 Medicare beneficiaries will be eligible for the AutoLITT™. Therefore, based on the applicant's estimate from FY 2011, we currently estimate that payments for the AutoLITT™ will increase overall FY 2012 payments by $900,000.

3. Effects of Requirements for Hospital Inpatient Quality Reporting (IQR) Program

In section VII.C. of Appendix A of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50662 through 50663), we discussed the impact of the FY 2011 through FY 2014 Hospital Inpatient Quality Reporting (IQR) Program requirements we adopted in that final rule. We estimated that 95 hospitals would not receive the full payment update in any fiscal year from FY 2012 through FY 2014. At the time that analysis was prepared, 104 hospitals did not receive the full payment update in FY 2010.

In section IV.A. of this final rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full update to the standardized amount for FY 2012 through FY 2015. We now estimate that approximately 104 hospitals may not receive the full update in any fiscal year. (In section IV.A.2.b. of this final rule, we finalized that, for the FY 2014 payment determination, we would retire four measures (AMI–4, HF–4, PN–4, and PN–5c) and suspend data collection for four measures (AMI–1, AMI–3, AMI–5, and SCIP–INF–6), beginning with January 1, 2012 discharges. We believe that these changes will not have a significant effect on our estimate.) We believe that most of these hospitals will be either small rural or small urban hospitals. However, at this time, information is not available to determine the precise number of hospitals that will not meet the requirements to receive the full annual percentage increase for FY 2012 through FY 2015.

In section IV.A.7. of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225 through 50229), we established Hospital IQR validation requirements for the FY 2012 and FY 2013 payment determinations. Beginning with the FY 2012 payment update, hospitals must pass our validation requirement of a minimum of 75 percent reliability, based upon our chart-audit validation process, for four quarters of data from the last quarter of CY 2011 through the third quarter of CY 2012.

In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45 days from the date of the request to submit the requested records. In section IV.A.6.a. of this final rule and in proposed § 412.140(d)(1), beginning with the FY 2012 we are reducing the deadline from 45 days to 30 days for hospitals to return requested medical record documentation to support our validation requirement. This may be an additional administrative burden to hospitals selected for validation. However, this deadline is in line with our QIO regulations at § 476.78 and the burden will be 18 charts for each for the four quarters that must be copied and mailed in a 30 day period for FY 2012 and subsequent years.

In addition, we are adding a new § 478.78(b)(2)(ii) that will require the submission of medical information within 21 days in those situations in which a ''serious reportable event'' or other circumstance has been identified during the course of a QIO review. We do not believe this will cause a significantly higher administrative burden on the hospitals, because CMS reimburses providers returning medical records to QIOs at the rate of 12 cents per page for copying and approximately $4.00 per chart for postage. Given that we reimburse for the data collection effort, we believe that this requirement represents a minimal burden to providers. We have continued our efforts to ensure that QIOs provide assistance to all hospitals that wish to participate in the Hospital IQR Program.

In section IV.A.6.b. of this final rule, for FY 2014 payment determinations and subsequent years, we are adding two strata to the current Hospital IQR validation sample of SCIP, AMI, HF, and PN cases. For the first stratum, we are selecting three cases per selected hospital per quarter to validate the CLABSI measure using a two step selection process that would target potential patients with positive infection from blood culture results and a Central Venous Catheter. The requirement of an additional 3 charts per hospital submitted for validation for the CLABSI measure will result in approximately 2,400 total additional charts per quarter being submitted to CMS by all selected hospitals. We reimburse hospitals for the cost of sending charts to the CDAC contractor at the rate of 12 cents per page for copying and approximately $4.00 per chart for postage. Our experience shows that the average chart received by the CDAC contractor is approximately 275 pages. Thus, we will expend approximately $88,800 per quarter to collect the additional charts we need to validate the CLASBI measure. Additionally, we will collect the CLABSI-specific data elements from all charts currently requested for the Hospital IQR validation. We will validate a total of 15 records per quarter per

validated hospital in 5 strata (SCIP, AMI, HF, PN, CLABSI and the ED/Global Immunization measure).

In section IV.A.6.b. of this final rule, for FY 2014 and subsequent years, we are adding a second stratum to our validation sample, which will enable us to validate the EDT and the Immunization for Influenza and Immunization for Pneumonia global measures. Thus, we will be validating a total of 18 records per quarter per selected hospital in 6 strata ((1) SCIP, (2) AMI, (3) HF, (4) PN, (5) CLABSI, and (6) EDT/immunization measures). Under the assumptions outlined above, we will expend approximately $88,800 per quarter to collect the additional charts for the EDT/immunization measures. The total requirement of 18 charts per hospital will result in approximately 14,400 charts per quarter being submitted to CMS. Using the assumptions discussed above, for the FY 2014 Hospital IQR Program, we estimate that CMS will have expenditures of approximately $532,800 per quarter related to the validation requirement. Additionally, we will collect the CLABSI-specific data and the EDT/Immunization data elements from all charts currently requested for Hospital IQR validation. We will validate a total of 18 records per quarter per validated hospital in 6 strata (SCIP, AMI, HF, PN, CLABSI and the ED/Global Immunization measure). We do not believe this will be an additional burden on the hospitals because these data will be abstracted from records already submitted.

Given that we reimburse for the data collection effort, we believe that a requirement for 18 charts per hospital per quarter represents a minimal burden to participating hospitals selected for validation.

Finally, with respect to our validation requirements, we also are providing that, for FY 2015, we will select additional hospitals for validation if they were open under their current CCNs in FY 2012 but not selected for validation in the three previous annual Hospital IQR Program validation selections. This provision could affect data collection costs and burdens, but we are unable to estimate any impact at this time.

4. Effects of Additional Hospital Value-Based Purchasing (VBP) Program Requirements

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 for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to the FY 2013 base operating MS–DRG payment for each discharge of 1 percent, as required by section 1886(o)(7)(B)(i) 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.

In section IV.B. of the preamble of this final rule, we are adding requirements for the FY 2014 Hospital VBP Program. Specifically, we are adding a Medicare Spending per Beneficiary Measure, how the measure will be scored, and the measure's performance period and baseline period. Because this additional measure is claims-based and is required for the Hospital IQR Program, its 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.

5. Effects of Requirements for Hospital Readmissions Reduction Program

In section IV.C. of the preamble of this final rule, we are selecting three high cost, high volume conditions for the Hospital Readmission Reduction Program FY 2013 payment reduction, and the definition of readmission for these conditions. We also are finalizing the use of the following three measures for these conditions for the FY 2013 payment determination:

- Heart failure [HF] 30-day Risk Standardized Readmission Measure
- Acute Myocardial Infarction [AMI] 30-day Risk Standardized Readmission Measure
- Pneumonia [PN] 30-day Risk Standardized Readmission Measure

These three risk-adjusted NQF endorsed measures will be calculated by CMS for hospitals subject to this provision using Medicare FFS Part A and B claims data, and require no submission of additional data by the hospital. Therefore, there is no data collection burden associated with this provision for FY 2013. These measures also are used under the Hospital IQR Program, and have been publicly reported on the *Hospital Compare* Web site since 2009. Therefore, there is a high degree of familiarity and acceptance among the stakeholder community with regard to these measures.

We also are establishing a methodology for calculating the Excess Readmission Ratio using these three measures for the FY 2013 payment determination. This is defined as a ratio of the number of risk-adjusted readmissions (based on actual readmissions) for the given condition at a specified hospital compared with the number of readmissions that will be expected for an average hospital caring for the same patients. Below is a description of this calculation:

Numerator—Adjusted number of readmission at specific hospital (calculated for each patient and add up results for all patients):

Hospital-specific readmission effect + average hospital contribution to readmission risk + [risk factor weights × patient risk factors]

Denominator—Number of readmissions if an average hospital treated the same patients (calculated for each patient and summed for all patients):

Average hospital contribution to readmission risk + [risk factor weights × patient risk factors]

We are providing a minimum case threshold of 25 cases for a given condition in order to have an Excess Readmission Ratio calculated. Using the 25-case threshold, we have analyzed the distribution of Excess Readmission Ratio calculations on various types of IPPS hospitals. The results of these analyses are shown in the three tables below.

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Distribution of Excess Readmission Ratio for Acute Myocardial Infarction (AMI): AMI Readmission Distribution of Excess Readmission Ratio (for hospitals with greater than 25 AMI cases between July 2006-June 2009)

Hospital Characteristic	Hospi-tals with (≥ 25 cases over 3-year period)	Hospitals with Excess Readmission Ratio ≤ 1*	Percent-age of Hospitals with Excess Readmission Ratio ≤ 1*	Percentile								
				Mean	5th	10th	25th	50th	75th	90th	95th	Hospitals with < 25 cases (not included in distri-bution)
OVERALL	2,477	1,248	50.4	1.0019	0.8953	0.9238	0.9627	0.9997	1.0412	1.0795	1.1065	1,999
Region**												
New England	148	72	48.6	1.0060	0.9172	0.9331	0.9623	1.0049	1.0400	1.0949	1.1104	30
Mid Atlantic	338	106	31.4	1.0325	0.9266	0.9544	0.9894	1.0292	1.0690	1.1137	1.1546	61
South Atlantic	448	235	52.5	0.9977	0.8918	0.9207	0.9608	0.9951	1.0370	1.0717	1.0938	203
East North Central	408	210	51.5	1.0046	0.9022	0.9260	0.9649	0.9991	1.0435	1.0884	1.1154	268
East South Central	171	69	40.4	1.0143	0.9338	0.9467	0.9747	1.0084	1.0518	1.0803	1.0967	209
West North Central	166	92	55.4	0.9930	0.8839	0.9190	0.9502	0.9928	1.0311	1.0710	1.0922	428
West South Central	288	149	51.7	0.9964	0.8928	0.9225	0.9612	0.9952	1.0352	1.0632	1.0799	300
Mountain	131	94	71.8	0.9726	0.8758	0.8913	0.9328	0.9744	1.0067	1.0511	1.0717	188
Pacific	275	172	62.5	0.9797	0.8707	0.8979	0.9355	0.9839	1.0229	1.0591	1.0750	191
Associated Areas	25	9	36.0	1.0306	0.9610	0.9649	0.9846	1.0276	1.0632	1.1039	1.1364	21
Bed Size**												
1 to 99 beds	395	220	55.7	0.9987	0.9279	0.9451	0.9710	0.9953	1.0275	1.0516	1.0717	1,556
100 to 199 beds	731	358	49.0	1.0015	0.9096	0.9345	0.9646	1.0019	1.0375	1.0713	1.0926	274
200 to 299 beds	517	272	52.6	0.9979	0.8868	0.9137	0.9541	0.9961	1.0423	1.0771	1.1059	41
300 to 399 beds	320	164	51.3	0.9994	0.8686	0.9036	0.9507	0.9989	1.0511	1.0923	1.1145	19
400 to 499 beds	170	78	45.9	1.0116	0.8816	0.9021	0.9610	1.0067	1.0636	1.1090	1.1391	7
500+ beds	265	116	43.8	1.0125	0.8839	0.9007	0.9643	1.0115	1.0632	1.1139	1.1516	2
Teaching Status**												
Teaching	896	439	49.0	1.0061	0.8840	0.9121	0.9580	1.0028	1.0530	1.0992	1.1293	175
Non-Teaching	1,502	769	51.2	0.9994	0.9058	0.9284	0.9649	0.9987	1.0353	1.0672	1.0914	1,724
Urban/Rural Status**												
Urban	2,279	1,146	50.3	1.0017	0.8928	0.9211	0.9615	0.9998	1.0418	1.0797	1.1072	972
Rural	119	62	52.1	1.0061	0.9409	0.9517	0.9713	0.9966	1.0328	1.0761	1.0887	927

* With ≥ 25 cases over 3-year period.

** Total number of hospitals with available hospital characteristics and with > 25 cases over 3-year period equals 2,398.

Distribution of Excess Readmission Ratio for Heart Failure (HF): Heart Failure Readmission Distribution of Excess Readmission Ratio (for hospitals with greater than 25 HF cases between July 2006-June 2009)

Hospital Characteristic	Hospitals with (≥ 25 cases over 3-year period)	Hospitals with Excess Readmission Ratio ≤ 1*	Percentage of Hospitals with Excess Readmission Ratio ≤ 1*	Percentile								
				Mean	5th	10th	25th	50th	75th	90th	95th	Hospitals with < 25 cases (not included in distribution)
OVERALL	4,209	2,171	51.6	1.0021	0.8799	0.9108	0.9527	0.9971	1.0484	1.0991	1.1362	550
Region**												
New England	174	99	56.9	0.9933	0.8830	0.9058	0.9418	0.9879	1.0382	1.0940	1.1121	5
Mid Atlantic	397	135	34.0	1.0376	0.9020	0.9314	0.9788	1.0354	1.0936	1.1485	1.1788	6
South Atlantic	639	323	50.5	1.0021	0.8860	0.9097	0.9517	0.9993	1.0507	1.0962	1.1304	26
East North Central	672	378	56.3	0.9933	0.8740	0.8983	0.9413	0.9890	1.0423	1.0937	1.1302	20
East South Central	381	156	40.9	1.0225	0.9059	0.9291	0.9646	1.0142	1.0708	1.1313	1.1708	14
West North Central	519	304	58.6	0.9918	0.8876	0.9174	0.9482	0.9867	1.0267	1.0730	1.1143	136
West South Central	560	256	45.7	1.0112	0.8920	0.9212	0.9650	1.0082	1.0549	1.1052	1.1373	81
Mountain	271	188	69.4	0.9664	0.8511	0.8789	0.9315	0.9706	1.0118	1.0435	1.0628	93
Pacific	418	247	59.1	0.9892	0.8671	0.9035	0.9458	0.9841	1.0392	1.0823	1.1111	83
Associated Areas	34	12	35.3	1.0304	0.9365	0.9515	0.9877	1.0253	1.0665	1.1122	1.1461	14
Bed Size**												
1 to 99 beds	1,755	947	54.0	0.9999	0.8980	0.9206	0.9556	0.9939	1.0394	1.0865	1.1190	414
100 to 199 beds	983	467	47.5	1.0080	0.8833	0.9145	0.9584	1.0042	1.0517	1.1119	1.1427	38
200 to 299 beds	547	284	51.9	1.0019	0.8647	0.8959	0.9476	0.9966	1.0565	1.1125	1.1485	15
300 to 399 beds	337	176	52.2	1.0003	0.8626	0.8939	0.9449	0.9964	1.0586	1.1052	1.1314	4
400 to 499 beds	176	93	52.8	0.9979	0.8501	0.8857	0.9290	0.9920	1.0596	1.1275	1.1578	3
500+ beds	267	131	49.1	1.0004	0.8506	0.8908	0.9397	1.0017	1.0549	1.1051	1.1577	4
Teaching Status**												
Teaching	1,036	547	52.8	1.0005	0.8681	0.9001	0.9454	0.9937	1.0534	1.1085	1.1476	49
Non-Teaching	3,029	1,551	51.2	1.0027	0.8838	0.9149	0.9554	0.9980	1.0469	1.0978	1.1328	429
Urban/Rural Status**												
Urban	3,160	1,666	52.7	0.9996	0.8742	0.9048	0.9487	0.9941	1.0476	1.1005	1.1366	205
Rural	905	432	47.7	1.0110	0.9126	0.9312	0.9631	1.0043	1.0517	1.0984	1.1378	273

* With ≥ 25 cases over 3-year period.

** Total number of hospitals with available hospital characteristics and with > 25 cases over 3-year period equals 4,065.

Distribution of Excess Readmission Ratio for Pneumonia (PN): Pneumonia Readmission Distribution of Excess Readmission Ratio (for hospitals with greater than 25 Pneumonia cases between July 2006-June 2009)

Hospital Characteristic	Hospitals with (≥ 25 cases over 3-year period)	Hospitals with Excess Readmission Ratio ≤ 1*	Percentage of Hospitals with Excess Readmission Ratio ≤ 1*	Percentile								
				Mean	5th	10th	25th	50th	75th	90th	95th	Hospitals with < 25 cases (not included in distribution)
OVERALL	4,450	2,351	52.8	1.0021	0.8763	0.9019	0.9435	0.9944	1.0531	1.1134	1.1538	363
Region**												
New England	178	88	49.4	1.0086	0.8750	0.9045	0.9488	1.0011	1.0603	1.1262	1.1605	3
Mid Atlantic	399	143	35.8	1.0458	0.9021	0.9360	0.9735	1.0326	1.1033	1.1773	1.2288	5
South Atlantic	653	301	46.1	1.0135	0.8858	0.9187	0.9586	1.0073	1.0639	1.1207	1.1494	16
East North Central	679	368	54.2	1.0003	0.8614	0.8907	0.9340	0.9889	1.0557	1.1231	1.1645	12
East South Central	381	132	34.6	1.0381	0.9032	0.9248	0.9719	1.0329	1.0938	1.1544	1.2052	17
West North Central	618	379	61.3	0.9831	0.8766	0.9027	0.9365	0.9785	1.0207	1.0741	1.1052	42
West South Central	590	343	58.1	0.9917	0.8682	0.8928	0.9344	0.9871	1.0399	1.0922	1.1427	59
Mountain	323	236	73.1	0.9605	0.8487	0.8812	0.9187	0.9615	1.0027	1.0525	1.0748	47
Pacific	443	273	61.6	0.9822	0.8590	0.8865	0.9369	0.9827	1.0258	1.0774	1.1090	65
Associated Areas	36	11	30.6	1.0395	0.9343	0.9575	0.9820	1.0382	1.0819	1.1441	1.1605	13
Bed Size**												
1 to 99 beds	1,982	1,187	59.9	0.9910	0.8784	0.9019	0.9386	0.9812	1.0348	1.0914	1.1327	214
100 to 199 beds	989	501	50.7	1.0067	0.8771	0.9044	0.9466	0.9989	1.0616	1.1199	1.1555	36
200 to 299 beds	547	261	47.7	1.0081	0.8684	0.8920	0.9450	1.0028	1.0609	1.1270	1.1670	18
300 to 399 beds	37	142	42.1	1.0139	0.8567	0.8933	0.9551	1.0154	1.0710	1.1370	1.1708	4
400 to 499 beds	177	80	45.2	1.0167	0.8763	0.9194	0.9488	1.0105	1.0646	1.1383	1.2018	3
500+ beds	268	103	38.4	1.0296	0.8579	0.9105	0.9583	1.0215	1.0819	1.1573	1.2268	4
Teaching Status**												
Teaching	1,049	470	44.8	1.0144	0.8614	0.8997	0.9492	1.0108	1.0682	1.1383	1.1971	46
Non-Teaching	3,251	1,804	55.5	0.9981	0.8786	0.9015	0.9418	0.9892	1.0476	1.1072	1.1428	233
Urban/Rural Status**												
Urban	3,215	1,651	51.4	1.0032	0.8671	0.8953	0.9421	0.9976	1.0565	1.1182	1.1595	179
Rural	1,085	623	57.4	0/9985	0.8924	0.9120	0.9460	0.9871	1.0405	1.1027	1.1416	100

* With ≥ 25 cases over 3-year period.

** Total number of hospitals with available hospital characteristics and with ≥ 25 cases over 3-year period equals 4,300.

The three tables above show the distribution of Excess Readmission Ratios for AMI hospitalizations, HF hospitalizations, and PN hospitalizations respectively. The data for these tables come from the publicly-reported risk-standardized rates of

readmission reported in 2010 on *Hospital Compare* (representing hospitalizations between July 2006 and June 2009). The distributions of the ratios are shown only for hospitals with at least 25 cases included in the measures over the 3-year period.

The first column of the tables lists hospital characteristics (census region, bed size, teaching status, and urban/rural location) and the second column shows the number of hospitals included in the distribution for the particular category. For example, for the first table, AMI readmission, a total of 2,477 hospitals had at least 25 included hospitalizations between July 2006 and June 2009. Of these hospitals, 148 were in the New England region.

The third and fourth columns show the number and percentage of hospitals (of those with 25 or more cases) in the particular category with an Excess Readmission Ratio less than or equal to 1; such hospitals would not have their payments adjusted due to the Readmission Reduction Program because they would not be found to have ''excess'' readmissions. For example in the first table, for AMI readmissions, 72 of the 148 hospitals in the New England region (that had 25 or more AMI hospitalizations) had an Excess Readmission Ratio of less than or equal to 1, which means that 48.6 percent of the hospitals in the New England region (with at least 25 cases of AMI in 3 years) would not have their payments affected by the Hospital Readmission Reduction Program, whereas the remaining hospitals would be at risk of a payment reduction based on excess readmissions.

The following eight columns show the distribution of the excess readmissions. For example, for AMI, in the New England region the mean Excess Readmission Ratio is 1.0060, the lowest 5th percentile hospitals had ratios of 0.9172 or less and the hightest 95th percentile of hospitals had Excess Readmission Ratios of 1.1104 or greater.

The final column of each table shows the number of hospitals, within the given category, that are not included in the distribution based on sample size. For example, for AMI, in the New England region 30 hospitals are not included in the distribution because they had fewer than 25 AMI hospitalizations over the 3-year period. Currently, 25 hospitalizations is the minimum number of hospitalizations for public reporting. Hospitals with fewer than 25 cases for a given condition do not have risk-standardized rates of readmission reported on *Hospital Compare.* We are finalizing this threshold for the Readmission Reduction Program.

Overall these analyses show, for all three conditions, that in all hospital categories approximately half of the hospitals are at risk of payment reductions based on excess readmissions. This percentage does not vary greatly by region; however for all three measures the Mid-Atlantic region has the lowest percentage of hospitals with Excess Readmission Ratios of less than or equal to 1 and, therefore, the Mid-Atlantic region is the region with the highest percentage of hospitals at risk of payment reduction. By contrast, the Mountain region has the largest percentage of hospitals with ratios of less than or equal to 1. The distributions do not differ greatly by bed size, though the largest hospitals have slightly lower percentages of hospitals with ratios less than or equal to 1 for AMI and PN. The distributions do not vary greatly by teaching status or rural/urban location for any of the measures.

We also are publicly reporting the readmission rates for these three measures on the *Hospital Compare* Web site using the current processes employed for public reporting of these measures, which includes a preview period. We believe that this also poses no additional burden to hospitals, as they currently employ this system for Hospital IQR public reporting.

6. Effects of Policy Changes Relating to Payment Adjustments for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME)

In section IV.G. of the preamble of this final rule, we are finalizing our proposal to exclude from the hospital's disproportionate patient percentage (DPP) of the Medicare DSH calculation and from the available bed day count used to calculate the DSH payment adjustment and the IME payment adjustments, patient days for hospice patients receiving inpatient hospice services in a hospital setting. For the purpose of the DSH payment adjustment calculation, the patient days for hospice patients receiving inpatient hospice services in the hospital are excluded from both the numerator and the denominator of the Medicare and Medicaid fractions. As such, the impact on hospitals' DSH payment adjustment will vary based on the demographic composition of an individual hospital's patient population. In other words, under this policy, some hospitals may receive increased DSH payment adjustments and other hospitals may expect to receive lower DSH payment adjustments, depending on the extent to which a hospital provides inpatient hospice services to hospice patients.

The final policy of excluding, from the available bed count, patient days for hospice patients receiving hospice services in an inpatient hospital setting only impacts DSH payment adjustments for limited situations. Specifically, urban hospitals with fewer than 100 beds or rural hospitals with fewer than 500 beds, with the exception of rural referral centers or MDHs, are subject to a cap of their DSH payment adjustment of 12 percent. Thus, a decrease in the number of available beds due to the exclusion of beds used to provide inpatient hospice services only impacts a provider's DSH payment adjustments if it results in the hospital's bed count falling below the bed count threshold. Should a hospital fall below the bed count threshold, it would become subject to the Medicare DSH payment adjustment cap and its DSH payment could decrease.

For IME payment purposes, a decrease in a hospital's number of available beds results in an increase in the resident-to-bed ratio. The exclusion of bed days associated with hospice patients from the available bed count for IME will reduce the available beds, increase the resident-to-bed ratio, and, consequently, may increase IME payments to teaching hospitals, depending on the extent to which these hospitals were providing inpatient hospice services to hospice patients.

7. Effects of the FY 2012 Low-Volume Hospital Payment Adjustment

As discussed in section IV.E. of the preamble to this final rule, we discuss the provisions of sections 3125 and 10314 of the Affordable Care Act that expand eligibility for the low-volume hospital payment adjustment at section 1886(d)(12) of the Act for FYs 2011 and 2012 to hospitals with less than 1,600 Medicare discharges (instead of the prior requirement of less than 800 total, Medicare and non-Medicare, discharges) and hospitals that are located more than 15 miles from other IPPS hospitals (rather than the prior requirement of more than 25 miles). The payment adjustment is also changed from an empirically determined additional 25 percent payment adjustment to qualifying hospitals with less than 200 total discharges (69 FR 49099 through 49102 and 70 FR 47432 through 47434) to a continuous, linear sliding scale adjustment ranging from an additional 25 percent payment adjustment to qualifying hospitals with 200 or fewer Medicare discharges to no additional payment to hospitals with 1,600 or more Medicare discharges (75 FR 50241).

Based on FY 2010 claims data (March 2011 update of the MedPAR file), we estimate that 514 out of the 529 hospitals in our database that qualified as a low-volume hospital for FY 2011 will continue to meet the Medicare discharges criterion to qualify as a low-volume hospital for FY 2012. For purposes of this impact analysis, we are assuming that all of these 514 hospitals will continue to meet the distance criterion in FY 2012. If all 514 hospitals qualified for the low-volume payment adjustment in FY 2012, we estimate that these hospitals will receive an additional estimated $293 million based on the FY 2012 low-volume payment adjustment (described in section IV.E. of the preamble of this final rule) as compared to FY 2012 payments without the proposed low-volume adjustment. (As discussed in section IV.E. of the preamble of this final rule, for FY 2012, we are determining a hospital's number of Medicare discharges based on the most recent update of the FY 2010 MedPAR files (that is, the March 2011 update for this final rule.)

In addition, we identified an additional 86 hospitals in our database that meet the Medicare discharges criterion to qualify as a low-volume hospital for FY 2012 based on our policy of determining a hospital's Medicare discharges based on data from the March 2011 update of the FY 2010 MedPAR file (as established in section IV.E. of the preamble of this final rule). (We note that these 86 hospitals did not meet the discharge criterion to qualify as a low-volume hospital for FY 2011.) However, we are not able to estimate the number of these 86 hospitals that will also meet the distance criterion. The actual number of hospitals that will also meet the distance criterion to qualify as a low-volume hospital is very likely be significantly less than the estimated 86 maximum number of potential additional low-volume hospitals for FY 2012 (as compared to FY 2011). (We note that approximately 40 percent of the hospitals that met the discharge criterion for

FY 2011 also met the mileage criterion and, therefore, are eligible to receive the low-volume payment adjustment in FY 2011.) If all these 86 hospitals were to qualify as low-volume hospitals in FY 2012, we estimate that an additional $23 million in payments will be made for the FY 2012 low-volume payment adjustment at section 1886(d)(12) of the Act.

8. Effects of Changes Relating to MDHs

As discussed in section IV.H. of the preamble to this final rule, section 3124 of Public Law 111–148 extended the MDH program for 1 additional year, from the end of FY 2011 (that is, for discharges before October 1, 2011) to the end of FY 2012 (that is, for discharges before October 1, 2012). The extension had no impact on FY 2011. For FY 2012, the extension allows the continuation of MDH status and the payment methodology, for an MDH to be paid its hospital-specific rate, based on its FY 1982, 1987, or 2002 updated costs per discharge, rather than the Federal rate, if this results in a greater aggregate payment. Therefore, the impact of the extension is one additional year of hospital-specific rate payments, when greater than Federal rate payments, for these hospitals as MDHs, rather than Federal rate payments for these hospitals without special treatment as MDHs.

9. Effects of Policy Relating to CRNA Services Furnished in Rural Hospitals and CAHs

In section IV.I. of the preamble of this final rule, we discuss the interim final rule with comment that appeared in the November 24, 2010 **Federal Register** (75 FR 72256) regarding pass-through payment for CRNA services. In that interim final rule with comment period, we stated that we were changing the effective date of our policy to allow hospitals and CAHs that have reclassified as rural under 42 CFR 412.103 to be eligible for CRNA pass-through from ''cost reporting periods beginning on or after October 1, 2010'' to an effective date of ''December 2, 2010.'' In section IV.I. of the preamble of this final rule, we respond to the comment received on the interim final rule with comment period and state that we are finalizing the effective date of December 2, 2010, that was established in the interim final rule with comment period. Also in the interim final rule with comment period (75 FR 72258), we stated that a change to the effective date would only affect at most a small subset of hospitals and CAHs affected by the change to the regulations adopted in the FY 2010 IPPS/LTCH PPS final rule and, for this reason, we expected the change to the effective date in the interim final rule with comment period to have a minor impact on Federal expenditures. We continue to expect that this change to the effective date will have a minor impact on Federal expenditures.

10. Effect of the Additional Payments to Qualifying Hospitals in Low Medicare Spending Counties

Under section 1109 of Public Law 111–152, Congress allocated $400 million to be spent for FYs 2011 and 2012 to qualifying hospitals located in a county that ranks, based upon its ranking in age, sex, and race adjusted spending for benefits under Medicare Parts A and B per enrollee, within the lowest quartile of counties. In the FY 2011 IPPS/LTCH PPS final rule, we identified the list of eligible counties, the qualifying hospitals, and their payment amounts and stated that we would distribute $150 million in FY 2011 and $250 million in FY 2012. In section IV.J. of the preamble to this final rule, we modified the lists of qualifying hospitals and their payment amounts for FYs 2011 and 2012 because we found that some of the hospitals listed as qualifying hospitals for section 1109 payments were no longer subsection (d) hospitals, a requirement to receive payments under section 1109 of the Act. Following these revisions, for FY 2011, there are 404 subsection (d) hospitals that are receiving payments under section 1109 of the Act. For FY 2012, there are 402 subsection (d) hospitals that will receive payments under section 1109 of the Act, although the number of qualifying hospitals may change should any of them cease to be a subsection (d) hospital prior to FY 2012. Furthermore, in this final rule, we finalized our proposal to spend the remaining $250 million in FY 2012. We also finalized our proposal to make payments to the qualifying hospitals through a one-time annual payment made by one Medicare contractor who would directly pay all of the qualifying hospitals. In section IV.J. of the preamble to this final rule, Table J1 lists the distribution of payments among the list of qualifying hospitals.

11. Effects of Changes Relating to ESRD Add-On Payment

In section IV.L. of the preamble of this final rule, we discuss our clarification that the term ''Medicare discharges'' as used in § 412.104(a) refers to discharges of all beneficiaries entitled to Medicare Part A; that is, discharges associated with individuals entitled to Part A, including discharges of individuals receiving benefits under original Medicare, discharges of individuals whose inpatient benefits are exhausted or whose stay was not covered by Medicare, and discharges for individuals enrolled in Medicare Advantage Plans, cost contracts under section 1876 of the Act (health maintenance organizations (HMOs)) and competitive medical plans (CMPs).

We are not able to provide a detailed analysis of the impact of the clarification of this definition. We are not making any changes to the existing regulations at § 412.104 under which we will continue to provide an additional Medicare payment to a hospital for inpatient services provided to Medicare beneficiaries with ESRD who receive a dialysis treatment during a hospital stay, if the hospital has established that ESRD Medicare beneficiary discharges, excluding certain MS–DRGs for renal failure, admission for renal dialysis, and kidney transplant, where the beneficiary received dialysis services during the inpatient stay, are 10 percent or more of its total Medicare discharges. We note that this clarification could change both the denominator (total Medicare discharges) and the numerator (ESRD Medicare beneficiary discharges, excluding certain MS–DRGs for renal failure, admission for renal dialysis, and kidney transplant) associated with this calculation. As a result of our clarification, these discharges will be included in the denominator of the calculation for the determination of eligibility for the ESRD additional payment to hospitals. Similarly, for the numerator of this calculation, we also will include all discharges of ESRD beneficiaries who are entitled to Medicare Part A and who receive inpatient dialysis, subject to the exclusions of certain MS–DRG codes described above. Depending on whether or not the additional discharges are for ESRD beneficiaries, the calculation may increase or decrease.

12. Effects of Changes Relating to the Reporting Requirements for Pension Costs for Medicare Cost-Finding and Wage Reporting Purposes

In sections III.D.3. and IV.M. of the preamble of this final rule, we are revising our policy for determining pension cost for Medicare purposes. We are setting forth two distinct policies: one for determining and reporting defined benefit pension costs on the cost report for Medicare cost-finding purposes and the other for determining and reporting defined benefit pension costs for Medicare wage index purposes. The allowable pension cost under the current rules and the revised policies are based on the amount funded. The current rules impose an actuarially based limit on the allowable amount and the rules adopted in this final rule limit the costs used in Medicare cost-finding based on historical funding data. Because the current rules and the policies adopted in this final rule are both tied to the amount funded, we expect that there will be minimal impact. We note that it is not possible to determine a precise impact for Medicare cost-finding purposes because we do not currently have data in the form and manner required to calculate the pension costs for all providers under our final policies. Moreover, because we lack these data, we are unable to determine a hospital-level impact for the Medicare wage index. We note that our policies may result in redistribution within the Medicare wage index, but section 1886(d)(3)(E) of the Act requires any adjustments or updates made to the Medicare wage index to be budget neutral.

13. Effects of Implementation of Rural Community Hospital Demonstration Program

In section IV.N. of the preamble of this final 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 IV.N. of the preamble of this final rule, in the IPPS final rules for each of the previous 7 fiscal years, we have estimated the additional payments made by the program for each of the participating hospitals as a result of the

demonstration. In order to achieve budget neutrality, we are adjusting the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are applying budget neutrality across the payment system as a whole rather than 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 making an adjustment in the FY 2012 IPPS final rule of $52,452,060 to the national IPPS rates to account for estimated demonstration cost for FY 2012 for the 7 ''pre-expansion'' participating hospitals that are currently participating in the demonstration and the 18 additional hospitals selected to participate as a result of the expansion of the demonstration under the Affordable Care Act. In addition, in the FY 2012 proposed rule, we stated that the budget neutrality adjustment would also account for any differences between the cost of the demonstration program for hospitals participating in the demonstration during FYs 2007 and 2008, represented by their cost reports beginning in FYs 2007 and 2008, and the amount that was offset by the budget neutrality adjustment for FYs 2007 and 2008. In the proposed rule, we stated that we could not establish the amount of this difference because settled cost reports beginning in FYs 2007 and 2008 in the demonstration were not available. Similarly, for this final rule, the estimated $52,452,060 that we are offsetting does not account for any differences between the cost of the demonstration program for hospitals participating in the demonstration during FYs 2007 and 2008 and the amount that was offset by the budget neutrality adjustment for FYs 2007 and 2008 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 settled cost reports beginning in FYs 2007 and 2008 of the hospitals participating during FYs 2007 and 2008 in the demonstration also are not available at this time.

14. Effects of Changes to the List of MS–DRGs Subject to Postacute Care Transfer and DRG Special Pay Policy

In section IV.P. of the preamble to this final rule, we discuss changes to the list of MS–DRGs subject to the postacute care transfer and DRG special payment policies. As reflected in Table 5 listed in section VI. of the Addendum to this final rule and available via the Internet, using criteria set forth in regulation at § 412.4, we evaluated MS–DRG charges, discharge, and transfer data to determine which MS–DRGs qualify for the postacute care transfer and DRG special pay policies. We note that we are making no change to these payment policies in this FY 2012 final rule. We are changing the status of certain MS–DRGs as a result of revision of the MS–DRGs for FY 2012. We are changing the status of five MS–DRGs to qualify for the postacute care transfer policy in FY 2012, after not qualifying in FY 2011. An additional three MS–DRGs that qualified under the policy in FY 2011 do not qualify in FY 2012, and we are changing their status accordingly. Finally, three MS–DRGs now qualify for the MS–DRG special pay policy in FY 2012 after not qualifying in FY 2011, and we are adding them to the list of qualifying MS–DRGs. Column 4 of Table I in this Appendix A shows the effects of the changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The analysis and methods determining the changes due to the MS–DRGs and relative weights accounts for and includes changes in MS–DRG postacute care transfer and special pay policy statuses. We refer readers to section I.G.2.f. of this Appendix for a more detailed discussion of payment impacts due to MS–DRG reclassification policies.

15. Effects of Changes Relating to Hospital Services Furnished Under Arrangements

In section IV.Q. of the preamble of this final rule, we are limiting the services that a hospital may provide under arrangement. Routine services must be provided in the hospital in which the patient is a registered inpatient in order for the services to be considered as being provided by the hospital. Only diagnostic and therapeutic services (that is, ancillary services) may be provided under arrangement outside the hospital. We are aware of only a few cases where routine services are being provided outside the hospital other than where the patient is a registered inpatient. Even in those few instances where a hospital (hospital A) is currently treating the services that are provided under arrangements at another hospital (hospital B), as if they are provided by hospital A and reporting the costs on hospital A's cost report, complying with this change should not be a burden on either the patient or the hospital. Under this policy, when the patient is transferred to hospital B for the services, the patient will need to be discharged from hospital A and admitted to hospital B. Therefore, we have determined that the impact of this change is negligible.

16. Effects of Change Relating to CAH Payment for Ambulance Services

In section VI.B. of the preamble of this final rule, we discuss our revision of the regulations at § 413.70(b)(5) to state that, effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or by a CAH-owned and operated entity is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. In addition, we are revising the regulations at § 413.70(b)(5) to state that, effective for cost reporting periods beginning on or after October 1, 2011, if there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH, but there is a CAH-owned and operated entity located more than a 35-mile drive from the CAH, the CAH owned and operated entity would be paid at 101 percent of reasonable costs for its ambulance services as long as that entity is the closest provider or supplier of ambulance services to the CAH. We believe this change will continue to allow for sufficient ambulance services to CAHs. We do not have sufficient information or data to determine how many CAH-owned and operated entities can qualify for reasonable cost-based payments under the change. As a result, we are unable to quantify the financial impact of this change for payment based on 101 percent of reasonable costs. However, even those entities that do not qualify for payment based on 101 percent of reasonable costs would be paid for ambulance services under the Medicare ambulance fee schedule.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the March 2011 update of the FY 2010 MedPAR file and the March 2011 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2011 update of the most recently available hospital cost report data (FYs 2008 and 2009) 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. In addition, as discussed in section V.E. of the preamble to this final rule, we are making a −1.0 percent documentation and coding adjustment to the national capital rate for FY 2012 in addition to the −0.6 percent adjustment established for FY 2008, the −0.9 percent adjustment for FY 2009, and the −2.9 percent adjustment for FY 2011. This results in a cumulative adjustment factor of 0.9479 that we applied in determining the FY 2012 national capital rate to account for improvements in documentation and coding that do not reflect real changes in case mix under the MS–DRGs. We note that we applied a −2.6 percent documentation and coding adjustment to the Puerto Rico-specific capital rate in FY 2011, which reflects the entire amount of our current estimate of the effects of documentation for FYs 2008 and 2009 that do not reflect real changes in case-mix under the MS–DRGs. Therefore, we are not adjusting the Puerto Rico-specific capital rate in FY 2012 to account for changes in documentation and coding.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some

individual hospitals are placed in the wrong category.

Using cases from the March 2011 update of the FY 2010 MedPAR file, we simulated payments under the capital IPPS for FY 2011 and FY 2012 for a comparison of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (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 2012 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 will increase by 1.0 percent in both FYs 2011 and 2012.
- We estimate that the Medicare discharges will be approximately 11.8 million in FY 2011 and 12.2 million in FY 2012.
- 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 preamble of this final rule, the update is 1.5 percent for FY 2012.
- In addition to the FY 2012 update factor, the FY 2012 capital Federal rate was calculated based on a GAF/DRG budget neutrality factor of 1.0004, and a outlier adjustment factor of 0.9382. As discussed in section III.A.4. of the Addendum to this final rule, an exceptions adjustment factor is not necessary in FY 2012 because there are no longer any hospitals eligible to receive special exceptions payments in FY 2012. However, the special exceptions adjustment factor was not built permanently into the capital rate; that is, was not applied cumulatively. Therefore, because there will be no special exceptions payments in FY 2012, we are only applying an adjustment to restore the special exceptions adjustment that was applied to the FY 2011 capital rate, that is, 1.0004 (calculated as 1/0.9996).
- For FY 2012, as discussed above and in section V.E. of the preamble to this final rule, we are applying a cumulative 0.9479 adjustment in determining the FY 2012 national capital rate for changes in documentation and coding that are expected to increase case-mix under the MS–DRGs but do not reflect real case-mix change. This cumulative adjustment of 0.9479 reflects the additional −1.0 percent adjustment in FY 2012 for the effects of documentation and coding in FYs 2008 and 2009.

2. Results

We used the actuarial model described above to estimate the potential impact of our changes for FY 2012 on total capital payments per case, using a universe of 3,419 hospitals. As described above, the individual hospital payment parameters are taken from the best available data, including the March 2011 update of the FY 2010 MedPAR file, the March 2011 update to the PSF, and the most recent cost report data from the March 2011 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2011 and estimated total payments per case for FY 2012 based on the FY 2012 payment policies. Column 2 shows estimates of payments per case under our model for FY 2011. Column 3 shows estimates of payments per case under our model for FY 2012. Column 4 shows the total percentage change in payments from FY 2011 to FY 2012. The change represented in Column 4 includes the 1.5 percent update to the capital Federal rate and other changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2012 are expected to increase as compared to capital payments per case in FY 2011. The capital rate for FY 2012 will increase approximately 0.34 percent as compared to the FY 2011 capital rate. The changes to the GAFs are expected to result, on average, in a slight decrease in capital payments for most regions with the certain exceptions. The regional variations in the estimated change in capital payments are consistent with the changes in payments due to changes in the wage index (and policies affecting the wage index) shown in Table I in section I of this Appendix.

We also are estimating a slight increase in outlier payments in FY 2012 as compared to FY 2011. This is primarily because, based on the FY 2010 claims from the March 2011 update of the MedPAR file, we are currently estimating that FY 2011 capital outlier payments are slightly less the projected percentage of 5.96 percent that we used to determine the outlier offset that we applied in determining the FY 2011 capital Federal rate.

The net impact of these changes, as discussed above, is an estimated 1.8 percent change in capital payments per discharge from FY 2011 to FY 2012 for all hospitals (as shown below in Table III).

The geographic comparison shows that, on average, all hospitals, urban and rural, are expected to experience an increase in capital IPPS payments per case in FY 2012 as compared to FY 2011. Capital IPPS payments per case for urban hospitals are estimated to increase 1.8 percent, while rural hospitals are expected to experience a 1.2 percent increase.

The comparisons by region show that all regions will experience, on average, increases in capital IPPS payments. For urban areas, the estimated increase in capital payments per discharge from FY 2011 to FY 2012 ranges from a 1.0 percent increase for the East North Central and East South Central urban regions to a 5.8 percent increase for the New England urban region. As discussed above, the New England urban region is estimated to have a larger than average increase in capital payments per case in FY 2012 as compared to FY 2011 due to the application of a rural floor. For rural regions, the estimated percent increase in capital payments per discharge from FY 2011 to FY 2012 ranges from a 0.7 percent increase for the East North Central rural region to a 2.6 percent increase for the Pacific rural region.

By type of ownership, voluntary hospitals and government hospitals are estimated to experience a 1.8 percent increase in capital payments per case; and proprietary hospitals are estimated to experience a 1.6 percent increase in capital payments per case from FY 2011 to FY 2012.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2012. 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 for FY 2012, we show the average capital payments per case for reclassified hospitals for FY 2012. All reclassified and nonreclassified hospitals are expected to experience an increase in capital payments in FY 2012 as compared to FY 2011. Urban reclassified hospitals are estimated to experience an increase of 1.7 percent, while urban nonreclassified are estimated to experience the largest increase of 1.9 percent. Rural reclassified hospitals are estimated to experience an increase of 1.4 percent, while rural nonreclassified hospitals are estimated to have a 0.8 percent increase 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 an increase of 0.5 percent in capital payments from FY 2011 to FY 2012.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2011 payments compared to FY 2012 payments]

	Number of hospitals	Average FY 2011 payments/ case	Average FY 2012 payments/ case	Change
By Geographic Location:				
All hospitals	3,423	786	800	1.8
Large urban areas (populations over 1 million)	1,371	865	882	1.9
Other urban areas (populations of 1 million of fewer)	1,127	774	787	1.7
Rural areas	925	542	549	1.2
Urban hospitals	2,498	824	839	1.8
0–99 beds	632	664	675	1.6
100–199 beds	782	711	724	1.9
200–299 beds	449	762	775	1.7
300–499 beds	430	842	856	1.6
500 or more beds	205	993	1,015	2.1
Rural hospitals	925	542	549	1.2
0–49 beds	320	433	439	1.3
50–99 beds	348	500	505	1.0
100–149 beds	152	536	543	1.3
150–199 beds	58	613	621	1.2
200 or more beds	47	656	664	1.2
By Region:				
Urban by Region	2,498	824	839	1.8
New England	120	862	912	5.8
Middle Atlantic	320	877	890	1.4
South Atlantic	380	770	781	1.6
East North Central	401	800	808	1.0
East South Central	153	729	737	1.0
West North Central	169	816	830	1.8
West South Central	366	779	796	2.1
Mountain	159	847	861	1.7
Pacific	380	983	1,004	2.2
Puerto Rico	50	378	388	2.5
Rural by Region	925	542	549	1.2
New England	23	721	728	1.0
Middle Atlantic	69	554	562	1.4
South Atlantic	165	529	536	1.3
East North Central	120	574	577	0.4
East South Central	170	498	501	0.7
West North Central	99	570	581	1.8
West South Central	183	484	491	1.4
Mountain	66	575	581	1.1
Pacific	29	685	703	2.6
Puerto Rico	1	163	166	1.8
By Payment Classification:				
All hospitals	3,423	786	800	1.8
Large urban areas (populations over 1 million)	1,384	864	881	1.9
Other urban areas (populations of 1 million of fewer)	1,135	774	787	1.7
Rural areas	904	544	550	1.2
Teaching Status:				
Non-teaching	2,391	671	682	1.7
Fewer than 100 Residents	792	784	795	1.5
100 or more Residents	240	1,112	1,137	2.2
Urban DSH:				
100 or more beds	1,547	848	864	1.9
Less than 100 beds	337	590	599	1.4
Rural DSH:				
Sole Community (SCH/EACH)	417	475	482	1.4
Referral Center (RRC/EACH)	222	596	604	1.3
Other Rural:				
100 or more beds	27	485	488	0.5
Less than 100 beds	134	450	453	0.7
Urban teaching and DSH:				
Both teaching and DSH	827	917	935	1.9
Teaching and no DSH	144	806	817	1.4
No teaching and DSH	1,057	711	725	1.9
No teaching and no DSH	491	734	745	1.5
Rural Hospital Types:				
Non special status hospitals	2,402	828	843	1.8
RRC/EACH	56	741	750	1.2
SCH/EACH	33	725	740	2.0
Medicare-dependent hospitals (MDH)	11	557	566	1.6
SCH, RRC and EACH	17	770	784	1.8

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2011 payments compared to FY 2012 payments]

	Number of hospitals	Average FY 2011 payments/ case	Average FY 2012 payments/ case	Change
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY 2012 Reclassifications:				
All Urban Reclassified	323	827	841	1.7
All Urban Non-Reclassified	2,142	826	841	1.9
All Rural Reclassified	332	588	596	1.4
All Rural Non-Reclassified	532	475	479	0.8
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	547	550	0.5
Type of Ownership:				
Voluntary	1,985	802	816	1.8
Proprietary	870	705	717	1.6
Government	566	801	815	1.8
Medicare Utilization as a Percent of Inpatient Days:				
0–25	358	1,005	1,026	2.1
25–50	1,695	836	852	1.9
50–65	1,081	667	676	1.4
Over 65	198	581	590	1.5

J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2012. In the preamble, we specify the statutory authority for the provisions that are presented, identify those policies, and present rationales for our decisions as well as alternatives that were considered. In this section of Appendix A to this final rule, we discuss the impact of the changes to the payment rates, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

Currently, our database of 426 LTCHs includes the data for 82 nonprofit (voluntary ownership control) LTCHs and 322 proprietary LTCHs. Of the remaining 22 LTCHs, 13 LTCHs are government-owned and operated and the ownership type of the other 9 LTCHs is unknown. In the impact analysis, we used the rates, factors, and policies presented in this final rule, including the 1.8 percent annual update, which is based on the full increase of the LTCH PPS market basket and the reductions required by sections 1886(m)(3) and (m)(4) of the Act, the update to the MS–LTC–DRG classifications and relative weights, the update to the wage index values and labor-related share, including the application of a budget neutrality adjustment for changes to the area wage adjustment, and the best available claims and CCR data to estimate the change in payments for FY 2012. The standard Federal rate for FY 2012 is $40,222.05. This rate reflects the 1.8 percent annual update to the standard Federal rate and the area wage level budget neutrality factor of 0.99775, which ensures that the changes in the wage indexes and labor-related share do not influence estimated aggregate payments.

Based on the best available data for the 426 LTCHs in our database, we estimate that the update to the standard Federal rate for FY 2012 (discussed in section V.A.2. of the Addendum to this final rule) and the changes to the area wage adjustment for FY 2012 (discussed in section V.B. of the Addendum to this final rule), in addition to an estimated increase in HCO payments and an estimated increase in SSO payments, will result in an increase in estimated payments from FY 2011 of approximately $126 million (or about 2.5 percent). Based on the 426 LTCHs in our database, we estimate that the FY 2012 LTCH PPS payments will be approximately $5.257 billion, an increase from FY 2011 LTCH PPS payments which were approximately $5.131 billion. Because the combined distributional effects and estimated changes to the Medicare program payments are approximately $100 million, this final rule is considered a major economic rule, as defined in this section. We note that the approximately $126 million for the projected increase in estimated aggregate LTCH PPS payments from FY 2011 to FY 2012 does not reflect changes in LTCH admissions or case-mix intensity in estimated LTCH PPS payments, which also will affect overall payment changes.

The projected 2.5 percent increase in estimated payments per discharge from FY 2011 to FY 2012 is attributable to several factors, including the 1.8 percent annual update to the standard Federal rate, and projected increases in estimated HCO and SSO payments. As Table IV shows, the change attributable solely to the final update to the standard Federal rate is projected to result in an increase of 1.6 percent in payments per discharge from FY 2011 to FY 2012, on average, for all LTCHs. Because we are applying an area wage level budget neutrality factor to the standard Federal rate, the update to the wage data and labor-related share does not impact the increase in payments.

As discussed in section V.B. of the Addendum to this final rule, we are updating the wage index values for FY 2012 based on the most recent available data. In addition, we are decreasing the labor-related share from 75.271 percent to 70.199 percent under the LTCH PPS for FY 2012, based on the most recent available data on the relative importance of the labor-related share of operating and capital costs of the FY 2008-based RPL market basket. We also are applying an area wage level budget neutrality factor to the standard Federal rate to ensure that annual changes to the area wage level adjustment (that is, the wage index and labor-related changes) are budget neutral. We are making an area wage level budget neutrality factor of 0.99775, which reduces the final standard Federal rate by 0.23 percent. Therefore, the changes to the wage data and labor-related share do not result in a change in aggregate LTCH PPS payments.

Table IV below shows the impact of the payment rate and policy changes on LTCH PPS payments for FY 2012 presented in this final rule by comparing estimated FY 2011 payments to estimated FY 2012 payments. The projected increase in payments per discharge from FY 2011 to FY 2012 is 2.5 percent (shown in Column 8). This projected increase in payments was attributable to the impacts of the change to the standard Federal rate (1.6 percent in Column 6), as well as the effect of the estimated increase in payments for HCO cases and SSO cases in FY 2012 as compared to FY 2011 (0.5 percent and 0.3 percent, respectively). That is, estimated total HCO payments are projected to increase from FY 2011 to FY 2012 in order to ensure that the estimated HCO payments would be 8 percent of the total estimated LTCH PPS payments in FY 2012. An analysis of the most recent available LTCH PPS claims data (that is, FY 2010 claims data from the March 2011 update of the MedPAR file) indicates that the FY 2011 HCO threshold of $18,785 (as established in the FY 2011 IPPS/LTCH PPS final rule) may result in HCO payments in FY 2011 that fall slightly below the estimated 8 percent. Specifically, we currently estimate that HCO payments will

be approximately 7.5 percent of the estimated total LTCH PPS payments in FY 2011. We estimated that the impact of the increase in HCO payments will result in approximately a 0.5 percent increase in estimated payments from FY 2011 to FY 2012, on average, for all LTCHs. Furthermore, in calculating the estimated increase in payments from FY 2011 to FY 2012 for HCO and SSO cases, we increased estimated costs by the applicable market basket percentage increase as projected by our actuaries, which increases estimated payments by 0.3 percent relative to last year. We note that estimated payments for all SSO cases comprised approximately 13 percent of the estimated total LTCH PPS payments, and estimated payments for HCO cases comprised approximately 8 percent of the estimated total 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 (over 65 percent) are based on the estimated cost of the SSO case.

As we discuss in detail throughout this final rule, based on the most recent available data, we believe that the provisions of this final rule relating to the LTCH PPS will result in an increase in estimated aggregate LTCH PPS payments and that the resulting LTCH PPS payment amounts will 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 3.5 percent increase in estimated payments per discharge for FY 2012 as compared to FY 2011 for rural LTCHs that will result from the changes presented in this final rule, as well as the effect of estimated changes to HCO and SSO payments. This estimated impact is based on the data for the 26 rural LTCHs in our database (out of 426 LTCHs) for which complete data were available.

The estimated increase in LTCH PPS payments from FY 2011 to FY 2012 for rural LTCHs is primarily due to the higher than average impacts from the changes to the area wage level adjustment, specifically, the reduction to the labor-related share from 75.271 to 70.199. Although we are applying an area wage level budget neutrality factor for changes to the wage indexes and labor-related share to ensure that there is no change in aggregate LTCH PPS payments due to those changes, we estimated rural hospitals will experience a 0.7 percent increase in payments due to the changes to the area wage level adjustment, as shown in Column 7 below. Rural hospitals generally have a wage index of less than 1; therefore, a decrease to the labor-related share results in their wage index reducing a smaller portion of the standard Federal rate, resulting in an estimated increase in payments in FY 2012 as compared to FY 2011.

3. Anticipated Effects of LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

As discussed above in section I.J.1. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2012 of approximately $126 million (or 2.5 percent) based on the 426 LTCHs in our database.

b. Effects of Requirements for LTCH Quality Reporting Program

In section VII.C. of the preamble of this final rule, we discuss our requirements for LTCHs to report quality data under the LTCH quality reporting program. As set forth at section 1886(m)(5)(A) of the Act, beginning with FY 2014, the Secretary must reduce by 2.0 percentage points any annual update to the standard Federal rate for discharges for any LTCH which does not comply with the LTCH quality data submission requirements. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26076), we estimated that should we adopt the proposed requirements for the LTCH quality reporting program for FY 2014, few LTCHs would not receive the full payment update in any fiscal year as a result of failure to comply with the quality reporting program that has been mandated by section 3004 of the Affordable Care Act. We stated this because we believe that most LTCHs will see the new quality reporting program as an important step in improving the quality of care patients receive in these facilities. We also believe that most LTCHs will quickly and easily adapt to this new quality reporting program and find that the benefits of this program outweigh the burdens.

At this time, information is not available to determine the precise number of LTCHs that will receive the 2-percent reduction to the annual update to the standard Federal rate for discharges due to noncompliance with the requirements of section 3004 of the Affordable Care Act. At this time, we have no way to estimate how many LTCHs will fully comply with the LTCH quality reporting program.

In section VII.C. of the preamble of this final rule, we are adopting three quality reporting measures for LTCHs for FY 2014: (1) Catheter-Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Blood Stream Infection Event (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26076), we estimated that the total LTCH costs 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 would be $1,128,440.

Comment: Several commenters expressed concern over the potential for negative financial implications and believed that large burdens would be imposed by requiring the reporting of CLABSI and CAUTI measures to the CDC via NHSN.

Response: We wish to minimize any burdens associated with the LTCH quality reporting program. We believe that using the NHSN minimizes the potential reporting burdens on LTCHs. We note that the CDC estimates that 200 LTCHs out of a total of 435 certified LTCHs currently submit HAI data to the CDC via NHSN. This means that 46 percent of LTCHs are already enrolled in NHSN, are familiar with the data collection mechanism, and have knowledge of the submission processes required by the CDC. For LTCHs that currently report both measures using the NHSN, there will be no additional burden.

For LTCHs that currently report only one of the HAIs to NHSN (for example, an LTCH that reports CAUTI to NHSN, but does not report CLABSI), there will be only modest additional burdens as a result of new LTCH quality reporting program. Because these LTCHs are currently reporting data to NHSN for other purposes, they have already registered with the NHSN and taken the mandatory training. In addition, these LTCHs should already have staff members whom are familiar with the reporting procedures used by NHSN.

LTCHs that do not already report information to NHSN will incur the most additional burden. This burden would consist of the following:

(1) Registration with the NHSN;

(2) Mandatory NHSN training (which is estimated to take approximately 4–5 hours);

(3) LTCH training of administrative staff on how to transmit data to the NHSN; and

(4) Quarterly reporting time.

NHSN does not charge a fee for registration or the submission of data. The mandatory training is also free. This training must be taken before the LTCH can become a registered user. The training must be taken by an administrator, but this may be a person such as an infection control specialist, Director of Nursing, or another person associated with the LTCH's quality reporting program. Only one person is required to take the NHSN mandatory training in order for the LTCH to become registered.

Once the LTCH is registered with the NHSN, it may wish to train other members of the staff about the use of the NHSN system. Each LTCH may decide how many additional staff should be trained. However, it is not likely that more than a few staff members per LTCH will need to be trained on the use of the NHSN system.

The new quality reporting program requires that each LTCH must collect the CLABSI and CAUTI data to submit to NHSN. However, the collection of data pertaining to infectious diseases incurred by patients in an LTCH is an important part of safe and effective patient care. We believe that most, if not all, LTCHs already collect and record data pertaining to CAUTI, CLABSI, and pressure ulcers as a part of their safe and effective patient care. This belief is supported by research and environmental scans which have been performed by our measure developer contractor, as well as statements by LTCH providers during open door forums and during TEP discussions. Therefore, we

do not believe that there will be any significant additional burden related to data collection for the three quality measures.

We anticipate that the amount of time that will be needed by each LTCH to report the data collected to the NHSN will be minimal for several reasons. First, these data will be aggregated and reported at intervals. Secondly, based on statistics provided by the CDC, we believe that only a small percentage of patients admitted to LTCHs will experience one of these serious HAIs. We estimate that there may be approximately six CAUTI and six CLABSI events per LTCH per month. This equates to approximately 144 HAI events per LTCH per year. We estimate that it will take approximately 15 minutes of administrative data entry time per submission to submit these data to NHSN. If the data are aggregated and submitted once per month, the time required of an administrative data entry person will be 3 hours per month. If the average wage of an administrative assistant is $20.57, the estimated cost to an LTCH for the monthly submission of the CAUTI and CLABSI data will be $61.71, or $740.52 per LTCH per year.

Comment: One commenter recommended that hospitals receive some payment to mitigate the additional cost associated with reporting this information.

Response: The Affordable Care Act amended the Act to require the Secretary to implement quality reporting programs in settings that have not been required to do so in the past, including LTCHs. As noted above, we wish to minimize any burdens associated with the LTCH quality reporting program. However, the Act does not provide for additional payments to LTCHs for quality data reporting. In addition, by using NHSN and a subset of the CARE data item set, we are attempting to minimize the burden of the LTCH quality reporting program by using data submission methods that have been used or are being used by some LTCHs.

After consideration of the public comments we received, we are finalizing the three quality reporting measures, namely (1) Catheter-Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Blood Stream Infection Event (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened as proposed for the FY 2014 payment determination.

At this time, the data reporting mechanism for transferring pressure ulcer data to CMS remains under development. As discussed elsewhere in the preamble to this final rule, we expect the data reporting mechanism to be used will be a subset of the CARE data item set. Upon completion of the pressure ulcer assessment subset of the CARE data item set, a PRA package will be published in the **FEDERAL REGISTER**, in which CMS will state burden estimates related to the quality measure entitled ''Pressure Ulcers that are New or Have Worsened.'' Additionally, CMS will release further details and specifications regarding the data collection mechanism via the CMS Web site by no later than January 31, 2012.

c. Impact of Application of LTCH Moratorium on the Increase in Beds at Section 114(d)(1)(B) of Public Law 110–173 (MMSEA) to LTCHs and LTCH Satellite Facilities Established or Classified as Such Under Section 114(d)(1)(B) of Public Law 110–173

As discussed in section VII.F. of the preamble of this final rule, at § 412.23(e)(8), for the period beginning October 1, 2011, and ending December 28, 2012, we are applying the moratorium on the increase in the number of beds under section 114(d)(1)(B) of the MMSEA, as specified in § 412.23(e)(7), to LTCHs and LTCH satellite facilities that were established or classified during the period after December 29, 2007 and ending September 30, 2011, under one of the exceptions to the moratorium at section 114(d)(2) of the MMSEA, as set forth in paragraph (e)(6)(ii) of § 412.23. The final regulation precludes a LTCH or LTCH satellite facility that was developed under an exception to the moratorium on the establishment of new LTCHs and LTCH satellite facilities from increasing the number of Medicare-certified beds beyond the number certified by Medicare on October 1, 2011. Approximately 50 LTCHs and 8 LTCH satellite facilities were developed under the exceptions at § 412.23(e)(6)(ii); and under the moratorium at section 114(d)(4) of the MMSEA, which solely applied to ''existing'' LTCHs and LTCH satellite facilities, additional beds may have been added to these LTCHs and LTCH satellite facilities since establishment. Under the new regulation at § 412.23(e)(8), these ''new'' LTCHs and LTCH satellite facilities will also be subject to the moratorium on bed increases. Because additional increases in the number of LTCH beds in these facilities could result in added costs to the Medicare program, the impact of precluding additional growth in the number of Medicare-certified beds in these facilities is expected to result in no additional spending under the Medicare program from these LTCHs and LTCH satellite facilities.

d. Impact of the Clarification to the Greater Than 25 Day Average Length of Stay Requirement for LTCHs

In section VII.E.5. of the preamble of this final rule, we present two clarifications to our existing policy for determining whether a hospital is meeting the greater than 25 day average length of stay requirement for payment under the LTCH PPS. First, we are clarifying and revising the regulations at § 412.23(e)(3)(iv) dealing with the average length of stay determination when there is a change of ownership of either a hospital seeking to qualify as an LTCH or of an existing LTCH. Second, we described and are clarifying our existing policy regarding the inclusion of Medicare Advantage days in the average length of stay calculation. Because typically LTCHs track the lengths of stay of their Medicare patients on an ongoing basis for purposes of maintaining their LTCH status, and Medicare contractors are already tasked with evaluating each LTCH's average length of stay, we do not believe that there is any actual impact resulting from the clarification of these existing policies nor do they impose any additional burdens on either LTCHs or Medicare contractors.

e. Impact on Providers

The basic methodology for determining a per discharge LTCH PPS payment is set forth in § 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 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 changes to the LTCH PPS payments presented in this final rule on different categories of LTCHs for FY 2012, it is necessary to estimate payments per discharge for FY 2011 using the rates, factors (including the FY 2011 GROUPER (Version 28.0), and relative weights and the policies established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50364 through 50400 and 50442 through 50449). It is also necessary to estimate the payments per discharge that would have been made under the LTCH PPS rates, factors, policies, and GROUPER (Version 29.0) for FY 2012 (as discussed in VII. of the preamble and section V. of the Addendum to this final rule). These estimates of FY 2011 and FY 2012 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 change in estimated FY 2011 payments to estimated FY 2012 payments (on a per discharge basis) for each category of LTCHs.

Hospital groups were based on characteristics provided in the OSCAR data, FY 2008 through FY 2009 cost report data in HCRIS, and PSF data. Hospitals with incomplete characteristics were grouped into the ''unknown'' category. 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 final payment rates and policy changes among the various categories of existing providers, we used LTCH cases from the FY 2010 MedPAR file to estimate payments for FY 2011 and to estimate payments for FY 2012 for 426 LTCHs. We believe that the discharges based on the FY 2010 MedPAR data for the 426 LTCHs in our database, which includes 322 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.

f. 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 2010 MedPAR files. For modeling estimated LTCH PPS payments for FY 2011, we applied the FY 2011 standard Federal rate (that is, $39,599.95, under which LTCH discharges occurring on or after October 1,

2010, to September 30, 2011 are paid). For modeling estimated LTCH PPS payments for FY 2012, we applied the FY 2012 standard Federal rate of $40,222.05, which will be effective for LTCH discharges occurring on or after October 1, 2011, and through September 30, 2012. The final FY 2012 standard Federal rate of $40,222.05 includes the application of an area wage level budget neutrality factor of 0.99775 (as discussed in section VII.E.4. of the preamble of this final rule).

Furthermore, in modeling estimated LTCH PPS payments for both FY 2011 and FY 2012 in this impact analysis, we applied the FY 2011 and the FY 2012 adjustments for area wage levels and the COLA for Alaska and Hawaii. Specifically, we adjusted for differences in area wage levels in determining estimated FY 2011 payments using the current LTCH PPS labor-related share of 75.271 percent (75 FR 50445) and the wage index values established in the Tables 12A and 12B of the Addendum to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50627 through 50646). We also applied the FY 2011 COLA factors shown in the table in section V.B.5. of the Addendum to that final rule (75 FR 50446) to the FY 2011 nonlabor-related share (24.729 percent) for LTCHs located in Alaska and Hawaii. Similarly, we adjusted for differences in area wage levels in determining the estimated FY 2012 payments using the LTCH PPS FY 2012 labor-related share of 70.199 percent and the FY 2012 wage index values presented in Tables 12A and 12B listed in section VI. of the Addendum to this final rule (and available via the Internet). We also applied the FY 2012 COLA factors shown in the table in section V.B.5. of the Addendum to the FY 2011 IPPS/LTCH PPS final rule to the FY 2012 nonlabor-related share (29.801 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.C. of the Addendum to this final rule). In modeling final payments for SSO and HCO cases in FY 2012, we are applying an inflation factor of 1.057 (determined by OACT) to the estimated costs of each case determined from the charges reported on the claims in the FY 2010 MedPAR files and the best available CCRs from the March 2011 update of the PSF. Furthermore, in modeling estimated LTCH PPS payments for FY 2012 in this impact analysis, we used the FY 2012 fixed-loss amount of $17,931 (as discussed in section V. of the Addendum to this final rule).

These impacts reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from the FY 2011 to FY 2012 based on the payment rates and policy changes presented in this final 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 2011 (as described above).
- The fifth column shows the estimated payment per discharge for FY 2012 (as described above).
- The sixth column shows the percentage change in estimated payments per discharge from FY 2011 to FY 2012 due to the update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final rule).
- The seventh column shows the percentage change in estimated payments per discharge from FY 2011 to FY 2012 for changes to the area wage level adjustment (that is, the final wage indexes and labor-related share), including the application of an area wage level budget neutrality factor (as discussed in section V.B.5. of the Addendum to the final rule).
- The eighth column shows the percentage change in estimated payments per discharge from FY 2011 (Column 4) to FY 2012 (Column 5) for all changes (and includes the effect of estimated changes to HCO and SSO payments).

TABLE IV—IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR FY 2012

[Estimated FY 2011 payments compared to estimated FY 2012 payments*]

LTCH Classification	Number of LTCHs	Number of LTCH PPS cases	Average FY 2011 LTCH PPS payment per case	Average FY 2012 LTCH PPS payment per case [1]	Percent change in estimated payments per discharge from FY 2011 to FY 2012 for the annual update to the federal rate [2]	Percent change in estimated payments per discharge from FY 2011 to FY 2012 for changes to the area wage level adjustment with budget neutrality [3]	Percent change in payments per discharge from FY 2011 to FY 2012 for all changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
All Providers	426	135,100	$37,977	$38,911	1.6	0.0	2.5
By Location:							
Rural	26	5,862	33,445	34,366	1.7	0.7	3.5
Urban	400	129,238	38,182	39,118	1.6	0.0	2.4
Large	204	77,420	39,911	40,884	1.6	−0.2	2.2
Other	196	51,818	35,599	36,478	1.6	0.3	2.8
By Participation Date:							
Before Oct. 1983	16	5,914	33,691	34,509	1.6	−0.6	1.9
Oct. 1983–Sept. 1993	44	16,673	40,019	41,075	1.5	−0.2	2.4
Oct. 1993–Sept. 2002	186	63,376	37,198	38,085	1.6	0.0	2.4
After October 2002	176	48,317	38,826	39,794	1.6	0.1	2.6
Unknown Participation Date	4	820	37,558	38,534	1.6	1.5	4.1
By Ownership Type:							
Voluntary	82	19,596	38,992	40,120	1.6	0.0	2.9
Proprietary	322	113,085	37,702	38,596	1.6	0.0	2.4
Government	13	1,720	42,710	44,026	1.6	−0.2	2.9
Unknown Ownership Type	9	699	42,249	43,546	1.6	−0.2	2.9
By Region:							
New England	15	7,313	33,726	34,501	1.5	−0.6	1.7
Middle Atlantic	30	7,970	38,866	39,802	1.6	−0.1	2.3
South Atlantic	59	15,577	41,327	42,388	1.5	0.0	2.6
East North Central	70	19,913	39,857	40,820	1.6	−0.5	2.0
East South Central	29	8,177	37,658	38,635	1.6	0.2	2.8

TABLE IV—IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR FY 2012—Continued

[Estimated FY 2011 payments compared to estimated FY 2012 payments*]

LTCH Classification	Number of LTCHs	Number of LTCH PPS cases	Average FY 2011 LTCH PPS payment per case	Average FY 2012 LTCH PPS payment per case [1]	Percent change in estimated payments per discharge from FY 2011 to FY 2012 for the annual update to the federal rate [2]	Percent change in estimated payments per discharge from FY 2011 to FY 2012 for changes to the area wage level adjustment with budget neutrality [3]	Percent change in payments per discharge from FY 2011 to FY 2012 for all changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
West North Central	26	5,903	39,877	40,921	1.6	0.3	2.9
West South Central	141	50,675	33,357	34,176	1.7	0.5	2.9
Mountain	32	6,742	41,479	42,579	1.6	−0.4	2.2
Pacific	24	12,830	48,595	49,716	1.5	−0.4	1.8
By Bed Size:							
Beds: 0–24	29	3,667	32,708	33,554	1.7	0.5	3.1
Beds: 25–49	199	43,952	37,489	38,410	1.6	0.1	2.6
Beds: 50–74	114	36,429	38,383	39,368	1.6	0.1	2.6
Beds: 75–124	47	21,072	40,614	41,622	1.6	−0.3	2.2
Beds: 125–199	23	16,057	36,539	37,410	1.5	−0.1	2.3
Beds: 200 +	14	13,923	37,509	38,339	1.6	0.0	2.2

[1] Estimated FY 2012 LTCH PPS payments based on the final payment rates and policy changes presented in the preamble and the Addendum to this final rule.

[2] Percent change in estimated payments per discharge from FY 2011 to FY 2012 for the annual update to the standard Federal rate, as discussed in section V.A.2. of the Addendum to this final rule.

[3] Percent change in estimated payments per discharge from FY 2011 to FY 2012 for changes to the area wage level adjustment at § 412.525(c) (as discussed in section V.B. of the Addendum to this final rule).

[4] Percent change in estimated payments per discharge from FY 2011 LTCH PPS (shown in Column 4) to FY 2012 LTCH PPS (shown in Column 5), including all of the changes presented in the preamble and the Addendum to this final rule. Note, this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the standard Federal rate (column 6) and the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in both estimated payments to SSO cases that are paid based on estimated costs and aggregate HCO payments (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

g. Results

Based on the most recent available data for 426 LTCHs, we have prepared the following summary of the impact (as shown above in Table IV) of the LTCH PPS payment rate and policy changes presented in this final rule. The impact analysis in Table IV shows that estimated payments per discharge are expected to increase approximately 2.5 percent, on average, for all LTCHs from FY 2011 to FY 2012 as a result of the payment rate and policy changes presented in this final rule, as well as estimated increases in HCO and SSO payments. We note that we updated the standard Federal rate for FY 2012 by 1.8 percent, which is based on the latest estimate of the LTCH PPS market basket increase (2.9 percent), the reduction of 1.0 percentage point for the multifactor productivity adjustment and the 0.1 percentage point reduction required under sections 1886(m)(3) and (m)(4) of the Act. 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 approximately 1.8 percent for the annual update to the standard Federal rate is projected to result in approximately a 1.6 percent change in estimated payments per discharge for all LTCHs from FY 2011 to FY 2012. Because payments to cost-based SSO cases and a portion of payments to SSO cases that are paid based on the ''blend'' option of the SSO payment formula at § 412.529(c)(2)(iv) are not affected by the annual update to the standard Federal rate, we estimated that the effect of the 1.8 percent annual update to the standard Federal rate will result in a 1.6 percent increase on estimated aggregate LTCH PPS payments for *all* LTCH PPS cases, including SSO cases. Furthermore, as discussed previously in this regulatory impact analysis, the average increase in estimated payments per discharge from the FY 2011 to FY 2012 for all LTCHs of approximately 2.5 percent (as shown in Table IV) was determined by comparing estimated FY 2012 LTCH PPS payments (using the rates and policies discussed in this final rule) to estimated FY 2011 LTCH PPS payments (as described above in section I.J.1. of this Appendix).

(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 4 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 2011 to FY 2012 for all hospitals is 2.5 percent for all changes. For rural LTCHs, the percent change for all changes is estimated to be 3.5 percent, while for urban LTCHs, we estimate the increase to be 2.4 percent. Large urban LTCHs are projected to experience an increase of 2.2 percent in estimated payments per discharge from FY 2011 to FY 2012, while other urban LTCHs are projected to experience an increase of 2.8 percent in estimated payments per discharge from FY 2011 to FY 2012, 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 majority (approximately 47 percent) of the LTCH cases are in hospitals that began participating in the Medicare program between October 1993 and September 2002, and are projected to experience nearly the average increase (2.4 percent) in estimated payments per discharge from FY 2011 to FY 2012, as shown in Table IV.

In the participation category where LTCHs began participating in the Medicare program before October 1983, LTCHs are projected to experience a lower than average percent increase (1.9 percent) in estimated payments per discharge from FY 2011 to FY 2012, as shown in Table IV. Approximately 4 percent of LTCHs began participating in Medicare before October 1983. The LTCHs in this

category are projected to experience a lower than average increase in estimated payments because of decrease in payments due to the changes to the area wage adjustment. Approximately 10 percent of LTCHs began participating in Medicare between October 1983 and September 1993. These LTCHs are projected to experience a 2.4 percent increase in estimated payments from FY 2011 to FY 2012. LTCHs that began participating in Medicare after October 2002 currently represent approximately 41 percent of all LTCHs, and are projected to experience an average increase (2.6 percent) in estimated payments from FY 2011 to FY 2012.

(3) Ownership Control

Other than LTCHs whose ownership control type is unknown, LTCHs are grouped into three categories based on ownership control type: voluntary, proprietary, and government. Based on the most recent available data, approximately 19 percent of LTCHs are identified as voluntary (Table IV). We expect that, for these LTCHs in the voluntary category, estimated FY 2012 LTCH payments per discharge will increase higher than the average (2.9 percent) in comparison to estimated payments in FY 2011 primarily because we project an increase in estimated HCO payments and SSO payments to be higher than the average for these LTCHs. The majority (76 percent) of LTCHs are identified as proprietary and these LTCHs are projected to experience a nearly average increase (2.4 percent) in estimated payments per discharge from FY 2011 to FY 2012. Finally, government-owned and operated LTCHs (3 percent) are also expected to experience a higher than average increase in payments of 2.9 percent in estimated payments per discharge from FY 2011 to FY 2012.

(4) Census Region

Estimated payments per discharge for FY 2012 are projected to increase for LTCHs located in all regions in comparison to FY 2011. 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 West North Central and West South Central regions (2.9 percent, as shown in Table IV). The estimated percent increase in payments per discharge from FY 2011 to FY 2012 for those regions is largely attributable to the changes in the area wage level adjustment.

In contrast, LTCHs located in the New England region are projected to experience the smallest increase in estimated payments per discharge from FY 2011 to FY 2012. The average estimated increase in payments of 1.7 percent for LTCHs in the New England region is primarily due to estimated decreases in payments associated with 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.

We project that payments for small LTCHs (0–24 beds) will experience a 3.1 percent increase in payments due to increases in the area wage adjustment while large LTCHs (200+ beds) will experience a 2.2 percent increase in payments. LTCHs with between 75 and 124 beds and between 125 and 199 beds are expected to experience a slightly below average increase in payments per discharge from FY 2011 to FY 2012 (2.2 percent and 2.3 percent, respectively) primarily due to an estimated decrease in their payments from FY 2011 to FY 2012 due to the area wage level adjustment.

4. Effect on the Medicare Program

As noted previously, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments in FY 2012 of approximately $126 million (or approximately 2.5 percent) for the 426 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries under the LTCH PPS, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

K. Alternatives Considered

1. General

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

2. Alternative Considered for Hospital Inpatient Quality Review (IQR) and Value-Based Purchasing (VBP) Programs: Medicare Spending per Beneficiary Measure

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25896 and 25897 and 76 FR 25927 and 25928), we described our proposed policy for implementing the claims-based Medicare spending per beneficiary measure for the FY 2014 Hospital IQR Program and the claims-based Medicare spending per beneficiary measure for the FY 2014 Hospital VBP Program. In addition, we described an alternative we considered for the Medicare spending per beneficiary measure (76 FR 26080 through 26082). We considered this alternative approach based on the principle that Medicare spending per beneficiary benchmarks for lower quality hospitals should not exceed the benchmarks for higher quality hospitals. This alternative approach was more complex than the approach we are finalizing. Due to its increased complexity, in the proposed rule, we included the discussion of this alternative approach in this section, rather than earlier in the preamble of the proposed rule, for ease of presentation. The approach consisted of setting differential spending benchmarks for different quality score-based cohorts of hospitals and applying an efficiency adjustment to the quality score.

We did not receive any public comments on the discussion of an alternative approach to incorporating a Medicare spending per beneficiary measure into the FY 2014 Hospital VBP Program or the Hospital IQR Program. We are finalizing the addition of a Medicare spending per beneficiary measure to the FY 2014 Hospital IQR Program, as described in section IV.A.3.b.(ii)(B) of the preamble to this final rule, and to the FY 2014 Hospital VBP Program, as described in section IV.B.3.b.(iii) of the preamble to this final rule.

L. Overall Conclusion

1. Acute Care Hospitals

Table I of section I.G. of this Appendix demonstrates the estimated distributional impact of the IPPS budget neutrality requirements for the MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows an overall increase of 1.1 percent in operating payments. We estimate that operating payments will increase by approximately $1.13 billion in FY 2012. For FY 2012, we are distributing $250 million to hospitals that qualify to receive additional payment under section 1109 of Public Law 111–152, which is an additional $100 million than what we had distributed under this provision in FY 2011. In addition, we estimate a savings of $21 million associated with the HACs policies in FY 2012, which is an additional $1 million in savings than in FY 2011. We estimate that we will spend $900,000 in new technology add-on payments in FY 2012, which is approximately $17 million less than what we spent in FY 2011. We estimate that low volume payments in FY 2012 will be $5 million more than the low volume payments made in FY 2011. These estimates, added to our FY 2012 operating estimate of $1.13 billion, will result in an increase of $1.22 billion for FY 2012. We estimate that capital payments will experience a 1.8 percent increase in payments per case, as shown in Table III of section I.I. of this Appendix. We project that there would be a $151 million increase in capital payments in FY 2012 compared to FY 2011. The cumulative operating and capital payments should result in a net increase of $1.369 billion to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments per discharge in FY 2012. In the impact analysis, we are using the rates, factors, and policies presented in this final rule, including updated wage index values and relative weights, and the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2012. Accordingly, based on the best available data for the 426 LTCHs in our database, we estimate that FY 2012 LTCH PPS payments will increase approximately $126 million (or approximately 2.5 percent).

M. Accounting Statements and Tables

1. Acute Care Hospitals

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table V below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions

of this final rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2011 TO FY 2012

Category	Transfers
Annualized Monetized Transfers.	$1.369 billion.
From Whom to Whom	Federal Government to IPPS Medicare Providers.
Total	$1.369 billion

2. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis for the changes under the LTCH PPS for this final rule projects an increase in estimated aggregate payments of approximately $126 million (or approximately 2.5 percent) for the 426 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table VI below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to changes to the LTCH PPS. Table VI provides our best estimate of the estimated increase in Medicare payments under the LTCH PPS as a result of the provisions presented in this final rule based on the data for the 426 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2011 LTCH PPS TO THE FY 2012 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	Positive transfer—Estimated increase in expenditures: $126 million.

II. 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 final rule relating to acute care hospitals will have a significant impact on small entities as explained in this Appendix. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. 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 final rule constitutes our regulatory flexibility analysis. In the FY 2012 IPPS/LTCH PPS proposed rule, we solicited public comments on our estimates and analysis of the impact of our proposals on those small entities. We did not receive any public comments.

III. 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 now define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the policy changes under the IPPS for operating costs.)

IV. 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 2011, that threshold level is approximately $136 million. This final rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

V. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this final rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the Puerto Rico-specific standardized amount, the hospital-specific rates for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs, IPFs, and IRFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2012

A. FY 2012 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 2012 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 and an additional reduction of 0.1 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 2012 adjustment of 0.1 percentage point may result in the applicable percentage increase being less than zero.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.K.3. of the preamble of the proposed rule, based on IGI's first quarter 2011 forecast of multifactor productivity (MFP), we proposed a MFP adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.2 percent.

Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, based on IGI's first quarter 2011 forecast of the FY 2012 market basket increase, we proposed an applicable percentage increase to the FY 2012 operating standardized amount of 1.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an

adjustment of 1.2 percentage points for economy-wide productivity and less 0.1 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 proposed an applicable percentage increase to the operating standardized amount of −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of increase of 2.8 percent less 2.0 percentage points for failure to submit quality data, less an adjustment of 1.2 percentage points for economy-wide productivity, and less an additional adjustment of 0.1 percentage point).

For this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, based on IGI's second quarter 2011 forecast of MFP, we are finalizing a MFP adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.0 percent for FY 2012.

Based on IGI's second quarter 2011 forecast of the FY 2012 market basket increase, we are finalizing an applicable percentage increase to the FY 2012 operating standardized amount of 1.9 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 1.0 percentage point for economy-wide productivity and less 0.1 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 making an applicable percentage increase to the operating standardized amount of −0.1 percent (that is, the FY 2012 estimate of the market basket rate-of increase of 3.0 percent less 2.0 percentage points for failure to submit quality data, less an adjustment of 1.0 percentage point for economy-wide productivity, and less an additional adjustment of 0.1 percentage point).

B. Update for SCHs and MDHs for FY 2012

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2012 applicable percentage increase in the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital specific rates for SCHs and MDHs 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, the applicable percentage increase to the hospital-specific rates applicable to SCHs and MDHs for FY 2012 is 1.9 percent for hospitals that submit quality data or −0.1 percent for hospitals that fail to submit quality data.

C. FY 2012 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, the applicable percentage increase to the Puerto Rico-specific standardized amount for FY 2012 is 1.9 percent.

D. 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 § 413.40, which also uses section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Section 1886(j)(3)(C) of the Act addresses the increase factor for the Federal prospective payment rate of IRFs. 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. In addition, section 124 of Public Law 106–113 provides the statutory authority for updating all aspects of the payment rates for IPFs.

Currently, children's hospitals, cancer hospitals, and RNHCIs are the remaining three types of hospitals still reimbursed under the reasonable cost methodology. In this final rule, we are providing our current estimate of the FY 2012 IPPS operating market basket percentage increase (3.0 percent) to update the target limits for children's hospitals, cancer hospitals, and RNHCIs for FY 2012.

For FY 2012, as discussed in section VII. of the preamble to this final rule, we are establishing an update to the LTCH PPS standard Federal rate for FY 2012 based on the full proposed LTCH PPS market basket increase estimate (2.9 percent). The annual update also includes the requirement at section 1886(m)(3)(A)(i) of the Act to reduce the annual update by the economy-wide productivity adjustment described in section 1886(b)(3)(B)(xi)(ii) of the Act, which is currently estimated to be 1.0 percent. In addition, section 1886(m)(3)(A)(ii) of the Act requires that any annual update for FY 2012 be reduced by the ''other adjustment'' at section 1886(m)(4)(C) of the Act, which is 0.1 percentage point. Accordingly, the update factor to the standard Federal rate for FY 2012 is 1.8 percent (that is, we are applying a factor of 1.018 in determining the LTCH PPS standard Federal rate for FY 2012).

Effective for cost reporting periods beginning on or after January 1, 2005, IPFs are paid under the IPF PPS. IPF PPS payments are based on a Federal per diem rate that is derived from the sum of the average routine operating, ancillary, and capital costs for each patient day of psychiatric care in an IPF, adjusted for budget neutrality. In the RY 2012 IPF PPS final rule (76 FR 26434 through 26435), we extended the IPF PPS RY 2012 by 3 months (a total of 15 months instead of 12 months) through September 30, 2012. Based on IGI's first quarter 2011 forecast, with history through the fourth quarter of 2010, the projected 15-month market basket update based on the FY 2008-based RPL market basket for the 15-month RY 2012 (July 1, 2011 through September 30, 2012) is 3.2 percent. In accordance with section 1886(s)(2)(A)(ii) of the Act, which requires the application of an ''other adjustment,'' described in section 1886(s)(3) of the Act (specifically, section 1886(s)(3)(A) for RYs 2011 and 2012), that reduces the update to the IPF PPS base rate for the rate year beginning in CY 2011, we adjusted the IPF PPS update by 0.25 percentage point for RY 2012. Therefore, we applied the 15-month FY 2008-based RPL market basket increase of 3.2 percent for RY 2012, which was then adjusted by the ''other adjustment'' of 0.25 percentage point.

IRFs are paid under the IRF PPS for cost reporting periods beginning on or after January 1, 2002. For cost reporting periods beginning on or after October 1, 2002 (FY 2003), and thereafter, the Federal prospective payments to IRFs are based on 100 percent of the adjusted Federal IRF prospective payment amount, updated annually (69 FR 45721). Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act require the application of a 0.1 percentage point reduction to the market basket increase factor for FYs 2012 and 2013. In addition, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of an economy-wide productivity adjustment. As published elsewhere in this **Federal Register**, in accordance with section 1886(j)(3)(C) of the Act, as amended by section 3401(d) of the Affordable Care Act, we base the FY 2012 market basket update, used to determine the applicable percentage increase for the IRF payments, on the second quarter 2011 forecast of the FY 2008-based RPL market basket (estimated to be 2.9 percent). This percentage increase is then reduced by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.0 percent, which was calculated based on IGI's second quarter 2011 forecast. Following application of the productivity adjustment, the applicable percentage increase is then reduced by 0.1 percentage point, as required by section 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act, as added and amended by sections 3401 (d) of the Affordable Care Act. Therefore the final FY 2012 IRF update is 1.8 percent (2.9 percent market basket update less 1.0 percentage point MFP adjustment less 0.1 percentage point legislative adjustment).

III. Secretary's Final Recommendations

MedPAC is recommending an inpatient hospital update equal to one percent for FY

2012. 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 1.9 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 3.0 percent less an MFP adjustment of 1.0 percentage point and less 0.1 percentage point). We are recommending that the same applicable percentage increase apply to SCHs and MDHs 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 all other types of hospitals. Consistent with our update for these facilities, we are recommending an update for children's hospitals, cancer hospitals, and RNHCIs of 3.0 percent.

For FY 2012, consistent with policy set forth in section VII. of the preamble of this final rule, we are recommending an update of 1.8 percent to the LTCH PPS standard Federal rate. In addition, consistent with the update specified in the FY 2012 IRF PPS final rule (as described above), we are recommending an update of 1.8 percent (that is, the market basket increase factor of 2.9 percent less 1.0 percentage point for the MFP adjustment and less 0.1 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act) to the IRF PPS Federal rate for FY 2012. Finally, consistent with the update specified in the FY 2012 IPF PPS final rule (as described above), we are recommending an update of 3.2 percent reduced by 0.25 percentage point to the IPF PPS Federal rate for RY 2012 for the Federal per diem payment amount.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2011 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 one percent. MedPAC expects Medicare margins to remain low in 2012. At the same time though, 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 make adjustments to inpatient payment rates in future years to recover all overpayments due to documentation and coding improvements. MedPAC noted that priority should be given to preventing future overpayments.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to one percent, for FY 2012, 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 2012 applicable percentage increase. Therefore, we are establishing an applicable percentage increase for FY 2012 of 1.9 percent, provided the hospital submits quality data, consistent with these statutory requirements.

Similar to our response last year, we agree with MedPAC that hospitals should control costs rather than have Medicare accommodate the current rate of growth. As MedPAC noted, the lack of financial pressure at certain hospitals can lead to higher costs and in turn bring down the overall Medicare margin for the industry.

With regard to MedPAC's recommendation that Congress should require the Secretary to make adjustments to inpatient payment rates in future years to recover all overpayments due to documentation and coding improvements, we refer the reader to section III. D. of the preamble to this final rule for a complete discussion on the FY 2012 MS–DRG documentation and coding adjustment. In section III. D. of the preamble to this final rule, we are making a prospective adjustment of 2.0 percent and a recoupment of 2.9 percent to the FY 2012 inpatient payment rates to recover overpayments due to documentation and coding improvements. We note that any recoupments for overpayments due to documentation and coding improvements beyond the authority of section 7(b)(1)(B) of Public Law 110–90 would require additional changes to current law by Congress. Therefore, without a change to current law, our ability to recoup all overpayments due to documentation and coding improvements is limited.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this final rule.

We address public comments related to MedPAC's recommendation of an update to the hospital inpatient rates equal to 1.0 percent in section II.D. of the preamble to this final rule.

[FR Doc. 2011–19719 Filed 8–1–11; 4:15 pm]

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Part III

Department of Homeland Security

Transportation Security Administration

49 CFR Parts 1515, 1520, 1522 et al.

Air Cargo Screening; Final Rule

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

49 CFR Parts 1515, 1520, 1522, 1540, 1544, 1546, 1548, and 1549

[Docket No. TSA–2009–0018; Amendment Nos. 1515–2, 1520–9, 1522–1, 1540–11, 1544–10, 1546–6, 1548–6, 1549–1]

RIN 1652–AA64

Air Cargo Screening

AGENCY: Transportation Security Administration, DHS.

ACTION: Final rule; request for comments.

SUMMARY: This rule amends two provisions of the Air Cargo Screening Interim Final Rule (IFR) issued on September 16, 2009, and responds to public comments on the IFR. The IFR codified a statutory requirement of the Implementing Recommendations of the 9/11 Commission Act of 2007 that the Transportation Security Administration (TSA) establish a system to screen 100 percent of cargo transported on passenger aircraft not later than August 3, 2010. It established the Certified Cargo Screening Program, in which TSA certifies shippers, indirect air carriers, and other entities as Certified Cargo Screening Facilities (CCSFs) to screen cargo prior to transport on passenger aircraft. Under the IFR, each CCSF applicant had to successfully undergo an assessment of their facility by a TSA-approved validation firm or by TSA. In response to public comment, this Final Rule removes all validation firm and validator provisions, so that TSA will continue to conduct assessments of the applicant's facility to determine if certification is appropriate.

The IFR also required that if an aircraft operator or foreign air carrier screens cargo off an airport, it must do so as a CCSF. The Final Rule deletes this requirement, as aircraft operators are already screening cargo on airport under a TSA-approved security program, and do not need a separate certification to screen cargo off airport.

This rule also proposes a fee range for the processing of Security Threat Assessments, and seeks comment on the proposed fee range and the methodology used to develop the fee. TSA will announce the final fee in a future **Federal Register** notice.

DATES: Effective September 19, 2011.

Comment Date: Comments must be received by September 19, 2011.

ADDRESSES: You may submit comments, identified by the TSA docket number to this rulemaking, to the Federal Docket Management System (FDMS), a government-wide, electronic docket management system, using any one of the following methods:

Electronically: You may submit comments through the Federal eRulemaking portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Mail, In Person, or Fax: Address, hand-deliver, or fax your written comments to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Fax 202–493–2251. The Department of Transportation (DOT), which maintains and processes TSA's official regulatory dockets, will scan the submission and post it to FDMS.

See **SUPPLEMENTARY INFORMATION** for format and other information about comment submissions.

FOR FURTHER INFORMATION CONTACT: *For questions related to air cargo screening program:* Tamika McCree, Manager, Air Cargo Stakeholder Relations, Air Cargo Security, TSA–28, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6028; telephone (571) 227–2632; facsimile (571) 227–1947; e-mail *AirCargoScreeningCommentsIFR@dhs.gov.*

For legal questions: Alice Crowe, Senior Counsel, Office of Chief Counsel, TSA–22, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6028; telephone (571) 227 –2652; facsimile (571) 227–1379; e-mail *alice.crowe@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

In this final rule, TSA seeks prior public comment on our proposed fee to cover the cost of the STAs. To the maximum extent possible, DHS provides an opportunity for public comment on regulations issued without prior notice. Accordingly, TSA invites interested persons to participate in this rulemaking by submitting written comments, data, or views on the proposed fee for the STA. See **ADDRESSES** above for information on where to submit comments.

With each comment, please identify the docket number at the beginning of your comments. TSA encourages commenters to provide their names and addresses. The most helpful comments reference a specific portion of the rulemaking, explain the reason for any recommended change, and include supporting data. You may submit comments and material electronically, in person, by mail, or fax as provided under **ADDRESSES**, but please submit your comments and material by only one means. If you submit comments by mail or delivery, submit them in an unbound format, no larger than 8.5 by 11 inches, suitable for copying and electronic filing.

If you would like TSA to acknowledge receipt of comments submitted by mail, include with your comments a self-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it to you.

TSA will file in the public docket all comments received by TSA, except for comments containing confidential information and sensitive security information (SSI).[1] TSA will consider all comments received on or before the closing date for comments and will consider comments filed late to the extent practicable. The docket is available for public inspection before and after the comment closing date.

Handling of Confidential or Proprietary Information and Sensitive Security Information (SSI) Submitted in Public Comments

Do not submit comments that include trade secrets, confidential commercial or financial information, or SSI to the public regulatory docket. Please submit such comments separately from other comments on the rulemaking. Comments containing this type of information should be appropriately marked as containing such information and submitted by mail to the address listed in **FOR FURTHER INFORMATION CONTACT** section.

Upon receipt of such comments, TSA will not place the comments in the public docket and will handle them in accordance with applicable safeguards and restrictions on access. TSA will hold documents containing SSI, confidential business information, or trade secrets in a separate file to which the public does not have access, and place a note in the public docket that TSA has received such materials from the commenter. If TSA determines, however, that portions of these comments may be made publicly available, TSA may include a redacted version of the comment in the public docket. If TSA receives a request to examine or copy information that is not

[1] ''Sensitive Security Information'' or ''SSI'' is information obtained or developed in the conduct of security activities, the disclosure of which would constitute an unwarranted invasion of privacy, reveal trade secrets or privileged or confidential information, or be detrimental to the security of transportation. The protection of SSI is governed by 49 CFR part 1520.

in the public docket, TSA will treat it as any other request under the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the FOIA regulation of the Department of Homeland Security found in 6 CFR part 5.

Reviewing Comments in the Docket

Please be aware that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual who submitted the comment (or signed the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the applicable Privacy Act Statement published in the **Federal Register** on April 11, 2000 (65 FR 19477) and modified on January 17, 2008 (73 FR 3316).

You may review TSA's electronic public docket on the Internet at *http://www.regulations.gov.* In addition, DOT's Docket Management Facility provides a physical facility, staff, equipment, and assistance to the public. To obtain assistance or to review comments in TSA's public docket, you may visit this facility between 9 a.m. to 5 p.m., Monday through Friday, excluding legal holidays, or call (202) 366–9826. This docket operations facility is located in the West Building Ground Floor, Room W12–140 at 1200 New Jersey Avenue, SE., Washington, DC 20590.

Availability of Rulemaking Document

You can get an electronic copy using the Internet by—

(1) Searching the electronic Federal Docket Management System (FDMS) web page at *http://www.regulations.gov;*

(2) Accessing the Government Printing Office's Web page at *http://www.gpoaccess.gov/fr/index.html;* or

(3) Visiting TSA's Security Regulations Web page at *http://www.tsa.gov* and accessing the link for ''Research Center'' at the top of the page.

In addition, copies are available by writing or calling the individual in the **FOR FURTHER INFORMATION CONTACT** section. Make sure to identify the docket number of this rulemaking.

Small Entity Inquiries

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires TSA to comply with small entity requests for information and advice about compliance with statutes and regulations within TSA's jurisdiction. Any small entity that has a question regarding this document may contact the person listed in **FOR FURTHER INFORMATION CONTACT**. Persons can obtain further information regarding SBREFA on the Small Business Administration's web page at *http://www.sba.gov/advo/laws/law_lib.html.*

Abbreviations and Terms Used in This Document

ACDMS Air Cargo Data Management System
CBP U.S. Customs and Border Protection
CCSF Certified Cargo Screening Facility
CCSP Certified Cargo Screening Program
CFR Code of Federal Regulations
CHRC Criminal History Records Check
DHS Department of Homeland Security
DOE Department of Energy
FSD Federal Security Director
IAC Indirect Air Carrier
IED Improvised Explosive Device
SIDA Security Identification Display Area
SSI Sensitive Security Information
STA Security Threat Assessment
S&T DHS Directorate of Science & Technology
STP Screening Technology Pilot
TSA Transportation Security Administration

Outline of Final Rule

I. Background
II. Summary of the Final Rule
III. Disposition of Comments
IV. Section-by-Section Analysis of Changes
V. Proposed Fee for Security Threat Assessments
VI. Paperwork Reduction Act
VII. Economic Impact Analysis
VIII. Executive Order 13132, Federalism
IX. Environmental Analysis
X. Energy Impact Analysis

I. Background

Sec. 1602 of the Implementing the Recommendations of the 9/11 Commission Act of 2007 (Pub. L. 110–53, 121 Stat. 266, 478, Aug. 3, 2007) (9/11 Act), which amended 49 U.S.C. 44901(g)(1), provides, in pertinent part:

> Not later than 3 years after the date of enactment of the [9/11 Act], the Secretary of Homeland Security shall establish a system to screen 100 percent of cargo transported on passenger aircraft operated by an air carrier or foreign air carrier in air transportation or intrastate air transportation to ensure the security of all such passenger aircraft carrying cargo.

As amended by the 9/11 Act, 49 U.S.C. 44901(g)(2) provides that the system used to screen cargo on passenger aircraft shall provide a level of security ''commensurate with the level of security for the screening of passenger checked baggage,'' and directs that one hundred percent of such cargo must be screened not later than August 3, 2010.

Summary of Interim Final Rule

Section 44901(g)(3)(B) explicitly authorizes TSA to issue an interim final rule to implement the requirements. On September 16, 2009, TSA issued the Air Cargo Screening IFR implementing these 9/11 Act requirements, and sought comments on the provisions contained in the IFR.[2] Section 44901(g)(3)(B)(i) of the 9/11 Act requires TSA to issue a final rule not later than one year after the effective date of the IFR, or by November, 16, 2010. TSA was unable to meet the November 16, 2010, deadline due to changes that had to be made to the Final Rule. Data from industry indicates that industry met the August 3, 2010, deadline for domestically up lifted cargo only. Neither the IFR nor the Final Rule apply to international inbound cargo.

Requirements of the IFR

The IFR established the Certified Cargo Screening Program (CCSP), a program to certify shippers, indirect air carriers (IAC), and other entities located in the United States to screen cargo prior to tendering it to aircraft operators for transport on passenger aircraft.[3] The CCSP requires certified cargo screening facility (CCSF) personnel to successfully undergo a TSA conducted security threat assessment (STA)[4] and submit to an evaluation of its facility by a TSA-approved validator or TSA.[5] Once certified, the CCSF must, among other responsibilities:

- Implement a TSA-approved standard security program.[6]
- Ensure that key personnel with unescorted access to screened cargo undergo an STA[7] including (1) Each employee and authorized representative who screens cargo or has unescorted access to screened cargo, and (2) each security coordinator and alternate, senior manager of the facility, and other individual who implements the cargo screening program.
- Adhere to strict physical and access control measures for the storage, handing, and screening of cargo.
- Screen cargo using TSA-approved methods.
- Initiate chain of custody measures to ensure the security of the cargo from the time the CCSF screens the cargo until it is loaded on passenger aircraft.[8]
- Appoint security coordinators at the corporate and facility levels and alternates to be available 24 hours per day, 7 days per week.

[2] 74 FR 47672. The IFR provides detailed information on TSA's reasoning behind the regulatory provisions for the CCSP. For further information refer to the IFR.

[3] 74 FR 47686 and 47706.

[4] 49 CFR 1549.111.

[5] 49 CFR 1549.7.

[6] 49 CFR 1549.5.

[7] 49 CFR 1540.203.

[8] 49 CFR 1549.101(d).

• Apply for recertification, including a new examination by TSA or a TSA-approved validator, every 36 months.

The IFR further stated that aircraft operators that wish to screen cargo off-airport must become a CCSF, and adopt and implement a CCSF security program for that purpose.[9] Additionally, the IFR established procedures under which firms may apply for TSA's approval to conduct validation assessments of CCSF facilities.[10] TSA believed these procedures would help quickly process many applications for CCSPs in a short amount of time.

The IFR also amended the threat assessment provisions that currently exist in 49 CFR part 1540, subpart C, for individuals who work in the air cargo sector to enhance TSA's ability to effectively conduct STAs.

Finally, the IFR explained the methodology by which TSA would calculate a fee that TSA would charge for conducting STAs and presented an expected fee range for these STAs. TSA invited comment on the amount of the fee and the methodology used to calculate the fee but did not establish a fee. The IFR explained that TSA would specify the final fee amount in a separate notice in the **Federal Register**.[11]

II. Summary of the Final Rule

In response to comments on the IFR, TSA decided to remove two major requirements, explained below, concerning validation firms and certification of aircraft operators. This final rule also makes a few clarifications and other minor revisions such as typographical errors. Further explanations of these changes can be found in section IV of this rule, in the Section-by-Section Analysis of Changes.

TSA deleted part 1522 regarding validation firms and validators as we do not believe they are needed. TSA will continue to conduct all assessments of the facilities applying to become CCSFs because TSA has the capacity to review and certify all CCSF applicants itself.

In addition, this final rule deletes the IFR requirement that an aircraft operator must become certified as a CCSF in order to screen air cargo off-airport. As explained in Section III. (Disposition of Comments) of this preamble, TSA will continue to update the security programs through the security program amendment process as described in 49 CFR 1544.105(c) and 156.105(c) for aircraft operators and foreign air carriers to ensure that the same level of security applies to cargo that those entities and CCSFs screen. Because aircraft operators will need to meet the same substantive requirements as CSSFs, they do not need to be certified under the CCSP to screen cargo off airport.

III. Disposition of Comments

TSA received approximately 40 comments from trade associations, aircraft operators, including a few from individuals. The issues raised in these comments are discussed below.

TSA Screening at Airports

Comment: Several commenters stated that TSA, not private industry through the CCSP, should conduct screening of cargo to be transported on passenger aircraft. These commenters stated that TSA should use existing statutory authority to establish TSA-operated screening operations at airports. One commenter stated that TSA should screen all cargo transported on passenger aircraft because Congress created TSA to replace screening by third parties. These commenters believe that TSA screening is the only way to screen 100 percent of cargo on passenger aircraft without impeding the flow of commerce. Some commenters suggested that the CCSP must be a complement to, but not a substitute for, a Federal air cargo screening program operated by TSA at all domestic airports.

Other commenters favored the CCSP. The International Air Cargo Association (TIACA) commented that either federalization or airline-only screening would unduly crowd screening onto airport grounds, potentially creating significant bottlenecks by imposing a one-size-fits-all approach to air cargo screening. TIACA commented that the flexibility allowed under the CCSP is a better fit with the diverse needs of the air cargo supply chain.

TSA Response: The 9/11 Act required the Secretary of Homeland Security to establish a system to screen 100 percent of cargo loaded in the United States on passenger aircraft. TSA has determined the most appropriate model to accomplish this mandate is for TSA to establish screening standards that allows airlines, shippers, and IACs and other entities to perform the necessary screening. The CCSP program satisfies the statutory directive. The 9/11 Act, 49 U.S.C. 44901(g)(1), requires TSA to "* * * establish a system * * *" for screening 100 percent of air cargo, and does not require TSA to conduct the screening. The 9/11 Act provides that screening includes "* * * a program to certify the security methods used by shippers * * *" and therefore, anticipates that an entity other than TSA may conduct the screening to TSA standards. 49 U.S.C. 44901(g)(5).

TSA believes that if TSA screened cargo at airports, the screening process would very likely impede the flow of commerce as described in the TIACA comment above. It would create many of the same problems that would occur if aircraft operators screened 100 percent of cargo. There is insufficient space at airports to screen the 7.6 million pounds of cargo transported on passenger aircraft daily. TSA believes airport screening would be time-consuming. A high volume of cargo reaches the airports on skids or loaded into unit load devices, which TSA would have to break down and screen, a process that could lead to congestion at the cargo screening locations.

A fundamental principle of the CCSP is to provide stakeholders with additional options for screening air cargo. Participation in the CCSP allows shippers to move screening away from the airport to avoid the bottlenecks that TSA expects would occur if all cargo were screened there. The CCSP also allows industry participants to conduct screening at stages earlier within the cargo supply chain and off-airport. Thus, the CCSP gives industry control to schedule screening of the cargo at the most financially sensible point in their business process while still meeting all security requirements. Screening conducted by the industry permits IACs and shippers to tender screened cargo to aircraft operators so that it can be transported immediately on passenger aircraft, thereby avoiding the backlog that would result from screening solely by TSA or aircraft operators on-airport. TSA is confident that the CCSP will achieve the security benefits that Congress sought in the statutory mandate without causing unnecessary delays.

TSA believes the CCSP, supplemented by TSA screening at Category II–IV airports[12] and other measures TSA has already taken (such as requiring 100 percent screening of cargo transported on narrow-body aircraft), combined with cargo screened directly by aircraft operators, has achieved the 100 percent screening requirement. TSA believes that the CCSP concept provides the greatest

[9] 49 CFR 1549.5.

[10] 49 CFR part 1522.

[11] 74 FR 47683 and 47684.

[12] TSA classifies the over 400 commercial airports in the United States into one of five airport security categories (I, II, III, IV, and X) based on various factors, such as the total number of take-offs and landings annually, the extent to which passengers are screened at the airport, and other special security considerations. In general, Category X airports have the largest number of passenger boardings and Category IV airports have the smallest.

degree of flexibility and efficiency and should be the centerpiece of the current air cargo screening program. TSA will continue to screen almost all cargo received at Category II–IV airports.[13] Cargo screened at these locations involves relatively lower volumes and smaller pieces, which are conducive to screening by existing baggage equipment. TSA will also continue to screen any cargo delivered to the ticket counter for shipment, known as a counter-to-counter express shipment.

Comment: The U.S. Chamber of Commerce recommended that TSA expand the use of TSA-certified explosive-detection canines to screen large air cargo consolidations.

TSA Response: TSA will continue to evaluate the need for additional canine teams. In the future, TSA is also considering the use of TSA-approved canine teams owned by regulated parties to screen air cargo.

Impact of the CCSP on Small and Mid-Sized Companies

Comment: Some commenters expressed the view that small and mid-sized freight forwarders do not have the financial resources to participate in the CCSP, and that the CCSP will put them out of business, or impose significant economic burdens. One commenter cited the costs that a CCSF would incur for maintaining a compliant facility and ensuring adequate employee training as placing a burden on the companies.

TSA Response: TSA designed the CCSP to give small- and medium-sized companies several options to avoid unnecessary costs while achieving the security benefits of the program. The CCSP is a voluntary program intended to give industry the flexibility to respond to new security requirements in the 9/11 Act. Participation in CCSP does not require a business to purchase any costly screening equipment, because TSA provides multiple options to participants. For example, entities that wish to join the CCSP may choose to screen by conducting a physical search of the cargo as they pack it for shipment. Physical search may be more cost effective for companies that would have to screen smaller volumes of cargo and for any company that is conducting the screening as they pack the cargo for shipment, as many CCSFs do. A physical search is likely to satisfy the screening requirement of the 9/11 Act at a much lower cost for such companies than purchasing screening equipment.

Moreover, a small- or mid-sized freight forwarder has several options for getting its cargo screened that do not require participation in the CCSP. They may choose to have their cargo screened by a CCSF IAC, a CCSF independent cargo screening facility (ICSF), or an aircraft operator, if that is more cost effective than participating in the CCSP.

We believe that the most viable option for many small to medium shippers and IACs who do not wish to join the CCSP may be to have their cargo screened by ICSFs located away from the airport. This fee-based solution provides the benefit of screening away from the potential congestion and delay at the airport, without necessitating an investment in facilities, training, or screening equipment. TSA has published a list of all CCSFs IACs and ICSFs, as well as other IACs authorized to transport screened cargo for CCSF shippers. See the ''Certified Cargo Screening Locations'' section at *http://www.tsa.gov/what_we_do/layers/aircargo/certified_screening.shtm.*

Comment: The House Committee on Homeland Security requested that TSA consider expanding Screening Technology Pilot (STP) locations and on-airport screening options to provide stakeholders, particularly small businesses, with screening options that do not involve the purchase of costly screening equipment.

The Committee also recommended that TSA find a way to incorporate grants, tax incentives, low-interest loans, or innovative financing measures into the CCSP.

TSA Response: TSA has attempted to mitigate the impacts of the new air cargo program on small businesses by offering options, described in the TSA Response immediately above, that allow small businesses to choose how best to get their cargo screened.

The STP, a Congressionally-funded pilot program designed to test screening technology, was a useful program that authorized TSA to reimburse participants for a portion of the cost of acquiring screening technology. At this time, the funding has been exhausted through reimbursement to companies that participate in the CCSP. The reimbursement did not include the cost of labor, training, consumables, maintenance, facility security, or any other costs associated with the CCSP. Therefore, it may not be the best option for small businesses. At this time, TSA has no other program to provide financial assistance for air cargo screening technology.

Validations by Independent Validation Firms

Comment: TSA received several significant comments on the validation firm and validator requirements of the IFR. Some commenters stated that TSA, not private entities, should perform the validations because they view the function as ''inherently governmental.'' Other commenters believed that TSA should bear the cost of the validation or set a fee for the service. Several commenters were concerned that there is an inherent conflict of interest between the facility and the validator, because the facility would pay the validator to conduct the assessment.

TSA Response: While TSA disagrees that the validation process set forth in this rule requires industry to perform ''inherently governmental'' functions, TSA has decided that it does not need independent validators to perform assessments of CCSF applicants. TSA is removing the validation firms and validators process in part 1522 because there were fewer CCSF applicants than TSA expected, and TSA is capable of processing the applications itself. The IFR, published in November 2009, included this feature based on a similar validation program successful in the United Kingdom and a concern that TSA lacked the capacity to quickly evaluate and certify the 15,000 applications TSA estimated it would receive. The actual number of CCSF applications, however, is much lower than the estimate. To date, TSA has certified over 1,000 CCSFs, and is able to process the new applications without the support of validation firms. These certified locations are already screening a large volume of cargo destined for transport on passenger aircraft. Further, we believe that the industry has achieved 100 percent air cargo screening for domestic uplift as of the beginning of August 2010. While we may see additional CCSF applicants as shippers decide they want to screen their own cargo rather than risking the cargo being opened during screening downstream, TSA has determined that it can handle the future facility assessment workload without undue delay.

Under the final rule, applicants for the CCSP will not have to pay a fee to independent validators, thereby reducing the cost of the CCSP. Approximately $65.9 million in costs, discounted at 7 percent, over the 10-year period of the rulemaking were removed from the IFR to the FR as a result of the elimination of the requirement for TSA-approved validation firms (TAVFs). Discounted at seven percent, the following are the

[13] A Category I airport is an airport where screening is performed pursuant to TSA regulations and the number of annual enplanements are 1 million or more. A Category X airport is an airport where screening is performed pursuant to TSA regulations, the number of annual enplanements is 5 million or more, and the number of international enplanements is 1 million or more.

specific cost reductions to the respective impacted entities: $11.7 million for TAVFs, $54.0 million for CCSFs, and $0.2 million for TSA. This reduction in the cost of CCSP participation should be particularly helpful to the small- and mid-sized companies concerned that the cost of joining the CCSP is too high.

Security Level of Cargo Screening Relative to the Security Level of Checked Baggage Screening

Comment: One commenter argued that the CCSP does not provide a level of security that is commensurate with the level of security for passenger checked baggage, as required by the 9/11 Act. This commenter stated that ''commensurate'' means ''equal'' and that such a standard limits the discretion of TSA. According to this commenter, it would be much easier for a third party to compromise the chain of custody under the CCSP and tamper with screened cargo than it would be to infiltrate the chain of custody for passenger-checked baggage. For example, this commenter believes that tamper evident tape, which may be used as a chain of custody procedure under the CCSP, is inexpensive, and could easily be acquired or manufactured by a terrorist. This commenter also believes that even if CCSFs use more technologically advanced methods to protect the chain of custody, the length of time an item of cargo is stored after it is screened and prior to its delivery to an airport could provide third parties with time to break the chain of custody.

TSA Response: Section 44901(g)(2) of the 9/11 Act establishes the parameters for meeting the 100 percent screening requirement—the system must provide a level of security for cargo commensurate with the level of security for checked baggage. ''Commensurate'' is not a statutorily defined term and must be understood to have its ordinary meaning of ''similar'' or ''analogous.'' ''Commensurate'' does not mean ''identical.'' Notably, it is not the ''method of screening'' that must be commensurate with that of checked baggage, but the resulting ''level of security'' that must be commensurate. Physical examination is but one of many layers of security in place to protect air transportation. Therefore, it is the entire system that must ultimately produce security of cargo commensurate with that in place for checked baggage.

Section 44901(g)(5) defines ''screening'' of air cargo placed on a passenger aircraft, and enumerates specific types of authorized screening, including x-ray systems, explosives detection systems (EDS), explosives trace detection, and explosives detection canine teams certified by TSA. In addition to the particular screening technologies and techniques listed, paragraph (g)(5) expressly provides that ''the Administrator may approve additional methods to ensure that the cargo does not pose a threat to transportation and to assist in meeting the requirements of this subsection.'' A system of screening that utilizes a combination of the screening methods planned for use in the CCSP will provide a level of security commensurate with that in place for checked baggage.

The methods of screening, in some cases, may be the same used for checked baggage. By statute, however, checked baggage must be screened using EDS. 49 U.S.C. 44901(d). There is no parallel requirement for cargo in 49 U.S.C. 44901(g); rather, any one or more of a number of methods, including EDS, may be used. Also, like checked baggage security, the overall system will rely on layers of security to protect cargo from terrorist threats. Those layers will include STAs of individuals with unescorted access to cargo, physical protection of cargo once it is screened, and chain of custody practices to protect cargo from the time it is screened until it is tendered for transport on passenger aircraft.

TSA believes that the chain of custody measures the CCSP requires will provide a high degree of security for air cargo throughout the supply chain. TSA has established multiple layers of security for cargo as it travels through the supply chain. For example, the CCSP security programs, which are sensitive security information (SSI), contain requirements, such as the use of tamper-evident tape on cargo that has been screened, and security measures for the trucks and other conveyances that transport screened cargo to the airport. The transport and handling measures established in the security programs for the CCSP are similar to those already in place for the ground transport of screened cargo that is in the custody of air carriers. Screened cargo in the supply chain is handled by secure facilities and modes of transport. Air cargo is not typically stored for any significant period once it has been tendered for transport, as the very nature of air cargo is to move materials as quickly as possible from shipper to consignee.

TSA's Funding for Implementing the CCSP

Comment: The House Committee on Homeland Security expressed concerns regarding the level of TSA's investment in the CCSP and stressed the importance of TSA having appropriate resources to support its regulatory oversight role. Specifically, the Committee noted that TSA would need appropriate staffing levels for inspectors to be able to certify TSA-approved validation firms, and process STAs for workers at such firms and for CCSFs. The Committee suggested that TSA seek multiple means of additional funding to ensure that the 100 percent screening mandate is met, including seeking funds through the American Recovery and Reinvestment Act (ARRA). The Committee was also concerned that TSA would not have enough resources to certify enough CCSFs by the August 3, 2010, deadline.

TSA Response: TSA has requested, and Congress has provided, sufficient resources to attain the 100 percent screening requirements set forth in the mandate. In addition, the FY 2010 Homeland Security Appropriations Act provided nearly $15 million above the Administration's request, including $3.45 million for additional air cargo inspectors and $9 million for technology development. TSA considered requesting ARRA funds, however, they are not available for TSA staffing for the CCSP; Congress restricted ARRA funds to the procurement and installation of checked baggage explosives detection systems and checkpoint explosives detection equipment.

TSA concurs that it is important to have the resources to certify CCSFs quickly so as not to disrupt commerce. In the months before the requirement to screen 100 percent of air cargo became effective, TSA coordinated with the different applicants to ensure that facilities desiring to be CCSFs received an assessment as soon as the facility declared that it was ready.

At the current pace of applications and certifications, TSA remains confident that it will be able to certify all current (and a significant number of additional) applicants that remain engaged and interested in proceeding. TSA believes it also has the capability to manage any short-term surges in activity. TSA will continue to monitor and evaluate resource and funding levels, and will request increases that may be required by the circumstances to carry out its oversight responsibilities. After evaluating the flow of applications and the certification process, TSA has determined that the usage of TSA-approved validation firms is no longer required. Not having to certify validation firms, as well as no longer needing to process STA's for their workers, will provide TSA inspectors with some additional time for oversight and compliance activities related to CCSFs.

Outreach to Stakeholders

Comment: The House Committee on Homeland Security urged TSA to conduct additional industry outreach to encourage participation in the CCSP. Suggestions for increasing CCSP participation through outreach included: Utilizing existing federal supply chain programs, such as the Customs-Trade Partnership Against Terrorism (C–TPAT) program to conduct industry outreach and training on a larger scale; obtaining statistical data on shippers from the U.S. Department of Commerce in order to perform targeted outreach; providing low-cost training and information sessions to small businesses; and increasing CCSP visibility to industry trade publications.

TSA Response: To ensure the cargo and shipping industry are aware of the impact and requirements of the 100 percent screening requirement, TSA conducted outreach through multiple organizations, and we continue our longstanding relationships with associations whose members are impacted by the 9/11 Act. These organizations include members of airports, airlines, and freight forwarders. TSA continues its contact with associations such as the Air and Expedited Motor Carriers Association, Air Forwarders Association, Air Transport Association, American Association of Exporters and Importers, Cargo Airline Association, Council of Supply Chain Management Professionals, Express Delivery and Logistics Association, International Air Transport Association, Meridian One Consulting, National Association of Manufacturers, National Association of Wholesalers-Distributors, National Customs Brokers and Forwarders Association of America, and National Industrial Transportation League.

In addition, TSA representatives speak at trade association conferences and participate in webinars and other public forums to share vital information regarding the CCSP. This on-going effort will continue throughout implementation of the CCSP.

In coordinating outreach efforts, TSA estimates that approximately 20 of the largest airports within the United States disproportionately account for most of the air cargo transported on passenger aircraft, and these locations are primarily the largest (Category I and Category X) airports. TSA continues its outreach efforts to these airports to ensure widespread understanding of the CCSP.

Applicability of CCSP to Cargo Loaded Outside the United States

Comment: One association commended TSA for clarifying that the IFR does not apply to cargo that is loaded on passenger aircraft outside the United States. This commenter supports TSA's two-pronged approach of working with the International Civil Aviation Organization (ICAO) standards, and applying risk assessments for air cargo. The commenter suggested that TSA should leverage other Government programs, such as pertinent U.S. Customs and Border Protection (CBP) programs, and adopt best security practices currently in use in other countries for international inbound cargo.

TSA Response: TSA is working closely with its foreign government counterparts to leverage existing air cargo security practices and to work towards compatibility across systems to the greatest extent possible. TSA has been working in both bilateral and multilateral forums to better understand the air cargo security regimes currently in place in other countries in order to promote best practices while also enhancing air cargo security systems, where necessary, in order to ensure commensurate levels of security from system to system. This is an ongoing effort and will take considerable time to review and analyze the information, and to coordinate and collaborate with our partners and industry stakeholders in the development of mutually recognizable systems. TSA is hopeful that with the continued cooperation of our international partners, this work will promote uniformity and recognition among countries. In addition, TSA has aligned its CCSP as closely as possible with CBP's C–TPAT program and continues to seek opportunities to create efficiencies where possible.

Aircraft Operators or Foreign Air Carriers as CCSFs

Comment: The IFR required any air cargo screening facility that is off-airport, including one operated by an aircraft operator, to become a CCSF in order to screen cargo. Several commenters objected to this requirement, stating that this requires aircraft operators to comply with two separate security programs. They claimed that this was unnecessary. However, another commenter argued that exempting aircraft operators from the certification requirements would be inappropriate; it would produce an economic disadvantage for non-air carriers that currently operate as CCSFs. A trade association argued that this portion of the rule (§ 1544.205(g)(3)) should be removed only if there is: (1) No difference in security requirements between existing air carrier rules and CSSP requirements, and (2) there is no economic benefit favoring air carriers over non-air carriers.

TSA Response: TSA has evaluated the issue of aircraft operators and foreign air carriers operating off-airport screening facilities, and is amending the IFR to eliminate the requirement for aircraft operators and foreign air carriers to become CCSFs in order to screen off-airport. The security programs for aircraft operators have been and will continue to be amended to ensure that the same level of security involving screened cargo are equivalent to that for CCSFs. Because aircraft operators will need to meet the same substantive requirements as other CCSFs and CCSFs will no longer need to be validated by a third party, TSA does not believe that non-aircraft operators will be at a disadvantage.

Comparable Programs

Comment: One commenter commended TSA for using some of the same chain of custody requirements for the CCSP as for the IAC Standard Security Program.

TSA Response: In developing the CCSP, TSA tried to leverage the existing IAC program to the extent possible. Using the IAC program as a base, TSA strengthened those requirements for handling screened cargo in the CCSP.

Comments: Several commenters expressed the view that compliance with other cargo security programs should substitute for compliance with TSA's regulation. Commenters listed a number of programs that they believed provide comparable security. A trade association expressed concern that many of its members have to comply with security provisions in other government programs, including DOD's National Industrial Security Program Operating Manual (NISPOM), International Traffic in Arms Regulations (ITAR), Export Administration Regulations (EAR), and C–TPAT. The commenter urged TSA and other agencies to consider recognizing security requirements in each other's programs as being commensurate with one another.

Another association also recommended aligning C–TPAT and CCSP security requirements.

TSA Response: TSA structured the CCSP to incorporate secure practices recommended by industry representatives, including many of the security measures and processes already used in programs such as C–TPAT and

Transported Asset Protection Association, to the extent that these programs were compatible with the security and other requirements of the CCSP. Initially, TSA structured the CCSP to basically align with CBP's C–TPAT program following its structure in areas such as: Facility security, background checks, and basic chain of custody. However; there are key differences that should be noted: (1) The CCSP requires individuals to have a TSA security threat assessment, (2) individuals must be trained and implement screening procedures, (3) individuals must complete training specified by TSA, and (4) each entity is identified by site-specific methods rather than company-wide methods. Additionally, TSA structured the CCSP to incorporate industry security ''best practice'' procedures recommended by industry representatives, including many of the security measures and processes already used in programs such as C–TPAT and Transported Asset Protection Association, (TAPA).

The CCSP was established to enable a flexible solution for achieving the U.S. domestic 100 percent screening requirements. The air cargo security environment will continue to change and therefore the security practices, both established by TSA and practiced by industry or other government agencies will continue to change. TSA will maintain its close working relationship with key stakeholders and evaluate ongoing security measures and processes as the threat and risk to air cargo change. This may include incorporating additional measures and practices into the CCSP.

Certification for CCSPs

Comment: One commenter recommended that TSA should allow companies to participate in the CCSP on a corporate basis, rather than have to enroll on a facility-by-facility basis. Under this scenario, TSA would certify a company as being CCSP-compliant through random inspections of a sampling of facilities per corporate entity.

TSA Response: TSA is retaining the CCSP as a facility-based program. In order to achieve the level of security that is the goal of the CCSP, every participating facility must be considered individually because of its unique design and security configuration. While a corporation may direct the types and level of security at its facilities, the CCSF must account for the security of cargo at each location where cargo is screened, packed, or consolidated before the cargo is transferred to an aircraft operator. TSA must be confident that each location will meet TSA's CCSF standards.

Comment: Several commenters feared that there may be a backlog of CCSF applications, and that it could take TSA over six months to certify a facility to become a CCSF. Commenters urged TSA to take measures to avoid disruptions and dislocations to the cargo shipping industry.

TSA Response: To keep up with the CCSF applicant pool, TSA prioritizes, coordinates, and assesses any CCSF facility based on the readiness of the CCSF facility to meet the requirements of the security program. Some applicants can be certified sooner than others can. TSA has found that IACs applying for the program are often ready to implement the regulatory security requirements of the CCSP, and TSA can certify them quickly. TSA does not expect future delays in certifying CCSFs.

Security Threat Assessments

Comment: One commenter stated that the CCSP's use of name-based STAs provides less security than criminal history records checks (CHRCs), which are required for individuals with access to passenger baggage. This commenter believed that STAs by themselves are not a robust enough vetting tool for the CCSP, and that all individuals who maintain unescorted access to air cargo should be vetted according to the same standard—a fingerprint-based CHRC, accompanied by an STA.

TSA Response: TSA agrees that fingerprint-based CHRCs provide a greater degree of security than the STA requirement in this final rule, and that there should be congruency among the STA requirements for workers in functions that present similar security concerns, such as checked baggage screeners and cargo screeners. TSA is considering proposing a rulemaking that would provide for more consistent application of the CHRC requirement in STAs, including STAs for air cargo workers. Rather than addressing a CHRC requirement for air cargo workers on a program-specific basis in this final rule, TSA intends to address the CHRC requirement in the broader context of all TSA programs. TSA believes this approach will result in a more consistent, efficient, and equitable outcome on this issue.

Comment: Several commenters objected to the five-year renewal requirement for STAs, stating their belief that it is overly burdensome to industry. Commenters believed that this is a particular issue for express consignment operators, who may find it difficult to segregate their employees who handle air cargo, and therefore would have to issue hundreds of thousands of STAs across their industry. These commenters stated that only a name change should trigger a new STA requirement. These commenters maintain that TSA tools, such as the IAC Management System (IACMS), provide the means necessary to continually check applicant names against watch lists, and should obviate the need for a reapplication process, except for cases where a person's name changes.

TSA Response: The five-year renewal requirement is consistent with the duration of renewal requirements in other similar programs, such as national security clearances administered by the Office of Personnel Management, the CBP Free and Secure Trade Credential, the CBP Nexus credential, and TSA's Transportation Worker Identification Credential (TWIC). It is important for TSA to have current biographic information, such as address, to identify the individual and to administer the program effectively. For example, even after an individual successfully completes the initial STA, he or she is continually re-checked against various databases and watch lists; in the event of a subsequent match, TSA needs accurate information regarding the individual to distinguish similar names and to contact the individual with information about redress rights if subsequent vetting produces a match. If TSA renews the STA only as often as the individual's name changes, the other important biographic data may become stale. A system that only tracks the names of individuals, such as the IACMS, is therefore not an adequate substitute for periodic renewals.

Comment: Several commenters expressed their belief that requiring an STA for certain individuals is duplicative and unnecessary. These parties submitted that individuals who have already completed an STA for airport credentialing purposes should not have to reapply for another STA under the CCSP. A third commenter approved of TSA's decision to accept Hazardous Materials Endorsements, TWICs, or Free and Secure Trade cards in lieu of redundant background checks for air cargo screening operations.

TSA Response: TSA attempts to avoid unnecessary redundancy in STA requirements. Therefore, TSA regulations provide for the possibility of comparable STAs. If TSA determines that another STA conducted by TSA or by another government agency is comparable to the STA required by part 1540, subpart C, individuals who have successfully completed such a

comparable STA are not required to undergo another STA under part 1540, subpart C. 49 CFR 1540.203(f).

TSA has already determined that an STA conducted for purposes of security identification display area (SIDA) access at airports, that is, a CHRC conducted in accordance with 49 CFR 1542.209, 1544.229, or 1544.230 that includes a name-based check conducted by TSA, is comparable to the check required under part 1540, subpart C. 49 CFR 1540.203(h). For other security threat assessments conducted by a governmental agency, the commenter may request a determination that the other governmental STA is comparable to the STA required under part 1540, subpart C. 49 CFR 1540.203(f), (g). If TSA grants the determination of comparability, the individuals who have successfully completed such a comparable STA are not required to undergo another STA under part 1540, subpart C. A background check or investigation conducted by a non-governmental agency would not qualify as a ''comparable'' STA. Non-governmental agencies are not necessarily focused on the factors underlying a governmental STA, and are unlikely to have access to the depth and breadth of information available to a governmental agency. Therefore, TSA does not consider the STA required by part 1540, subpart C, to be duplicative with such non-governmental checks.

Screening of Animals

Comment: The Association of Zoos and Aquariums expressed concern with screening procedures for live animals, and warned that opening containers with live animals inside could create potential hazards for the animals, handlers, and cargo personnel.

TSA Response: TSA agrees that screening live animals provides special challenges. Aircraft operator and CCSF security programs, as required under 49 CFR parts 1544, 1546, and 1549, already provide procedures for screening live animals to ensure the safety of both the screeners and the animals.

Use of Non-Citizens To Perform Screening

Comment: One commenter expressed concern that the air carriers' and freight forwarders' use of non-U.S. citizens to screen cargo violates International Traffic in Arms Regulations (ITAR) and Export Administration Regulations (EAR) for cargo that is designated as sensitive military technology.

TSA Response: Section 1549.103(d) requires, in part, that each certified cargo screening facility must ensure that each individual who screens cargo or who supervises cargo screening is a citizen or national of the United States or an alien lawfully admitted for permanent residence. TSA sets minimum standards for the screening of cargo to be transported on passenger aircraft, which the CCSF must meet. However, if there are additional standards that apply, for example, for sensitive military technology, the CCSF must meet those additional requirements as well.

Time Concerns

Comment: Several commenters expressed concern about the time it takes a CCSF to break down palletized shipments for screening.

TSA Response: TSA agrees that having to break down and screen cargo consolidations at the airport could lead to significant delays. The CCSP allows entities to screen cargo before it is consolidated. TSA will continue to evaluate technologies that allow for bulk screening of some types of consolidated cargo. As such technologies become available, TSA may authorize their use.

Reporting Burden; Estimated Number of CCSFs

Comment: Several commenters stated that TSA's estimate of 7,514 entities seeking CCSP membership annually was an overestimate, but that TSA's estimate of annual cargo reporting burden of 293,037 hours was an underestimate. Furthermore, one air carrier argued that TSA's estimate that CCSFs will complete monthly cargo reports at an estimated time of one hour per week is an underestimate of the time required. The air carrier maintained that dealing with thousands of shipments and hundreds of thousands of pieces in a reporting period produces a data collection burden that will far surpass TSA's estimate.

TSA Response: With respect to the estimate of 7,514 entities applying to the CCSP annually, TSA agrees that this was an overestimate and has revised the population estimate in the regulatory evaluation and fee model so that this final rule better reflects where the CCSP is today. The new estimate also takes into account recent information from shippers and IACs as to the types and sizes of entities that will most likely join the CCSP in the future.

TSA's original estimate that it takes CCSFs one hour per week to report monthly cargo statistics was based on how long it might take a CCSF to record the data by hand on the form provided by TSA, resolve any identified discrepancies in that data, and transmit that information to TSA.

Subsequently, TSA created the Cargo Reporting Tool (CRT) as a convenience for CCSFs, IACs, and aircraft operators, to allow these entities to more easily submit cargo screening data to TSA. A small group of air carriers, freight forwarders, and shippers was asked to beta test the CRT for approximately one year and the users indicated it took approximately one hour to enter information into the system. Accordingly, TSA believes that the one-hour time limit is a reasonable estimate, and is retaining this estimate for the final rule.

In addition, TSA is developing an Air Cargo Data Management System (ACDMS) to facilitate compliance with this requirement and minimize the reporting burden on industry. The ACDMS will allow industry to submit certain information to a single point of entry online, which then will provide industry access to several systems and services.

Comment: The House Committee on Homeland Security asked TSA to review the recordkeeping provisions to ascertain how to streamline these requirements while maintaining the appropriate regulatory oversight.

TSA Response: TSA reviewed the recordkeeping requirements [14] and has decided to maintain these recordkeeping requirements. These requirements are consistent with those required by other regulated entities within the air cargo supply chain (for example, air carriers, aircraft operators, and indirect air carriers). These requirements are necessary to ensure that regulated parties are in compliance with CCSF regulations. Additionally, TSA is developing ACDMS to assist industry in complying with this requirement. TSA expects the ACDMS to reduce the time required to comply with the recordkeeping requirements.

Issuance of IFR

Comment: One commenter expressed the view that TSA's issuance of an IFR was inappropriate, and that TSA should have provided prior opportunity for public comment.

TSA Response: The 9/11 Act required TSA to put in place an air cargo screening program within a short time period. Accordingly, 49 U.S.C. 44901(g)(3)(A) provides that ''the Secretary of Homeland Security may issue an interim final rule * * * to implement this subsection without regard to the provision of chapter 5 of title 5.'' Thus, Congress concluded that the significant benefits of strengthening air cargo security within the statutory

[14] Section 1549.105.

time period warranted implementing the program through an IFR. TSA could not have had the CCSP operational by the August deadline without being able to issue an IFR.

TSA conducted outreach to a wide range of stakeholders before issuing the IFR. In addition, TSA provided a 60-day notice and an opportunity to submit written comments on the IFR. TSA considered these comments in developing this final rule and before establishing the final STA fee.

Screening Technology

Comment: One commenter expressed the view that most of the approved screening methods and equipment are appropriate for the passenger screening environment, but are ill-suited to the air cargo environment where palletized or other consolidated shipments are the norm. The commenter stated that CCSFs are currently technologically incapable of effectively screening large pallets of cargo without breaking down shipments and urged TSA to use the $4 million Congress appropriated to TSA for FY2010 to develop and deploy technologies capable of screening skids and pallets, including vapor and metal detection technologies. Another commenter also urged TSA to test and approve effective screening technology equipment that could be used to screen palletized shipments.

TSA Response: TSA is exploring newer technologies for screening cargo, especially those technologies that screen palletized and consolidated cargo. In order to effectively evaluate and qualify technologies for screening cargo, TSA is working closely with the DHS Science and Technology Directorate (S&T), and the Department of Energy (DOE) National Laboratories and Technology Centers to continue to evaluate new and emerging technologies. TSA has qualified three technologies for screening some skid-level cargo configurations and commodities on the Air Cargo Screening Technology List (ACSTL), and is currently in the process of evaluating additional large aperture technologies for screening cargo. A non-SSI version of the ACSTL may be found at *http://www.tsa.gov/assets/pdf/non_ssi_acstl.pdf.* In addition to these efforts, screening protocols in security programs have also been refined for use in a cargo environment.

Congress appropriated $18 million for TSA to specifically evaluate and deploy screening technologies. TSA added to the Congressional appropriation to fund a $40 million Screening Technology Pilot (STP) for IACs. This pilot is evaluating the effectiveness of screening technologies for screening cargo at the piece level, as well as for cargo consolidations, such as TSA Advanced Technology X-Ray (AT X-Ray) and Explosives Trace Detection (ETD), by commodity class, at each participant's consolidation facility. TSA provided some distributed funding to 47 participants at 111 different locations among 17 airports nationwide that handle large volumes of cargo, and that build cargo pallets for transport on passenger wide-body aircraft. TSA's objectives for the pilot program include determining the effectiveness of screening technology on various commodity classes of cargo, including palletized shipments. The pilot is evaluating 11 different X-ray models and 4 different ETD models, totaling 226 systems.

TSA was also appropriated $4M in FY2010 for the evaluation and qualification of other technologies for air cargo screening including metal detectors and vapor detection systems with the intent to focus on perishable commodities and screening skids and pallets. These types of systems are currently undergoing the qualification process and results of these evaluations will be complete by the fourth quarter 2010.

Comment: A commenter requested that TSA ensure transparency in its review procedures and expedite its evaluation of new technologies. In addition, the House Committee on Homeland Security also expressed concerns about TSA's approval of new technologies, adding their view that the lack of a Qualified Product List (QPL) for cargo screening technology makes industry stakeholders hesitant to purchase expensive equipment on the Approved List of Technology without the assurances that this equipment will be certified in future years. The Committee urged TSA to work with S&T to strengthen their processes in order to give timely attention to the development and certification of technology for cargo screening.

TSA Response: DHS has expedited the evaluation process for new technologies by instituting simultaneous field and laboratory testing, and is working to qualify dozens of technologies. TSA is working closely with DHS S&T and the DOE National Laboratories to determine new and emerging technologies that exhibit proficiency in detecting improvised explosive devices and other prohibited items. Additionally, TSA's implementation of the CCSP is also mitigating the impact of screening consolidations on the air cargo supply chain, as CCSFs may tender screened cargo that does not need to be broken down to the piece level for additional screening.

TSA has expedited the evaluation of these new technologies and is working to encourage industry to invest in new technology research and development by releasing Requests for Information (RFIs), holding industry forums with potential developers, and conducting other ongoing outreach. All of these efforts support the development and qualification of additional cargo screening technologies providing more technologies to meet industry's needs. As part of these activities, TSA must be confident that new technologies will meet the CCSP's security objectives before approving them. TSA has posted a Qualified Technology List.[15] TSA will continually update this list with additional qualified technologies as those qualifications are completed.

IV. Section-by-Section Analysis of Changes

Part 1515—Appeal and Waiver Procedures for Security Threat Assessments for Individuals

In part 1515 TSA removed references to part 1522, validation firms, and validators because that part is being removed from the CFR, as discussed below.

Part 1522—TSA-Approved Validation Firms and Validators

As explained in Section III., TSA decided it does not need independent validators to perform assessments of CCSF applicants because TSA has the capacity to review and certify all CCSF applicants itself. Thus, TSA has deleted part 1522 in its entirety.

Part 1540—Civil Aviation Security: General Rules

TSA is amending § 1540.201(a), Applicability and terms used in this subpart, to correct an incorrect citation. The IFR reference to 49 CFR 1549.113 was incorrect and is changed in this final rule to 49 CFR 1549.111.

Part 1544—Aircraft Operator Security: Air Carriers and Commercial Operations; and Part 1546—Foreign Air Carrier Security

Under the IFR, § 1544.105(a) provided that each aircraft operator must submit a security program to TSA at least 90 days before the intended date of passenger operations. In this final rule, TSA deleted the term ''passenger'' from the provision, because the requirement

[15] See *http://www.tsa.gov/what_we_do/layers/aircargo/certified_screening.shtm#approved* for information about the CCSP, including links to qualified vendor lists.

applies to both passenger and all-cargo operations.

Paragraphs (g)(3) of §§ 1544.205 and 1546.205, Acceptance and Screening of Cargo, Subpart C, of the IFR provided that an aircraft operator that screens cargo off-airport must become a certified cargo screening facility in accordance with part 1549. In response to comments, TSA is deleting this requirement for both aircraft operators and foreign air carriers for the reasons stated in Section III. of this preamble.

Part 1548—Indirect Air Carrier Security

Sections 1548.15(a) and § 1548.15(a)(2) incorrectly referred to the ''aircraft operator.'' TSA corrected these sections by inserting the word ''indirect air carrier'' in place of ''aircraft operator.''

Part 1549—Certified Cargo Screening Program

TSA clarified the language in § 1549.7(b)(1) to make it clear that a CCSF must apply for renewal of its security program and its certification every 36 months.

V. Proposed Fee for Security Threat Assessments

TSA is authorized to collect fees to offset the cost of conducting security threat assessments (STAs). 6 U.S.C. 469.

TSA issued the Air Cargo Security Requirements final rule on May 26, 2006 (2006 rulemaking),[16] which, in part, required certain cargo workers of aircraft operators, foreign air carriers, and indirect air carriers (IACs) to obtain a security threat assessment. That final rule established a fee for STAs of $28, and incorporated the fee amount in 49 CFR 1540.209. TSA published the Air Cargo Screening IFR on September 16, 2009,[17] that establishes requirements for certain additional individuals to successfully complete security threat assessments conducted by TSA. These individuals are CCSF employees and authorized representatives that screen cargo, have unescorted access to screened cargo or carry out certain other cargo security duties. The IFR amended § 1540.209 to remove the specific fee amount. In the preamble to the IFR, we described how TSA would calculate the fee for STAs, and stated that the fee would be between $13 and $21, depending on the size of the population and whether costs involved in the calculation may change. We invited comment on the proposed fee, and the methodology and population estimates we used to arrive at the proposed fee. We stated that TSA would publish specific fee amounts and changes to fee amounts as a notice in the **Federal Register**.

However, since the IFR, TSA has further reviewed costs and population data. Due to significant decreases in the population estimate, the fee necessary to recover our costs of conducting threat assessments would need to be increased. In this final rule, we propose that the user fee for the security threat assessments under 49 CFR 1540.209 will be between $31 and $51. As stated above, we will announce the final fee in a notice in the **Federal Register**.

Discussion

TSA proposes a fee range of $31 to $51 for STAs for aircraft operators, foreign air carriers, and IAC personnel who have unescorted access to screened cargo to be transported on passenger aircraft, screen cargo, supervise the screening of cargo, or perform certain other security functions as provided for in § 1540.201.[18] Applicants who have previously completed a TSA STA under the Air Cargo Security Requirements final rule, 71 FR 30478 (May 26, 2006) (2006 rulemaking), were subject to the security fee in effect at that time and will not be subject to this fee until their existing STA reaches its five year expiration mark. At the time of expiration, applicants re-applying for an STA will be asked to pay a new air cargo screening fee that will be between $31 and $51.

To ensure consistency and equity across the entire air cargo community, TSA combined the costs and populations of individuals, or applicants, who would need STAs under both the 2006 IAC Air Cargo Security Requirements Final Rule and the 2009 IFR to create one harmonious fee. TSA calculated the fee based on historical counts of IAC applications and an estimate of the number of CCSF applicants (population), the cost of processing the applications, the cost of performing the STAs, and the cost of maintaining the information systems to support the process. Table 1, below in the Costs section, presents the calculations supporting the estimated fee.

Costs

TSA proposes that individuals required to undergo an STA would be required to pay a fee to cover the following costs:

TABLE 1—AIR CARGO COST ESTIMATES

Operational year	1st Year	2nd Year	3rd Year	4th Year	5th Year	Total
Cost Components:						
Name Check	$445,705	$659,710	$874,730	$721,160	$557,350	$3,258,656
Platforms/Systems	3,240,521	1,890,265	1,718,315	1,781,956	1,845,597	10,476,654
Personnel	2,538,286	2,489,620	2,663,626	2,685,010	2,706,329	13,082,872
Grand Totals	6,224,512	5,039,595	5,256,671	5,188,126	5,109,276	26,818,182

For the TSA STA, each applicant's information will be name-checked against multiple databases and other information sources. The threat assessment process includes an appeals process for individuals who believe the records upon which TSA bases its determination are incorrect. TSA would also need to implement and maintain the appropriate systems, resources, and personnel to process applicant information and to allow TSA to receive, and act on, the results of the STA.

TSA's fee methodology begins with estimating the unit cost for each name-check, and then builds on costs for threat assessment investments used by all applicants. These investments are estimated as fixed costs over a five-year period and then equally distributed to all applicants over that same five-year period. In doing so, TSA has established a constant fee that will be imposed

[16] 71 FR 30478.

[17] 74 FR 47672.

[18] Section 1540.209 of the 2006 rule stated that a fee of $28 is required for TSA to conduct an STA. The 2009 IFR, however, revised § 1540.209 so that the regulation no longer contains a specific fee amount. Section 1540.209 now states that TSA will publish fee amounts and any revisions to the fee amounts as a notice in the **Federal Register.**

equitably across the population that is receiving and benefiting from this unique service.

TSA estimates that the cost, net of appropriations,[19] of STA services for both the IAC and CCSF populations will be $26,818,182 over five years. The estimate for STA services includes $3,258,656 for TSA name-based checks, $10,476,654 for platforms/systems costs, and $13,082,872 for fully-loaded personnel costs necessary to facilitate the STA processing. TSA arrived at these cost estimates using information gathered from subject matter experts in the program office. Please see Table 2 below for detailed breakout of the Air Cargo fee:

TABLE 2—AIR CARGO FEE BREAKOUT

Cost category	Total cost	Fee (%)
Security Threat Assessment	$3,258,656	12
Equipment/Systems	10,476,654	39
Personnel	13,082,872	49
Total	26,818,182	100

Population

TSA estimates that approximately 651,713 applicants would be required to complete a STA during the next five years of the program. This estimate is derived from the following population figures that have been gathered for specific segments of the regulated population.

TABLE 3—AIR CARGO POPULATION ESTIMATES

Operational year	1st Year	2nd Year	3rd Year	4th Year	5th Year	Total
CCSP:						
Applicants	30,165	67,598	53,878	50,852	55,370	257,863
IAC:						
Applicants	58,976	64,344	121,068	93,380	56,100	393,868
Grand Totals	89,141	131,942	174,946	144,232	111,470	651,731

The CCSP population segment includes an estimated number of STAs to be performed for CCSP enrolled shippers and independent cargo screening facilities from 2010 to 2014. The number of STAs is based on a projected 1,745 entities and an average 131 STAs per entity over five years. The number of projected entity enrollments and average number of STAs per entity were based on information known about currently enrolled CCSFs and the types of entities that may enroll in the future. The turnover estimate is based on the 2009 BLS JOLT transportation, warehousing, and utilities worker hires rate. The turnover rate is also used to estimate the number of employees that received an STA in 2009, which would still be employed in 2014 when they are required to renew their STA. For the IAC population segment, TSA utilized historical actual enrollments over the past four years to develop an estimate for the next five years.

When the IFR was published, TSA anticipated as many as 15,000 applicants would apply to participate in the CCSP. This was based on the assumption that the CCSP would be comprised of a high number of individual shippers. TSA surmised that individual shippers would participate in the program to screen their own cargo to minimize additional handling and the potential for delay or damage to the cargo if it were screened at a later point in the supply chain. Instead, the indirect air carrier industry (i.e., freight forwarders) led enrollment in CCSP and has taken on a significant percentage of the screening performed under the program. This has resulted in significantly fewer applicants and participants in the program than originally estimated, as a single indirect air carrier has the capacity to screen cargo for multiple shippers. This redistribution of screening led to a significant reduction in the number of STAs required by personnel who have access to screened cargo.

TSA will continue to work to minimize all costs and will finalize the proposed fee in a notice in the **Federal Register**. Additionally, pursuant to the Chief Financial Officers Act of 1990 (Pub. L. 101–576, 104 Stat. 2838, Nov. 15, 1990), DHS/TSA is required to review fees no less than every two years (31 U.S.C. 3512). Upon review, if TSA finds that the fees are either too high (that is, total fees exceed the total cost to provide the services) or too low (total fees do not cover the total costs to provide the services) TSA would adjust the fee. Finally, TSA would be able to adjust the fees for inflation following publication of the final rule. If TSA were to adjust the fees for this reason, TSA would publish a notice in the **Federal Register** notifying the public of the change.

Fee Range

The fee TSA establishes for the STA should cover all the costs related to the STA process. TSA estimates that the final fee to the applicant will be between $31 and $51 per applicant based on the total estimated cost of services provided ($26,818,182). This cost will be equally apportioned to the estimated population (651,731) receiving the threat assessment service. The resulting fee will be sufficient to fully recover the remaining STA costs.

TSA invites comment on the proposed fee range of $31 to $51 and the methodology and population estimates we used to arrive at this amount. Additional detailed information regarding the fee determination has been provided in the ''Air Cargo Screening Security Threat Assessment Fee Development Report.'' This report

[19] TSA utilized appropriations to fund certain start-up systems costs. These appropriations have not been included in the fee model and therefore, will not be recovered through the imposition of security fees.

has been placed in the public docket established for this rulemaking. After reviewing all comments received, TSA will issue a notice in the **Federal Register** that summarizes and addresses the comments we receive, and establishes the final fee amount, after which the fee will be charged to applicants.

Revised § 1540.209 provides that TSA will calculate fees for STAs based on widely accepted accounting principles and practices and in accordance with the provisions of 31 U.S.C. 9701 and other Federal law as applicable.

Comments on the Fee Calculation

TSA received two comments on the IFR relating to the STA fee. The comments raised several points, discussed below.

Comment: Two commenters stated that the proposed fee range in the IFR indicated that TSA has been overcharging by applying an STA fee of $28 for IACs since the 2006 rulemaking.

TSA Response: TSA based the fee of $28, established in 2006, on the population and costs of conducting STAs only on cargo workers covered under the 2006 rulemaking. TSA set that fee to cover TSA's cost of conducting STAs for that population. Further, as we established the CCSP in the 2009 IFR, both the overall estimated costs of processing the STAs and the overall number of estimated individuals that would be required to undergo the STA increased. Because the IFR population estimate had increased in greater proportion to the costs, TSA estimated a fee range of $13 to $21. Ultimately, in this final rule, TSA utilized the most robust cost and population estimates to determine the STA fee range. Compared to IFR estimates, both cost and population estimates have decreased. But because the population estimate decreased in greater proportion to the cost estimate, TSA must increase the fee to a range between $31 and $51 to recover the full cost of the STA services from the estimated population regulated under this rulemaking.

Comment: A commenter stated that TSA's failure to impose fees for processing the STAs for CCSF applicants prior to this notice amounted to discrimination against the regulated entities that have been paying the fee of $28 under the 2006 rulemaking. The commenter believes that TSA should have waited to process STAs for the CCSFs until we had the rulemaking authority in place to charge fees.

TSA Response: TSA considered it necessary to initiate the CCSP in order to meet the mandatory screening requirements imposed by the Implementing the Recommendations of the 9/11 Act. To protect the public from explosives on passenger aircraft, Congress required that 50 percent of cargo transported on passenger aircraft be screened by February 3, 2009, and that 100 percent of such cargo be screened by August 3, 2010. TSA commenced a screening pilot to build the CCSP so that industry could meet the deadlines of the 9/11 Act. STAs were needed to implement the pilot program to ensure that key personnel with unescorted access to screened cargo, and thus, the opportunity to compromise security, were checked against the relevant domestic and international watch lists.

VI. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that TSA consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from the Office of Management and Budget (OMB) for each collection of information it conducts, sponsors, or requires through regulations. OMB has approved information collection requirements associated with this rule and has assigned OMB Control Number 1652–0053 to these collections. However, TSA has adjusted its burden estimates to reflect information actually collected following the publication of the IFR, as well as the elimination of TAVF requirements from the IFR to the final rule, and has submitted the following information requirements to OMB for its review.

Title: Certified Cargo Screening Program Final Rule.

Summary: Section 1602 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (Pub. L. 110–53, 121 Stat. 266, Aug. 3, 2007) requires the development of a system to screen 100 percent of the cargo transported on a passenger aircraft operating within the United States by August 2010 and to screen 50 percent of all air cargo by February 2009. This rule amends several parts of title 49 of the Code of Federal Regulations (CFR), as described in prior sections of this preamble. The rule involves several information collections already approved by OMB.

This final rule includes the following information collections, which were included in the IFR:

First, an entity that seeks to become a CCSF under 49 CFR part 1549 must submit an application to TSA.

Second, TSA must conduct STAs for key personnel of CCSFs. These key personnel must submit personal data to TSA for the STAs. This STA portion is a previously approved collection under OMB control number 1652–0040. This FR under OMB control number 1652–0053 expands the population from which the information is collected.

Third, CCSFs (49 CFR 1549.7) must accept the TSA-approved security program or submit amendments to the TSA-approved security program. CCSFs must accept a standard security program provided by TSA or submit a proposed modified security program to the designated TSA official for approval initially and periodically thereafter as required.

Fourth, CCSP participants must maintain records of compliance with the final rule and make them available for TSA inspection (see 49 CFR 1549.105 and 1522.129).

Finally, CCSFs must submit TSA-determined monthly cargo screening metrics to TSA in accordance with their security programs.

Use of: TSA uses the applications of entities seeking to become CCSFs to approve the entity as a CCSF. TSA collects personally identifiable information from CCSFs about their key personnel in order to conduct STAs on these individuals. STAs are required for individuals who screen cargo, those who have unescorted access to screened cargo, and other key individuals who support those functions. CCSF security programs are necessary because they contain specific measures to deter incidents that may jeopardize transportation security. CCSFs must maintain records and provide TSA Inspectors and Principal Cargo Security Analysts (PCSAs) access to their records, equipment, and facilities necessary to conduct inspections and assessments. Finally, TSA requires CCSFs to provide information on the amount of cargo screened at an approved facility in order to evaluate the compliance and performance of the CCSFs and to provide information needed for congressional reporting and future rulemaking relating to air cargo security.

Respondents (including number of): Over a three-year period, the likely respondents to this proposed information requirement are the 2,902 entities that seek to become CCSFs under 49 CFR part 1549.

Frequency: CCSFs will submit an application for recertification every three years. CCSFs will submit personally identifiable information of their key personnel so that TSA can conduct STAs every five years. The rule requires CCSFs to accept the TSA-approved security program or submit

amendments to the TSA-approved security program once. TSA estimates CCSFs will submit updates to their security program on average once annually. The recordkeeping requirements must be continuous in accordance with their security program. The requirement for CCSFs to provide information on the amount of cargo screened and other screening data at an approved facility will be a monthly collection.

Annual Burden Estimate: TSA estimates that the 967 entities who seek to become CCSFs annually will spend approximately 2 hours each to complete the applications for an annual burden of 1,934 hours. TSA estimates 51,172 annual responses from CCSFs submitting applications to TSA for processing STAs. TSA estimates an average of 15 minutes per application for an annual burden of 12,793 hours. TSA has estimated that a total of 1,778 CCSFs will adopt their security programs over the three years for an average of 593 security programs annually. Each CCSF will devote approximately 42 hours to their initial security program, resulting in an annual burden of 24,906 hours. TSA has estimated that a total 3,701 CCSFs will be required to maintain and update their security programs over the three years for an average of 1,234 security programs updated annually. Each CCSF will devote approximately four hours annually, beginning in the second year, updating their security programs for an annual hour burden of 4,936. TSA estimates all CCSFs over the three years will be required to maintain records of compliance with the final rule. This includes a time burden of approximately 5 minutes (0.083 hours) for every CCSF employee required to have an STA as well as other records of compliance. This recordkeeping requirement results in 51,172 annual record updates for an annual burden of approximately 4,247 hours. TSA estimates that 1,826 CCSFs, the estimated annual average in the program, will complete monthly cargo reports at an estimated time of one hour per week for an annual burden of approximately 94,952 hours.

Function	Average annual respondents	Average annual responses	Time per response	Annual hours	TSA form No.	FR cite
CCSF Applications	Collected every 36 months after initial application.					
One Year	967	967	2 hours	1,934	419E	§ 1549.7
Three Years	2,902	2,902	2 hours	5,804		
STA Applications	Collected every five years after initial application.					
One Year	51,172	51,172	.25 hours	12,793	419F	§ 1549.11
Three Years	153,516	153,516	.25 hours	38,379		§ 1549.103
Security Programs						
Creations	One time collection.					
One Year	593	593	42 hours	24,906	N/A	§ 1549.5
Three Years	1,778	1,778	42 hours	74,676		
Updates	Once annually					
One Year	1,234	1,234	4 hours	4,936	N/A	§ 1549.5
Three Years	3,701	3,701	4 hours	14,804		
Recordkeeping	Continuous as needed.					
One Year	51,172	51,172	.083 hours	4,247	N/A	§ 1549.105
Three Years	153,516	153,516	.083 hours	12,742		
Cargo Reporting	Monthly collection.					
One Year	1,826	21,912	52 hours/yr	94,952	N/A	§ 1549.105
Three Years	5,479	65,748	52 hours/yr	284,908		
Total for One Year	106,964	127,050		143,768		
Total for Three Years	320,892	381,161		431,313		

Note: One year burdens may not multiply to three year burdens due to rounding.

As a protection provided by the Paperwork Reduction Act, as amended, 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.

VII. Economic Impact Analyses

A. Regulatory Evaluation Summary

Changes to Federal regulations must undergo several economic analyses. First, Executive Order (EO) 12866, Regulatory Planning and Review, as supplemented by EO 13563, Improving Regulation and Regulatory Review, directs each Federal agency to propose or adopt a regulation only if the agency makes a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996) requires agencies to consider the economic impact of regulatory changes on small entities when an agency is required to issue a notice of proposed rulemaking. Third,

the Trade Agreements Act (19 U.S.C. 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. Fourth, the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation).

TSA has prepared a Regulatory Evaluation, with detailed analyses, which is available to the public in this docket. With respect to these analyses, TSA provides the following conclusions and summary information:

• This rule is considered an economically significant rule within the definition of EO 12866, as supplemented by EO 13563, as estimated annual costs or benefits exceed $100 million in any year. TSA has included the mandatory OMB Circular A–4 Accounting Statement in the Regulatory Evaluation and thus has not repeated it here.

• Under the Regulatory Flexibility Act of 1980, TSA is not required to perform a Regulatory Flexibility Analysis because we did not publish a proposed rule.

• The Regulatory Evaluation provides the required assessment of the Trade Agreement Act of 1979.

• The Regulatory Evaluation provides the required written assessment of Unfunded Mandates. This final rule is not likely to result in the expenditure by State, local, or Tribal governments, in the aggregate, of $100 million or more annually (adjusted for inflation). This rule, however, does impose an unfunded mandate of greater than $100 million or more annually (adjusted for inflation) on the private sector. The separate analysis of the costs and benefits of the rule in the Regulatory Evaluation, found in the public docket, satisfies the analysis requirements of the Unfunded Mandates Reform Act.

B. Executive Order 12866 and Executive Order 13563 Assessments

The following summary highlights the costs and benefits of the rule. The following table presents the annualized, monetized costs of the rule, discounted at both seven and three percent, along with a discussion of the qualitative benefits, which have not changed from the IFR to this final rule. This information is also found in the OMB Circular A–4 in the Regulatory Evaluation Summary of the regulatory evaluation.

Category	Estimates			Units	
	Primary	Low	High	Year dollar	Discount rate
Costs					
Annualized	$178.1	$146.1	$210.9	2009	7%
Monetized ($millions/year)	$180.1	$147.7	$213.1	2009	3%
Benefits					
Qualitative	Increased protection of passengers and cargo from acts of terrorism. Prevent the introduction of unauthorized persons, explosives, incendiaries, and other destructive substances or items into the air cargo supply chain. Protect citizens on the ground, in buildings, and elsewhere in our society from acts of terrorism involving the use of aircraft.				

Costs

TSA issued an IFR implementing the CCSP on September 16, 2009 (74 FR 47672). This final rule makes only two changes to the program TSA established in the IFR—the elimination of the requirement for aircraft operators to be certified as a CCSF in order to screen cargo off-airport and the elimination of TSA-approved validation firms (TAVFs) in favor of TSA assessments because of the reduction in the expected number of CCSF participants. In response to public comments and changes in the expected CCSF population, TSA has adjusted the estimated costs for the CCSP. The effect of eliminating the TAVF requirement will be to lower the cost of the rulemaking by $65.9 million, discounted at 7 percent, over the 10-year period of the rulemaking. However, TSA is unable to quantify any potential impacts on cargo volumes or shipping/screening prices that may stem from changes in requirements which removed the TAVFs. The TAVF concept was never implemented by TSA, consequently there is no data that can be used as a baseline. The Regulatory Evaluation accompanying this rule contains a further qualitative discussion of these potential impacts.

The Regulatory Evaluation accompanying this rule summarizes the revised cost estimates of the CCSP, which would be borne by four relevant parties: aircraft operators (including, in this context, both U.S. aircraft operators and foreign air carriers), CCSFs, non-CCSF entities that receive screened cargo from CCSFs, and TSA.

Total

In summary, over the 10-year period of the analysis, TSA estimates the aggregate costs of the CCSP to total approximately $1.5 billion discounted at three percent and approximately $1.3 billion discounted at seven percent. The Regulatory Evaluation, available in the public docket, provides detailed estimates of these costs.

TSA estimates costs of this Regulatory Evaluation using two methods: a top-down approach and a bottom-up approach. TSA's bottom-up cost approach is based primarily on the projected participation of IACs, ICSFs, and shippers in the CCSP. TSA uses these estimates in conjunction with estimated costs of program compliance to estimate a total cost for the rule from the bottom up.

TSA expects IACs and ICSFs choosing to become CCSFs to charge a service fee for screening cargo. TSA believes that this fee, similar to that charged by United Kingdom Known Consignors, would include all costs and profit associated with screening of cargo and is therefore a useful proxy in determining the cost to firms of screening cargo. TSA's top-down method estimates the cost of CCSP using a range of fees seen in the United

Kingdom Known Consignor program as the basis for costs incurred by industry.

TSA considers the top-down cost approach more accurate considering the level of uncertainty in TSA's estimate of the number of firms choosing to become CCSFs. Also, the top-down approach is more likely to reflect the efficiencies captured by allowing the market to allocate screening measures. Thus, the top-down cost estimate is TSA's preferred approach.

Both the bottom-up and the top-down cost estimates decreased from the IFR to the final rule due to changes in assumptions, based on having better data available for the final rule. For example, TSA used Bureau of Transportation Statistics data in the IFR to estimate cargo volume, but in the final rule, actual cargo volume data were available from the air carriers. The only change in rule requirements that impacted the cost estimates was the elimination of the TSA-approved validation firms. In the top-down approach, only the TSA costs were reduced by the elimination of TAVFs. In the bottom-up approach, costs were reduced for CCSFs, TSA, and the potential TAVFs.

The following table presents the annual costs of the rule over the 10-year analysis period. The total is broken out by costs to TSA, cost to industry (using the preferred approach), and the estimated delay costs due to screening. The TSA total represents the estimated costs TSA will incur to implement the CCSP and enforce compliance.

The industry cost is estimated using a range of fees observed in the United Kingdom Known Consignor Program as the basis, and accounts for the 57 percent of cargo shipped on passenger planes expected to be screened at CCSFs as well as the additional 28 percent that aircraft operators are expected to screen. The remaining 15 percent is assumed to have been screened by the air carriers prior to the rulemaking. The delay cost assumes the 43 percent of cargo (15 percent screened prior to the CCSP and an additional 28 percent under the CCSP) expected to be screened by the aircraft operators will be the only cargo subject to delay. The high and low estimates represent variance around TSA's primary estimate to allow for uncertainties with the inputs used to estimate the total cost of the rule.

TABLE 1—10-YEAR TOTAL COST SUMMARY OF CCSP

[$ millions]

Year	TSA cost	Industry cost	Delay cost	Total cost	Discounted (3 percent)	Discounted (7 percent)
1	$32.7	$109.7	$30.1	$172.5	$167.5	$161.2
2	5.4	115.0	31.6	152.0	143.3	132.7
3	4.9	120.5	33.1	158.5	145.1	129.4
4	4.1	126.3	34.7	165.1	146.7	126.0
5	4.1	132.3	36.4	172.9	149.1	123.3
6	4.5	138.7	38.2	181.4	151.9	120.9
7	4.3	145.3	40.1	189.7	154.3	118.2
8	4.3	152.3	42.0	198.6	156.8	115.6
9	4.6	159.6	44.0	208.2	159.6	113.3
10	4.4	167.3	46.2	217.9	162.1	110.8
Total	73.4	1,367.0	376.5	1,816.8	1,536.3	1,251.2
Low	55.0	1,139.2	296.5	1,490.7	1,260.2	1,026.1
High	91.7	1,594.8	463.3	2,149.9	1,818.2	1,481.1

Changes in Cost Estimates From Interim Final Rule

The CCSP final rule cost estimates differ from the IFR in large part to reflect actual data gathered since the implementation of the program. TSA uses the current state of the program, technology purchased, screening distribution, and numerous other sources of information to better estimate population projections and program costs. The tables below identify these cost differences for the CCSP top-down approach (which is TSA's preferred approach), CCSP bottom-up approach, and the 100 percent Air Carrier Alternative at the undiscounted, three percent, and seven percent discounted rate.

TABLE 2—CHANGES TO COST ESTIMATES FROM IFR

[$ millions]

Estimate	Undiscounted 10-year total costs		
	IFR	Final rule	Difference
CCSP Top-down	$2,836.4	$1,816.8	($1,019.6)
CCSP Bottom-up	5,199.5	2,300.0	(2,899.5)
Air Carrier Alternative	11,141.6	3,513.7	(7,627.9)

TABLE 2a—CHANGES TO COST ESTIMATES FROM IFR

[$ millions]

Estimate	3% Discount 10-year total costs		
	IFR	Final rule	Difference
CCSP Top-down	$2,394.0	$1,536.3	($857.7)
CCSP Bottom-up	4,403.9	1,946.1	(2,457.7)
Air Carrier Alternative	9,427.0	2,966.4	(6,460.6)

TABLE 2b—CHANGES TO COST ESTIMATES FROM IFR

[$ millions]

Estimate	7% Discount 10-year total costs		
	IFR	Final rule	Difference
CCSP Top-down	$1,945.0	$1,251.2	($693.8)
CCSP Bottom-up	3,597.0	1,585.4	(2,011.5)
Air Carrier Alternative	7,683.0	2,410.4	(5,272.6)

The tables below identify the major driving forces behind the changes for the CCSP Bottom-up approach. The Regulatory Evaluation explains in detail the reasons for the changes.

TABLE 3—CHANGES TO AIR CARRIER AND NON-CCSF IAC COSTS

[$ millions]

Cost component	10-year total costs			Major cost driving changes
	IFR	Final rule	Difference	
Personnel	$709.9	$564.1	($145.8)	TSA increased the percentage of cargo screened by air carriers and updated tendering percentage configuration assumptions based on current screening data.
Equipment	57.3	34.8	(22.5)	
Screener Training	6.4	3.7	(2.7)	
Chain of Custody Training	75.5	55.2	(20.3)	TSA updated with a more industry-specific wage.
Undiscounted Total	849.1	657.8	(191.3)	
3% Discounted Total	717.7	556.3	(161.4)	
7% Discounted Total	584.3	453.0	(131.2)	

TABLE 4—CHANGES TO TSA APPROVED VALIDATION FIRM (TAVF) COSTS

[$ millions]

Cost component	10-year total costs			Major cost driving changes
	IFR	Final rule	Difference	
Enrollment	$0.002	$0.00	($0.002)	TSA will perform assessments on CCSFs and has eliminated the need for TAVFs.
Validator Training	14.10	0.00	(14.10)	
STA Cost	0.10	0.00	(0.10)	
Undiscounted Total	14.20	0.00	(14.20)	
3% Discounted Total	14.0	0.0	(14.0)	
7% Discounted Total	11.7	0.0	(11.7)	

TABLE 5—CHANGES TO CCSF COSTS

[$ millions]

Cost component	10-year total costs			Major cost driving changes
	IFR	Final rule	Difference	
Validations	$75.4	$0.0	($75.4)	TSA will now perform assessments at no charge to CCSFs and eliminated the need for TAVFs.
Facility Security	172.3	19.1	(153.2)	TSA updated the CCSF population projection based on current participation and the types of entities expected to enroll in the future.
Training	902.2	107.0	(795.2)	
Security Coordinators	593.8	53.2	(540.6)	
Enrollment	119.0	17.0	(102.0)	TSA updated CCSF population projection. Also, based on current program included new cost for a two-hour application per CCSF.
Screening Equipment	914.8	309.6	(605.2)	TSA updated CCSF population projection and equipment expected to be purchased based on technology purchased by currently enrolled CCSFs. Also revised purchase prices to reflect industry experience.
Chain of Custody	58.8	24.5	(34.3)	TSA updated assumptions based on current practice.
STA Cost	31.0	20.7	(10.3)	TSA updated CCSF population projection and STA fee. In addition, estimated firms will pay STA fee in years 3–10. Previously, TSA was assumed responsible for the duration of the analysis.
Personnel	785.5	641.4	(144.1)	TSA updated tendering percentage assumptions based on current screening data.
Undiscounted Total	3,652.8	1,192.4	(2,460.4)	
3% Discounted Total	3,094.8	1,006.4	(2,088.4)	
7% Discounted Total	2,529.1	816.6	(1,712.6)	

TABLE 6—CHANGES TO TSA COSTS

[$ millions]

Cost component	10-year total costs			Major cost driving changes
	IFR	Final rule	Difference	
Inspections	$200.2	$9.5	($190.7)	TSA updated the CCSF population projections based on current participation and the types of entities expected to enroll in the future.
Training	10.0	5.1	(4.9)	TSA updated with more industry-specific wages.
Security Plan Review	30.0	4.3	(25.7)	TSA updated CCSF population projection.
Assessments	0.0	9.6	9.6	TSA will be performing assessments and eliminated the need for TAVFs.
Assessment Review	42.3	1.0	(41.3)	TSA updated CCSF population projection.
Validation Firm Enrollment	0.3	0.0	(0.3)	TSA will be performing assessments and has eliminated the need for TAVFs.
ACDMS	9.0	14.0	5.0	TSA updated costs based on current ACDMS development.
STAs	71.4	1.5	(69.9)	TSA updated CCSF population projections. TSA estimates industry will pay an STA fee in years 3–10. Previously, TSA was assumed responsible for the duration of the analysis.
Equipment for Screening Technology Pilot (STP).	23.6	28.4	4.8	TSA updated cost to reflect actual cost incurred for pilot.
Undiscounted Total	386.8	73.4	(313.4)	
3% Discounted Total	326.8	66.0	(260.8)	

TABLE 6—CHANGES TO TSA COSTS—Continued

[$millions]

Cost component	10-year total costs			Major cost driving changes
	IFR	Final rule	Difference	
7% Discounted Total	268.7	58.3	(210.4)	

TABLE 7—CHANGES TO CCSP DELAY COST

[$millions]

Cost component	10-year total costs			Major cost driving changes
	IFR	Final rule	Difference	
Undiscounted Total Delay Cost	$297.1	$376.5	$79.4	TSA updated the percentage of cargo screened by CCSFs and tendering percentage configuration assumptions based on current screening data. In addition, TSA corrected errors in the delay model.
3% Discounted Total	250.3	317.4	67.2	
7% Discounted Total	202.9	257.5	54.6	

Benefits

The CCSP allows for more standardized governance in cargo screening and provides fourfold benefits in terms of increased security of commercial passenger aviation. First, by screening 100 percent of cargo shipped on passenger aircraft, the passenger airline industry will have more protection against an act of terrorism or other malicious behavior. Second, allowing the screening process to occur throughout the supply chain via the CCSP reduces potential bottlenecks and delays at the airports. Third, the CCSP allows the market to identify the most efficient venue for screening along the supply chain thereby permitting any entity in the supply chain to apply for TSA certification to screen the cargo and apply chain-of-custody procedures. Finally, the CCSP enables members to screen valuable cargo earlier in the supply chain and avoid any potentially invasive screening that may occur at the aircraft operator level.

The main benefit of this regulation, decreased terrorism risk, cannot be quantified given current data limitations. When it is not possible to quantify or monetize the important incremental benefits of a regulation, OMB recommends conducting a threshold, or ''break-even'' analysis. According to OMB, such an analysis answers the question, ''How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?'' [20] Consequently, to better inform the comparison of the costs of implementing the rule with the benefits to homeland security of the CCSP, TSA performed a series of break-even analyses. In these break-even analyses, TSA compared the annualized costs of the rule's requirements to the expected benefits of preventing certain potential terrorist attacks. To evaluate the potential range of attacks, TSA considers four relevant attack scenarios.

For example, TSA considered the direct costs of a scenario where an explosive device placed in cargo shipped on a passenger plane destroys a standard narrow body aircraft (from the fleets used by major U.S. aircraft operators) during flight. This incident is assumed to result in the loss of the lives of all passengers and crewmembers on board, along with the total destruction of the aircraft. Based on data reported in the FAA Critical Values Guidance,[21] TSA used an average capacity of 142 passengers with a load factor of 80 percent [22] and an average crew size of five to estimate 119 (142 passengers × 80 percent + 5 crewmembers) total people to be on board. TSA estimates the value of these statistical lives is approximately $714.0 million, based on the Department of Transportation's Value of a Statistical Life (VSL) estimation of $6.0 million per person.[23] The VSL represents an individuals' willingness to pay to avoid a fatality, based on economic studies of the value individuals place on small changes in risk and is not meant to represent the actual value of a specific life. TSA notes the VSL used in the final rule has increased to $6.0 million from the $5.8 million used in the IFR. This increase was done to remain in alignment with the VSL used by DOT, which was raised from $5.8 million to $6.0 million.[24] A further discussion of VSL is included in the Break Even Analysis section of the Regulatory Evaluation.

The estimated aircraft cost is $18.5 million. The aircraft replacement costs are from an FAA guide on economic values in regulatory analysis.[25] The values in the FAA guidance are in 2003 dollars. In the IFR, TSA inflated these 2003 prices to 2006 price levels using the BLS Producer Price Index (PPI) Commodity Data for Civilian Aircraft. The final rule inflated them to 2009 dollars using the PPI Industry Data for Aircraft Manufacturing of Civilian Aircraft.[26] The eight percent increase from the IFR shows the PPI increase for this industry from 2006 to 2009, and is

[20] U.S. Office of Management and Budget, Circular A–4, September 17, 2003, p.2.

[21] ''Economic Values for FAA Investment and Regulatory Decisions, a Guide'' (updated Oct 2007).

[22] FAA Aerospace Forecast 2008–2025 (load factor across all aircraft). The FAA Aerospace Forecast is updated annually and provides the best available data on load factors.

[23] U.S. Department of Transportation memorandum, ''Treatment of the Economic Value of a Statistical Life in Departmental Analyses—2009 Annual Revision.'' Office of the Secretary of Transportation, March 18, 2009. *http://gov.rosenet.org/uploads/254/treatment_of_a_statistical_life_dot.pdf.*

[24] Ibid.

[25] *http://www.faa.gov/regulations_policies/policy_guidance/benefit_cost/media/050404%20Critical%20Values%20Dec%2031%20Report%2007Jan05.pdf.*

[26] *http://bls.gov/ppi/.*

consistent across all aircraft types used in the Regulatory Evaluation.

Assuming that the aircraft is destroyed and minimal impact damage is done, TSA estimates the total direct monetary consequence of the attack, the value of the lives on board and the aircraft, at $732.5 million. Dividing the $732.5 million in estimated direct consequences, by the $178.1 (the annualized cost of the rule discounted at seven percent), shows that in order for the rule to break even, it will need to reduce the existing or baseline frequency of terror attack by one attack every 4.1 years ($732.5/$178.1 = 4.1).

The estimate of the economic impacts of the attack scenarios used in these break-even analyses is limited to direct costs only (value of casualties and loss of aircraft). This analysis does not consider any indirect or macroeconomic consequences these terrorist attacks might cause. Consequently, the economic impacts of the terrorist attacks estimated for this series of break-even analyses is a lower-bound estimate of the economic impact of these attacks. A full discussion of the break-even analysis including an analysis of each of the four scenarios analyzed is presented in Chapter 4 of the Regulatory Evaluation accompanying this rule.

C. Regulatory Flexibility Act Assessment

Section 604(a) of the Regulatory Flexibility Act (RFA) requires that, when an agency promulgates a final rule ''after being required * * * to publish a general notice of proposed rulemaking,'' the agency must determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities and, if so, must prepare a regulatory flexibility analysis as described in the Act. Because TSA did not issue a proposed rule prior to this final rule, we are not required to perform a Regulatory Flexibility Analysis. Although a Regulatory Flexibility Analysis was not prepared, TSA analyzed the impact of costs of the program on all CCSFs currently enrolled. This analysis is presented in Appendix A of the Regulatory Evaluation accompanying this rule.

D. International Trade Impact Assessment

The Trade Agreements Act of 1979 prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. TSA has assessed the potential effect of this final rule and has determined that the same measures must apply to both U.S. aircraft operators and foreign air carriers loading cargo on passenger aircraft.

E. Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (UMRA) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and Tribal governments. Title II of UMRA requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector, such a mandate is deemed to be a ''significant regulatory action''. This final rule does not exceed this threshold with respect to State, local, and Tribal governments, because it does not require them to take any action. The impact on the private sector, however, does exceed the threshold, resulting in an unfunded mandate on the private sector; the regulatory evaluation documents the costs and alternatives associated with this regulatory action.

VIII. Executive Order 13132, Federalism

TSA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have federalism implications.

IX. Environmental Analysis

We have analyzed this final rule under DHS Management Directive 5100.1 ''Environmental Planning Program'' (see also 71 FR 16790, Apr. 4, 2006), which guides DHS in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). We have concluded that this rule is part of a category of actions described in items A3, A4, A7, B3, H1 and H2 of Table 1 in Appendix A of the Management Directive. This final rule would not have individually or cumulatively a significant effect on the human environment and, therefore, neither an environmental assessment nor an environmental impact statement is necessary.

X. Energy Impact Analysis

TSA has assessed the energy impact of this rule in accordance with the Energy Policy and Conservation Act (EPCA), Public Law 94–163, as amended (42 U.S.C. 6362). We have determined that this rulemaking is not a major regulatory action under the provisions of the EPCA.

List of Subjects

49 CFR Part 1515

Appeals, Commercial driver's license, Criminal history background checks, Explosives, Facilities, Hazardous materials, Incorporation by reference, Maritime security, Motor carriers, Motor vehicle carriers, Ports, Seamen, Security measures, Security threat assessment, Vessels, Waivers.

49 CFR Part 1520

Air transportation, Law enforcement officers, Maritime carriers, Reporting and recordkeeping requirements, Security measures.

49 CFR Part 1522

Accounting, Aircraft operators, Aviation safety, Reporting and recordkeeping requirements, Security measures.

49 CFR Part 1540

Air carriers, Aircraft, Airports, Civil aviation security, Law enforcement officers, Reporting and recordkeeping requirements, Security measures, Screening.

49 CFR Part 1544

Air carriers, Aircraft, Aviation safety, Freight forwarders, Incorporation by reference, Reporting and recordkeeping requirements, Security measures.

49 CFR Part 1546

Aircraft, Aviation safety, foreign air carriers, Incorporation by reference, Reporting and recordkeeping requirements, Security measures.

49 CFR Part 1548

Air transportation, Aviation safety, Reporting and recordkeeping requirements, Security measures.

49 CFR Part 1549

Air transportation, Reporting and recordkeeping requirements, Security measures.

The Amendments

Under 49 U.S.C. 114(l) and as discussed in the preamble, the Transportation Security Administration

amends Chapter XII, of Title 49, Code of Federal Regulations as follows:

SUBCHAPTER A—ADMINISTRATIVE AND PROCEDURAL RULES

PART 1515—APPEAL AND WAIVER PROCEDURES FOR SECURITY THREAT ASSESSMENTS FOR INDIVIDUALS

■ 1. The authority citation for part 1515 continues to read as follows:

Authority: 46 U.S.C. 70105; 49 U.S.C. 114, 5103a, 40113, and 46105; 18 U.S.C. 842, 845; 6 U.S.C. 469.

■ 2. Revise § 1515.1(a)(2) to read as follows:

§ 1515.1 Scope.

(a) * * *

(2) 49 CFR part 1540, subpart C, which includes individuals engaged in air cargo operations who work for certain aircraft operators, foreign air carriers, indirect air carriers (IACs), or certified cargo screening facilities.

* * * * *

■ 3. In § 1515.9 remove paragraph (c)(1)(v), and revise paragraphs (a)(3) and (f)(3) to read as follows:

§ 1515.9 Appeal of security threat assessment based on other analyses.

(a) * * *

(3) TSA had determined that an individual engaged in air cargo operations who works for certain aircraft operators, foreign air carriers, IACs, or certified cargo screening facilities, poses a security threat as provided in 49 CFR 1549.109.

* * * * *

(f) * * *

(3) If TSA withdraws a Determination of No Security Threat for an individual engaged in air cargo operations who works for certain aircraft operators, foreign air carriers, IACs, or certified cargo screening facilities.

■ 4. Revise § 1515.11(a)(3) to read as follows:

§ 1515.11 Review by administrative law judge and TSA Final Decision Maker.

(a) * * *

(3) An individual engaged in air cargo operations who works for certain aircraft operators, foreign air carriers, IACs, or certified cargo screening facilities who has been issued a Final Determination of Threat Assessment after an appeal as described in 49 CFR 1515.9.

* * * * *

SUBCHAPTER B—SECURITY RULES FOR ALL MODES OF TRANSPORTATION

PART 1520—PROTECTION OF SENSITIVE SECURITY INFORMATION

■ 5. The authority citation for part 1520 continues to read as follows:

Authority: 46 U.S.C. 70102–70106, 70117; 49 U.S.C. 114, 40113, 44901–44907, 44913–44914, 44916–44918, 44935–44936, 44942, 46105.

■ 6. Revise § 1520.7(b) to read as follows:

§ 1520.7 Covered persons.

* * * * *

(b) Each indirect air carrier (IAC), as described in 49 CFR part 1548; and each certified cargo screening facility and its personnel, as described in 49 CFR part 1549.

* * * * *

PART 1522—[REMOVED]

■ 7. Remove part 1522.

SUBCHAPTER C—CIVIL AVIATION AUTHORITY

PART 1540—CIVIL AVIATION AUTHORITY: GENERAL RULES

■ 8. The authority citation for part 1540 continues to read as follows:

Authority: 49 U.S.C. 114, 5103, 40113, 44901–44907, 44913–44914, 44916–44918, 44935–44936, 44942, 46105.

Subpart C—Security Threat Assessments

■ 9. In § 1540.201 remove paragraphs (a)(10), (11), and (12), and revise paragraph (a) introductory text and paragraph (b) definition of ''Operator'' to read as follows:

§ 1540.201 Applicability and terms used in this subpart.

(a) This subpart includes the procedures that certain aircraft operators, foreign air carriers, indirect air carriers, and certified cargo screening facilities must use to have security threat assessments performed on certain individuals pursuant to 49 CFR 1544.228, 1546.213, 1548.7, 1548.15, 1548.16 and 1549.111. This subpart applies to the following:

* * * * *

(b) * * *

Operator means an aircraft operator, foreign air carrier, and indirect air carrier listed in paragraphs (a)(1) through (a)(3) of this section, and a certified cargo screening facility described in paragraph (a)(6) of this section.

* * * * *

§ 1540.203 [Amended]

■ 10. In § 1540.203 remove paragraph (a)(1) and redesignate paragraphs (a)(2) through (a)(6) as paragraphs (a)(1) through (a)(5).

■ 11. Revise § 1540.209 introductory text and paragraph (c)(1) to read as follows:

§ 1540.209 Fees for security threat assessment.

This section describes the payment process for completion of the security threat assessments required under this subpart.

* * * * *

(c) * * *

(1) The fees required under this subpart must be remitted to TSA in a form and manner acceptable to TSA each time the applicant or an aircraft operator, foreign air carrier, indirect air carrier, or certified cargo screening facility submits the information required under § 1540.203 or § 1540.207 to TSA.

* * * * *

PART 1544—AIRCRAFT OPERATOR SECURITY: AIR CARRIERS AND COMMERCIAL OPERATORS

■ 12. The authority citation for part 1544 continues to read as follows:

Authority: 49 U.S.C. 114, 5103, 40113, 44901–44905, 44907, 44913–44914, 44916–44918, 44932, 44935–44936, 44942, 46105.

Subpart C—Operations

■ 13. Revise § 1544.105(a) introductory text to read as follows:

§ 1544.105 Approval and amendments.

(a) *Initial approval of security program.* Unless otherwise authorized by TSA, each aircraft operator required to have a security program under this part must submit its proposed security program to the designated official for approval at least 90 days before the intended date of operations. The proposed security program must meet the requirements applicable to its operation as described in § 1544.101. Such requests will be processed as follows:

* * * * *

■ 14. Revise § 1544.205(g)(3) to read as follows:

§ 1544.205 Acceptance and screening of cargo.

* * * * *

(g) * * *

(3) *Limitation on who may conduct screening.* Screening must be conducted by the foreign air carrier on an airport, by another aircraft operator or foreign

air carrier operating under a security program under this chapter with a comparable cargo security program on an airport with a complete program under 49 CFR part 1542, by a certified cargo screening facility in accordance with 49 CFR part 1549, or by TSA.

* * * * *

PART 1546—FOREIGN AIR CARRIER SECURITY

■ 15. The authority citation for part 1546 continues to read as follows:

Authority: 49 U.S.C. 114, 5103, 40113, 44901–44905, 44907, 44914, 44916–44917, 44935–44936, 44942, 46105.

Subpart C—Operations

■ 16. Revise § 1546.205(g)(3) to read as follows:

§ 1546.205 Acceptance and screening of cargo.

* * * * *

(g) * * *

(3) *Limitation on who may conduct screening.* Screening must be conducted by the foreign air carrier on an airport, by another aircraft operator or foreign air carrier operating under a security program under this chapter with a comparable cargo security program on an airport with a complete program under 49 CFR part 1542, by a certified cargo screening facility in accordance with 49 CFR part 1549, or by TSA.

* * * * *

PART 1548—INDIRECT AIR CARRIER SECURITY

■ 17. The authority citation for part 1548 continues to read as follows:

Authority: 49 U.S.C. 114, 5103, 40113, 44901–44905, 44913–44914, 44916–17, 44932, 44935–44936, 46105.

■ 18. Revise § 1548.15(a) to read as follows:

§ 1548.15 Access to cargo: Security threat assessments for individuals having unescorted access to cargo.

(a) Before an indirect air carrier authorizes and before an individual performs a function described in paragraph (b) of this section—

(1) Each individual must successfully complete a security threat assessment or comparable security threat assessment described in part 1540 subpart C of this chapter; and

(2) Each indirect air carrier must complete the requirements in part 1540 subpart C.

* * * * *

PART 1549—CERTIFIED CARGO SCREENING PROGRAM

■ 19. The authority citation for 1549 continues to read as follows:

Authority: 49 U.S.C. 114, 5103, 40113, 44901–44905, 44913–44914, 44916–44917, 44932, 44935–44936, 46105.

Subpart A—General

■ 20. In § 1549.7 revise paragraphs (a)(2)(ii), (a)(3)(ii), (a)(5), and (b)(2) to read as follows:

§ 1549.7 Approval, amendment, renewal of the security program and certification of a certified cargo screening facility.

(a) * * *

(2) * * *

(ii) An applicant must successfully undergo an assessment by TSA.

(3) * * *

(ii) The applicant has successfully undergone an assessment by TSA;

(5) *Commencement of operations.* The certified cargo screening facility may operate under a security program when it meets all TSA requirements, including but not limited to an assessment by TSA, successful completion of training, and Security Threat Assessments by relevant personnel.

* * * * *

(b) * * *

(2) The certified cargo screening facility must demonstrate that it has successfully undergone a revalidation of its operations by TSA prior to the first day of the 36th anniversary month of initial approval of its security program.

* * * * *

Subpart B—Operations

■ 21. Revise § 1549.105(a)(2) to read as follows:

§ 1549.105 Recordkeeping.

(a) * * *

(2) Copies of all documents related to applications for, or renewals of, TSA certification to operate under part 1549.

* * * * *

Issued in Arlington, Virginia, on August 10, 2011.

John S. Pistole,

Administrator.

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H.R. 2553/P.L. 112–27
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H.R. 2715/P.L. 112–28
To provide the Consumer Product Safety Commission with greater authority and discretion in enforcing the consumer product safety laws, and for other purposes. (Aug. 12, 2011; 125 Stat. 273)

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