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Presidential Documents

Title 3—

The President

Proclamation 8759 of November 21, 2011

50th Anniversary of the United States Agency for International Development

By the President of the United States of America

A Proclamation

This year, the United States Agency for International Development (USAID) commemorates 50 years of progress dedicated to saving lives, building partnerships, and promoting peace and prosperity for the developing world and the American people.

Since President John F. Kennedy founded USAID in 1961, the men and women of USAID have worked on the front lines of poverty and conflict to support communities and countries as they build a better future. By promoting sustainable growth in the developing world, we spur new markets abroad and energize our economy here at home. By encouraging good governance, we empower transparency, accountability, and strong institutions that are responsive to citizens' needs. By driving innovations in agriculture, education, and global health, we strengthen global stability and advance our national security. And by delivering aid in the wake of natural disasters and humanitarian crises, we express the generosity and goodwill that unite us as a people.

The impact of these efforts is remarkable. In the past five decades, USAID has helped developing countries across the globe transform into stable and prosperous nations, vibrant trading partners, and foreign assistance donors themselves. These countries stand as beacons of hope for people striving toward democracy, free economies, and respect for human rights. The critical work of USAID enables these transitions forward, helping prevent and end conflict around the world.

Even after these successes, we know there is more to do. To advance America's interests and promote global development, USAID has instituted a series of ambitious reforms that will bring new partnerships, a greater emphasis on innovation, and a relentless focus on real results. These actions will help ensure we invest every development dollar in the most effective, efficient, and transparent way possible. And they will ensure that those with the greatest needs in this world are extended a helping hand from the American people.

On this anniversary, we honor the men and women of USAID whose dedication to public service has improved millions of lives around the world, and we honor the vision of those whose spirit of innovation has opened new frontiers in the global fight against hunger, poverty, and disease. As USAID continues to shape a brighter future for generations to come, its mission will remain of vital importance to our Nation.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim the 50th Anniversary of the United States Agency for International Development. I call upon all Americans to observe this anniversary with appropriate programs, ceremonies, and activities that honor USAID and its workers, past and present, for their enduring commitment to a safer, more peaceful world.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-first day of November, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-sixth.

[FR Doc. 2011–30722
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Rules and Regulations

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FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1278

RIN 2590–AA37

Voluntary Mergers of Federal Home Loan Banks

AGENCY: Federal Housing Finance Agency.

ACTION: Final rule.

SUMMARY: Section 1209 of the Housing and Economic Recovery Act of 2008 (HERA) amended section 26 of the Federal Home Loan Bank Act (Bank Act) to permit any Federal Home Loan Bank (Bank) to merge with another Bank with the approval of its board of directors, its members, and the Director of the Federal Housing Finance Agency (FHFA). This final rule establishes the conditions and procedures for the consideration and approval of voluntary Bank mergers.

DATES: The final rule is effective on December 28, 2011.

FOR FURTHER INFORMATION CONTACT: John P. Foley, Senior Financial Analyst, Policy and Program Development, *john.foley@fhfa.gov,* (202) 408–2828 (this is not a toll-free number), Federal Housing Finance Agency, 1625 Eye Street NW., Washington, DC 20006; Eric M. Raudenbush, Assistant General Counsel, *eric.raudenbush@fhfa.gov,* (202) 414–6421 (this is not a toll-free number); Federal Housing Finance Agency, Fourth Floor, 1700 G Street NW., Washington, DC 20552. The telephone number for the Telecommunications Device for the Hearing Impaired is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Federal Home Loan Bank System

The 12 regional Banks are instrumentalities of the United States organized under the Bank Act.[1] The Banks are cooperatives; only members of a Bank may purchase the capital stock of a Bank, and only members or certain eligible housing associates (such as state housing finance agencies) may obtain access to secured loans, known as advances, or other products provided by a Bank.[2] Each Bank is managed by its own board of directors and serves the public interest by enhancing the availability of residential mortgage and community lending credit through its member institutions.[3] Any eligible institution (generally a federally insured depository institution or state-regulated insurance company) may become a member of a Bank if it satisfies certain criteria and purchases a specified amount of the Bank's capital stock.[4]

B. HERA Provisions Addressing Voluntary Mergers

Section 1209 of HERA added new paragraphs (b)(1) and (b)(2) to section 26 of the Bank Act to address voluntary mergers of Banks. Section 26(b)(1) authorizes any Bank to merge voluntarily with another Bank with the approval of the Director of FHFA (Director) and the boards of directors of the Banks involved in the merger. Section 26(b)(2) requires FHFA to promulgate regulations establishing the conditions and procedures for the consideration and approval of voluntary mergers, including approval by Bank members.[5] The HERA amendments do not provide any further details about the terms on which Banks may merge or on which FHFA may approve such mergers.

As required by section 26(b)(2), the final rule establishes the conditions and procedures for the consideration and approval of voluntary mergers of Banks. The rule does not relate to liquidations, reorganizations, conservatorships, or receiverships undertaken by the Director pursuant to the authority set forth at section 26(a) of the Bank Act and section 1367 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (Safety and Soundness Act).[6]

[1] *See* 12 U.S.C. 1423, 1432(a).
[2] *See* 12 U.S.C. 1426(a)(4), 1430(a), 1430b.
[3] *See* 12 U.S.C. 1427.
[4] *See* 12 U.S.C. 1424; 12 CFR part 1263.
[5] *See* 12 U.S.C. 1446(b)(1), (2).
[6] *See* 12 U.S.C. 1446(a), 4617.

C. The Proposed Rule

On November 26, 2010, FHFA published in the **Federal Register** a proposed rule to implement section 26(b) of the Bank Act by adding to FHFA's regulations a new part 1278 to govern voluntary mergers of Banks.[7] The 60-day comment period closed on January 25, 2011.

The proposed rule would have established procedures for Banks to follow in order to consummate a merger, including: Execution of a written merger agreement that has been authorized by each merging Bank's board of directors; joint submission of a merger application to FHFA by the merging Banks; preliminary approval of the terms of the merger by the Director; ratification of the merger by the merging Banks' member institutions; and final approval by the Director. In developing the proposed rule, FHFA looked for guidance to governance practices that are common under general principles of corporate law, disclosure practices that are required under the federal securities laws, and the approval standards required under federal banking laws relating to mergers of insured depository institutions.

D. Considerations of Differences Between the Banks and the Enterprises

Section 1313 of the Safety and Soundness Act, as amended by HERA, requires the Director, when promulgating regulations relating to the Banks, to consider the following differences between the Banks and the Enterprises (Fannie Mae and Freddie Mac) with respect to the Banks' cooperative ownership structure; mission of providing liquidity to members; affordable housing and community development mission; capital structure; and joint and several liability.[8] In preparing this final rule, the Director considered the differences between the Banks and the Enterprises as they relate to the above factors, and determined that the rule is appropriate. No commenters raised any issues relating to this statutory requirement.

II. The Final Rule

FHFA received six comment letters in response to the proposed rule. All twelve Banks jointly submitted one

[7] *See* 75 FR 72751 (Nov. 26, 2010).
[8] *See* 12 U.S.C. 4513.

comment letter which addressed the issues raised in the proposed rule in a comprehensive manner. Three Banks submitted individual comment letters to supplement the Banks' joint letter, and two trade associations also provided comments. All six of the comment letters expressed general support for the proposed rule, although there were a number of recommendations regarding changes to be made in the final rule.

FHFA considered all of the comments in developing the final rule, which establishes merger conditions and procedures that are substantially similar to those that were proposed, except that the two-step preliminary/final FHFA approval process embodied in the proposed rule has been replaced with a single-step approval in the final version, as suggested by some commenters. FHFA has made a number of minor revisions to the rule in order to address concerns raised by commenters, as well as to provide greater clarity. Specific comments, FHFA's responses, and changes adopted in the final rule are described in greater detail below in the sections describing the relevant rule provisions.

A. Section 1278.1—Definitions

Proposed § 1278.1 set forth definitions of terms used in proposed part 1278. With two minor exceptions, all of these definitions have been adopted as proposed and are set forth in § 1278.1 of the final rule. A definition for the term ''Financial Statements'' has been added to the final rule to refer to statements of condition, income, capital, and cash flows, with explanatory notes, in such form as the Banks are required to include in their filings made under the Securities and Exchange Act of 1934 (Exchange Act).[9] In addition, definitions for the terms ''GAAP'' (referring to accounting principles generally accepted in the United States as in effect from time to time) and ''Record Date'' (referring to the date established by a Bank's board of directors for determining the members that are entitled to vote on the ratification of a merger agreement) have been added. A definition for the term ''Office of Finance,'' which was inadvertently omitted from the proposed rule, has also been added. The terms ''Record Date'' and ''Financial Statements,'' as well as comments received on certain proposed definitions and revisions to the definitions of the terms ''Disclosure Statement'' and ''Effective Date'' are discussed below in the context of the relevant substantive provisions of the final rule.

B. Section 1278.2—Authority

Section 1278.2 of the proposed rule would have authorized any two or more Banks to merge, provided that they satisfied the various procedural and substantive requirements of proposed part 1278 relating to the merger agreement, merger application, approval by the Director, ratification by the members, and final consummation of the merger. Proposed § 1278.1 defined the words ''merge'' and ''merger'' broadly to include not only a traditional merger (where one surviving entity absorbs another disappearing entity), but also a consolidation, a purchase and assumption transaction, and any other type of business combination that could occur between or among Banks. The intent behind proposed § 1278.2 was to permit each Bank wide latitude to pursue beneficial business combinations with other Banks, subject to the proviso that any such combination could be consummated only with the express approval of the Director, obtained in accordance with the conditions and procedures set forth in proposed part 1278. The Banks expressed support for the broad definition of ''merge'' and ''merger,'' and no commenters opposed the definition, which the final rule retains without change.

In the final rule, the introductory paragraph of § 1278.2 has been revised to make clear that the provisions of part 1278 apply only to voluntary mergers undertaken pursuant to section 26(b) of the Bank Act.[10] Part 1278 is not intended to govern liquidations and reorganizations of Banks carried out by the Director under section 26(a) of the Bank Act.[11] Paragraphs (a) through (e) of § 1278.2 have also been revised, principally to reflect the decision to replace the two-step FHFA approval process with a single-step approval, but also to provide greater clarity. Except for the revisions relating to the changes in the approval process, the substance of the provisions remains the same. Thus, the final rule continues to authorize any two or more Banks to merge provided that they satisfy the procedural and substantive requirements of part 1278.

C. Section 1278.3—Merger Agreement

Section 1278.3 of the proposed rule would have required that any merger of Banks be consummated only pursuant to a written merger agreement meeting the requirements of paragraphs (a) and (b) of that section, which addressed the authorization of the agreement by the Constituent Banks' boards of directors and the contents of the agreement, respectively.[12]

Specifically, proposed § 1278.3(a) would have required that a merger agreement be authorized by the affirmative vote of a simple majority of a quorum of the board of directors of each Constituent Bank at a meeting on the record and that it be executed by authorized signing officers of each Constituent Bank. FHFA requested comment upon whether a standard other than a majority vote of a quorum of the boards of directors would be appropriate. The Banks opposed the imposition of a regulatory standard for board authorization of a merger agreement, preferring instead that each Bank be permitted to establish board voting requirements under its bylaws, which they asserted is consistent with the approach taken by most state corporation statutes. One commenter questioned the sufficiency of a simple majority of a quorum of the board of directors to authorize a merger agreement, and advocated that the final rule instead require a supermajority of the full board of each Constituent Bank.

As discussed in the proposed rule, section 26(b) of the Bank Act, while requiring a board vote as part of the merger process, does not address specific requirements with respect to such a vote. Although the absence of statutory requirements would allow FHFA to include in the final rule either of those suggestions, FHFA has decided to retain this provision as proposed. As a matter of policy, FHFA believes that a uniform standard for board authorization is preferable to allowing each Bank to set its own approval standard. Unlike general business corporations, all of the Banks are very similar in business model and operations, as governed by the Bank Act and the regulations adopted thereunder, and they were created to further uniform purposes. Given those circumstances, FHFA believes that each Bank should also be subject to the same approval standards in determining whether to enter into a merger agreement. In addition, FHFA has concluded that the appropriate uniform standard is one that corresponds with the manner in which board decisions currently are made under the bylaws of all of the Banks—that is, by vote of a majority of a quorum of the board.

[9] 15 U.S.C. 78a, *et seq.*

[10] 12 U.S.C. 1446(b).

[11] 12 U.S.C. 1446(a).

[12] In this **SUPPLEMENTARY INFORMATION,** as in the rule, the term ''Constituent Bank'' refers to a Bank that is proposing to merge with one or more other Banks, and the term ''Continuing Bank'' refers to a Bank that will continue following the merger of two or more Constituent Banks.

Although a supermajority requirement may be permissible under state corporate laws for mergers, FHFA does not believe that it is appropriate in the case of cooperative institutions such as the Banks, and does not believe that the comments suggesting the adoption of a supermajority standard have provided persuasive reasons for doing so. Moreover, the required ratification by each Banks' members, the required approval of the Director, and the other detailed requirements of the rule provide for sufficient deliberation by the various constituencies.

Proposed § 1278.3(b) addressed the minimum content for a merger agreement. It would have required generally that the agreement set forth all material terms and conditions of the merger, and would have further required that the agreement include provisions addressing nine specified matters. FHFA proposed to require agreement on those matters early in the merger process because, in the agency's judgment, they would be the central issues to be negotiated between Constituent Banks under most merger scenarios, and are matters of major regulatory concern to the agency. The nine matters enumerated in the proposed rule were: (1) The proposed Effective Date of the merger; (2) the proposed organization certificate and bylaws of the Continuing Bank; (3) the proposed capital structure plan for the Continuing Bank; (4) the proposed size and structure of the board of directors for the Continuing Bank; (5) the formula to be used to exchange the stock of the Constituent Banks for the stock of the Continuing Bank; (6) any conditions that must be satisfied prior to the Effective Date of the proposed merger; (7) a statement of any representations or warranties; (8) a description of any legal opinions or rulings; and (9) a statement that the board of directors of a Constituent Bank can terminate the merger agreement before the Effective Date upon a determination that certain events have occurred. FHFA's intent in including these provisions in the proposed rule was to ensure that a merger agreement reflects the understandings that the Banks have reached with respect to each of these critical matters. The agency did not intend to require that the documents that may be necessary to implement these understandings be prepared at the same time as the merger agreement.

FHFA received a number of comments regarding the nine specific matters to be addressed in a merger agreement. The agency has made some minor revisions to § 1278.3(b) in response to some of these comments, which are discussed below, and has also made a few minor wording changes for greater clarity and consistency.

Paragraph (1) of proposed § 1278.3(b) would have required that a merger agreement set forth the proposed Effective Date of the merger. In the proposed rule, the term ''Effective Date'' was defined as the date on which the Constituent Banks consummate the merger, or, in the case of a merger encompassing two or more component transactions, the date on which the relevant Constituent Banks consummate each component transaction. As discussed below, § 1278.7 has been revised in order to provide greater specificity as to the time that the organization certificate of the Continuing Bank, and consequently the consummation of the merger, becomes legally effective. In conjunction with this change, the definition of ''Effective Date'' has been revised to refer to the date on which the organization certificate of the Continuing Bank (or Banks) becomes effective as provided under § 1278.7. As stated in the **SUPPLEMENTARY INFORMATION** to the proposed rule, the proposed Effective Date need not be stated as a specific date, but should be described in a manner such that the date can be reasonably determined—for example, as within a specified period after the occurrence of a particular event.

In the final rule, paragraph (1) of § 1278.3(b) has been revised to require that, in addition to the proposed Effective Date, the merger agreement set forth the proposed acquisition date for purposes of accounting for the transaction under GAAP, if that date is to be different from the Effective Date. Under GAAP, a business combination is recorded as of the ''acquisition date.'' Thus, among other things, the fair value of the assets acquired, liabilities assumed, and consideration exchanged is measured as of that date. The acquirer also begins to consolidate the acquired entity's financial position, results of operations, and cash flows as of that date. Under GAAP, the ''acquisition date'' is considered to be the date on which the acquirer obtains control of the acquiree. Typically, this would be the date on which the acquirer legally transfers the consideration, acquires the assets, and assumes the liabilities of the acquiree—*i.e.,* the Effective Date in the case of a voluntary Bank merger under part 1278. However, for various reasons, control of the acquiree may pass to the acquirer on a date that is either earlier or later than the date on which the legal transfers occur.[13] In a case where the Constituent Banks intend to effect a transfer of control on a date other than the Effective Date, this proposed acquisition date must be set forth in the merger agreement. As with any aspect of a Bank merger, the establishment of a separate GAAP acquisition date is subject to the approval of the Director under § 1278.5 of the final rule.[14]

Paragraphs (2) and (3) of proposed § 1278.3(b) would have required that a merger agreement describe, respectively, the proposed organization certificate and bylaws, and the proposed capital structure plan, for the Continuing Bank. In their joint comment letter, the Banks stated that the rule should not require descriptions of these items, but should instead require the items to be attached to the merger agreement. FHFA has considered this suggestion, but has decided to adopt these requirements in their proposed form. In all cases, the types of material understandings that are required to be addressed in the merger agreement must precede the preparation of the detailed documents that are intended ultimately to implement those understandings. Although, in practice, the Constituent Banks may choose to negotiate the specifics of the capital structure plan, organization certificate, and bylaws prior to executing a final merger agreement, FHFA can discern no compelling reason to require these documents to be prepared contemporaneously with the agreement. In a legal sense, the understandings memorialized in the merger agreement will determine the scope and content of these implementing documents. FHFA believes that the better approach is the one embodied in the proposed rule, which requires that the merger agreement reflect the material understandings that the Banks have reached with respect to each of these matters. That approach allows the Banks the opportunity to prepare related documents contemporaneously with the merger agreement if they so desire, but also affords them the flexibility to agree in principle as part of the merger agreement how certain matters, such as the organization certificate, bylaws, or capital structure plan, are to be addressed, but leave the drafting of those documents to a later date.

The final rule requires that a merger agreement set forth all material terms and conditions of the merger. As

[13] For example, this may be done by written agreement in order to establish an acquisition date that is on the last day of a financial reporting period.

[14] *See generally,* FASB ASC 805–10–25–6 and 25–7.

reflected by their inclusion in the non-exclusive list of issues that must be addressed in the merger agreement, FHFA considers the major features of the organization certificate, bylaws, and capital structure plan of the Continuing Bank to be among the material terms of any Bank merger. Therefore, even if these documents have not been finalized at the time the merger agreement is executed, descriptions of their material features must be included in the agreement. If the Constituent Banks have developed these documents contemporaneously with the merger agreement, the Banks may fulfill the requirements of paragraphs (b)(2) and (3) of § 1278.3 of the final rule by attaching the documents as appendices to the agreement, so long as the documents are made part of the agreement. For example, a merger agreement may state that ''the capital structure plan for the Continuing Bank shall be as set forth in Attachment X.''

Proposed § 1278.3(b)(4) would have required that a merger agreement address the proposed size and structure of the board of directors for the Continuing Bank. The proposed rule also requested comments on how best to address the transition from the separate boards of the Constituent Banks to the combined board of the Continuing Bank, and the manner in which FHFA should establish the size and composition of the board for the Continuing Bank. In their joint comment letter, the Banks requested that Constituent Banks be permitted to include in either a merger agreement or a merger application their proposals as to the size and composition of the board immediately following the merger, and as to the gradual reduction in size of the board over time through FHFA's annual designation of Bank directorships process. The Banks opposed the imposition of any requirement to provide a detailed long-term plan regarding such matters as the number and composition of board committees and the responsibilities to be delegated to those committees, stating that they wish to preserve the flexibility to allow more detailed governance matters to evolve over time. Another commenter also agreed that any reduction in post-merger directorships should be a gradual process effected through the annual designation process.

FHFA has considered these comments and has decided to carry over the language of proposed § 1278.3(b)(4) without change. Final § 1278.3(b)(4) allows the Banks some flexibility with respect to the level of detail that must be included in the merger agreement. At a minimum, the merger agreement must include the Banks' proposal for the size and composition of the board of directors, *i.e.,* the number of directorships and their allocation among the states, of the Continuing Bank immediately after the merger. The language is sufficiently broad, however, to allow the Banks also to include in the agreement their proposal for the longer term restructuring of the board of the Continuing Bank if they choose to do so. If the Banks do not address their proposal for the longer term board size and composition as part of the merger agreement, FHFA expects that they will do so as part of the merger application, which is consistent with the Banks' comment letter. In this regard, FHFA has included a conforming revision to § 1278.4(a)(1)(vi) of the final rule making clear that if the size and composition of the board over the longer term are not addressed in the merger agreement, they must be addressed in the merger application submitted to FHFA.

Ultimately, the size and composition of the board of the Continuing Bank will be determined by the Director. Section 7 of the Bank Act generally requires the Director to establish the size and structure of the board of directors of each Bank and gives the Director additional discretion to adjust the board size in connection with any Bank merger.[15] In order for the Director to make an informed decision about the appropriate size and composition of the board of the Continuing Bank, both immediately after the merger and over the longer term, the Director should have the benefit of the Banks' views on those matters, and thus the final rule requires the Banks to provide that information. However, the rule does not require the Constituent Banks to address, in either the merger agreement or merger application, such details as the number and composition of board committees and the responsibilities to be delegated to those committees.

Proposed § 1278.3(b)(7) would have required that a merger agreement contain a statement of the representations or warranties, if any, made or to be made by any Constituent Bank, or its officers, directors, or employees. In their joint letter, the Banks requested clarification that any representations and warranties made by Bank officers, directors, or employees would not be signed in their individual capacities, but on behalf of their respective Banks. The proposed provision was not intended to require that any individual or Bank make any particular representations or warranties in connection with a merger, or to address the capacity in which any individual might make such representations or warranties. Instead, it was intended merely to require that the merger agreement set forth any representations or warranties made by any of the parties in connection with the merger. In recognition of the fact that the parties to the merger agreement will be the Constituent Banks as corporate entities, and in order to avoid any implication that Banks directors, officers, or employees should be making representations or warranties in their individual capacities, as opposed to doing so as a representative of his or her Bank, FHFA has revised § 1278.3(b)(7) in the final rule to remove the reference to Banks' ''officers, directors, or employees.'' Thus, the text of final § 1278.3(b)(7) requires that the merger agreement include ''a statement of the representations or warranties, if any, made or to be made by any Constituent Bank.''

Section 1278.3(b)(8) of the proposed rule would have required that a merger agreement describe any legal opinions or rulings that have been obtained or furnished by any party in connection with the proposed merger. In their joint comment letter, the Banks stated that if legal opinions are required in connection with a merger, they are frequently conditions to consummation and, therefore, are not available until after the merger agreement is signed. Consequently, the Banks suggested that FHFA modify the provision to require that a merger agreement include descriptions of any legal opinions that are required to be obtained as a condition to the consummation of the merger, as well as those that have already been completed at the time the agreement is executed. The Banks further suggested that the rule require that a merger agreement describe any accounting opinions obtained or furnished in connection with the merger. FHFA has accepted both of these suggestions and has revised final § 1278.3(b)(8) to require that a merger agreement describe the legal or accounting opinions or rulings, if any, that are required to be obtained or furnished by any party in connection with the proposed merger.

Section 1278.3(b)(9) of the proposed rule would have required that a merger agreement contain a statement that the board of directors of a Constituent Bank may terminate the agreement before the Effective Date of the merger upon a determination by the Bank, with the concurrence of FHFA, that: (i) The information disclosed to members contained material errors or omissions; (ii) material misrepresentations were

[15] 12 U.S.C. 1427(a), (c).

made to members regarding the impact of the merger; (iii) fraudulent activities were used to obtain members' approval; or (iv) an event occurred between the time of the members' vote and the merger that would have a significant adverse impact on the future viability of the Continuing Bank. In their joint comment letter, the Banks expressed concern that this requirement could be interpreted as limiting the circumstances under which a merger agreement may be terminated prior to the Effective Date, but questioned whether this was the intent of the proposed provision. The Banks requested that FHFA clarify this provision to make clear that Constituent Banks may negotiate termination rights in addition to those enumerated. The Banks also opposed requiring the concurrence of FHFA before a merger agreement may be terminated, stating that the decision to terminate should be made by the parties.

In the final rule, FHFA has removed the requirement for FHFA concurrence with a termination decision, but has otherwise retained the substance of the proposed provision. The intent behind the proposed requirement of FHFA concurrence was primarily to aid FHFA in carrying out its supervisory duties, and to a lesser extent, to decrease the likelihood of a Bank alleging the existence of fraud as a pretext for terminating a merger agreement. FHFA acknowledges that the language of the proposed rule lacked standards for the agency's concurrence, and thus could be construed as authorizing it to compel an unwilling Bank to consummate a merger that the statutory regime intends to be voluntary, even if one of the Banks has concluded that grounds for termination exist, although such a result was not intended.

As in the proposed rule, final § 1278.3(b) states that a written merger agreement must set forth all material terms and conditions of the merger, including, ''without limitation,'' provisions addressing each of the matters enumerated in paragraphs (b)(1) through (b)(9). While, under paragraph (b)(9), the Constituent Banks are required to include within the merger agreement a provision authorizing a Bank to terminate the agreement for the reasons enumerated in the regulation, nothing in the language of § 1278.3 precludes the Banks from including in the agreement other grounds for termination that may be agreed upon by the respective boards and, in the case of a termination occurring after the member votes, by the members themselves. Thus, to the extent that Banks wish to include within a merger agreement provisions specifying additional grounds for termination of the agreement, they are free to do so under the final rule.

D. Section 1278.4—Merger Application

Section 1278.4 of the proposed rule addressed the application process to be followed in order to obtain FHFA approval for any merger of Banks. Proposed § 1278.4(a) would have required that the Constituent Banks submit to FHFA a merger application addressing all material aspects of the merger including, at a minimum: (1) A written statement summarizing the material features of the proposed merger and addressing certain enumerated issues; (2) a copy of the executed merger agreement and certified copies of the board resolutions authorizing the merger agreement; (3) a copy of the proposed organization certificate of the Continuing Bank; (4) a copy of the proposed bylaws of the Continuing Bank; (5) a copy of the proposed capital structure plan of the Continuing Bank; (6) the most recent annual audited financial statements for each Constituent Bank; and (7) pro forma financial statements for the Continuing Bank. No commenter objected to these proposed application requirements, but there were several comments regarding particular aspects of the requirements. Section 1278.4(a) of the final rule retains the proposed requirements, with some minor revisions as noted below.

As a general matter, the Banks expressed concern over the treatment of confidential commercial information that may be included in a merger application and requested that the final rule permit the submission of confidential information in a separate binder, specify that such information is exempt from disclosure under the Freedom of Information Act (FOIA), and give examples of types of information that would be considered confidential. FHFA has adopted only the first of these suggestions. The introductory clause of final § 1278.4(a) has been revised to include a new sentence specifying that a Bank may submit separately any portions of the merger application that it believes contain confidential or privileged trade secrets or commercial or financial information, and that such information will be handled in accordance with FHFA's FOIA regulations set forth at 12 CFR part 1202.

The procedures for the handling of information submitted to FHFA that the submitter believes to be confidential commercial information protected from FOIA disclosure under 5 U.S.C. 552(b)(4) and 12 CFR 1202.4(a)(4) are set forth in 12 CFR 1202.8. Section 1202.8(b) specifies that submitters of commercial information should use good-faith efforts to designate, by appropriate markings, either at the time of submission or at a reasonable time thereafter, those portions of the information they deem to be protected. Once so designated, such information may be released only pursuant to the procedures set forth in 12 CFR 1202.8(c) through (i), which provides in most cases for prior notice to the submitter and an opportunity for the submitter to object to the release of the information. Because the handling of confidential commercial information is addressed directly by FHFA's FOIA regulations, FHFA has declined to address separately in final part 1278 the FOIA status of any materials or information submitted as part of the merger application process.

With regard to the contents of the merger application, proposed § 1278.4(a)(1) would have required a written statement including: (i) A summary of the material features of the proposed merger; (ii) the reasons for the proposed merger; (iii) the effect of the proposed merger on the Constituent Banks and their members; (iv) the planned Effective Date of the merger; (v) a summary of the material features of any related transactions and the bearing that the consummation of, or failure to consummate, the related transactions is expected to have upon the merger; (vi) the names of the persons proposed to serve as directors and senior executive officers of the Continuing Bank; (vii) a description of all proposed material operational changes; (viii) information demonstrating that the Continuing Bank will comply with all applicable capital requirements after the Effective Date; (ix) a statement explaining all officer and director indemnification provisions; and (x) an undertaking that the Constituent Banks will continue to disclose all material information, and update all items, as appropriate. The topics required to be addressed in the application statement under § 1278.4(a)(1) of the final rule are substantially the same as those that were proposed, although the final version reflects a few minor additions and clarifications.

The first of these appears in paragraph (a)(1)(iv), which has been revised to require the statement to include, in addition to the proposed Effective Date: the Record Date established by each Constituent Bank's board of directors for purposes of determining the rights of member institutions to participate in the merger ratification vote (discussed in detail below); and the GAAP acquisition

date (discussed in detail above), if that date is to be different from the Effective Date, including an explanation of the reasons for establishing an acquisition date that is different from the Effective Date.

Second, paragraph (a)(1)(vi), which as proposed would have required the names of the persons to serve as directors and senior officers of the Continuing Bank, has been revised to require the Banks also to include in the merger application information regarding their proposal for the ultimate size and composition of the board of directors, *i.e.,* the size and composition of the board for the longer term, along with their proposed transition plan for reducing the size of the board, if that matter is not addressed in the merger agreement. If the merger agreement includes provisions dealing with the Banks' proposals for both the immediate and long-term size and composition of the board, that information need not be resubmitted as part of the merger application. The final rule also retains the proposed requirement that the Banks identify the persons who will serve as directors and executive officers immediately after the merger.

Third, paragraph (a)(1)(vii), which in its proposed form would have required that the application statement address any staff reductions as part of a discussion of anticipated material operational changes, has been revised to require that the statement address such reductions only to the extent such information is known. This revision was made in response to the Banks' comment that it may be more prudent to defer decisions about specific reductions in staff until after the merger has occurred and management of the Continuing Bank has assessed its staffing needs and that, therefore, the Banks should not be required to provide such specific information at the time the merger application is filed. The fourth revision appears in paragraph (a)(1)(x), and is meant to clarify that the Constituent Banks' undertaking to update ''all items,'' as appropriate, applies specifically to items required to be included in the merger application.

FHFA has declined to make a requested change to proposed paragraph (a)(1)(vi), which would have required that the merger application set forth the names of the persons proposed to serve as directors and senior executive officers of the Continuing Bank. In their joint comment letter, the Banks expressed concern that the identity of the directors and senior executive officers of the Continuing Bank may not yet be determined at the time that the merger application is submitted, and requested that the rule permit this information to be added later as a supplement to the application. Although FHFA believes that the better practice would be for the Banks to file a complete merger application as a single submission, the rule does not require the Banks to do so, and therefore would allow the Banks to file portions of the required materials as a supplement to their initial merger application. Thus, if the Constituent Banks have not reached agreement as to the identity of the persons who will serve as directors and senior executives of the Bank when they initially file the merger application, they may submit this information as a supplement to the initial merger application. However, if they choose to do so, FHFA will not deem the application to be complete, and the time periods for FHFA review prescribed under § 1278.5 will not commence, until all information required by the final rule has been submitted. Corporate governance of the Continuing Bank is a critical issue, and the Director must know the identity of these individuals in order to determine whether the Continuing Bank will have adequate managerial resources—a factor that the Director is required to consider as part of the decision to approve or deny a merger request under § 1278.5(a).

Paragraphs (2) through (7) of proposed § 1278.4(a) addressed the additional items to be included as part of the merger application. Paragraph (a)(2) would have required that a merger application include a copy of the executed merger agreement, accompanied by a certified copy of the resolution of the board of directors of each Constituent Bank authorizing the execution of the merger agreement. In addition, paragraphs (a)(3) through (a)(5) would have required the Banks to provide, respectively, copies of the proposed organization certificate, the proposed bylaws, and the proposed capital structure plan of the Continuing Bank. These paragraphs have been carried over unchanged in the final rule. As discussed previously, if the items addressed in paragraphs (a)(3) through (a)(5) have already been attached to the merger agreement, additional copies need not be provided so long as the application makes clear that they are so attached.

Proposed paragraph (a)(6) would have required that the Banks include as part of a merger application the most recent annual audited financial statements for each Constituent Bank. In the final rule, this provision has been revised to require that the Banks also provide their quarterly financial statements for the current year-to-date. The most current available financial information for each of the Constituent Banks will obviously be a critical element of the official record to be reviewed by the Director, and the omission of this requirement from the proposed rule was an oversight. As mentioned above, FHFA also has added a definition of the term ''Financial Statements'' to § 1278.1 to clarify that these are to comprise statements of condition, income, capital, and cash flows, with explanatory notes, in such form as the Banks are required to include in their filings made under the Exchange Act.

Paragraph (a)(7) of proposed § 1278.4 would have required the Banks to include as part of a merger application pro forma financial statements for the Continuing Bank in such form as would be required to be included in the Disclosure Statement that the Banks must provide to their members in connection with the member vote under proposed § 1278.6—*i.e.,* those that would be required in completing a Form S–4 promulgated by the United States Securities and Exchange Commission (SEC) (as discussed in more detail below).[16] In the Supplementary Information to the proposed rule, FHFA stated that the Form S–4 provides merging entities with the option to include either purely historical pro forma statements, or pro forma statements including forecasted results for up to twelve months following the date of the most recent statement of condition, and stated that it was considering whether it should require the Constituent Banks to provide as part of the merger application pro forma forecasted results for as many as three years following the date of the most recent statement of condition.

In their joint comment letter, the Banks asserted that Regulation S–X [17] (which is incorporated, in part, into the Form S–4) does not permit inclusion of forward-looking pro forma statements in a Form S–4 where historical pro forma information is required under Generally Accepted Accounting Principles (GAAP), as they assert is the case with the Banks. For this reason, the Banks believe that the pro forma statements required to be included in the Disclosure Statement should be historical only. The Banks therefore supported the language of the proposed rule, which, based on their reading of the Form S–4 and GAAP requirements, would not have required forward-looking pro forma statements to be included in either the merger application or in the Disclosure

[16] *See* 17 CFR 239.25.

[17] *See* 17 CFR part 210.

Statement. The Banks further stated that, if FHFA decided to require any pro forma forecasts to be prepared under the final rule, such forecasts should be limited to twelve months, should be required as part of the merger application only, and should remain confidential.

Having concluded that the Form S–4 requirements are the appropriate template upon which to base the requirements for the Disclosure Statement under part 1278, and given the detailed nature of the Form (including the SEC regulations cross-referenced), FHFA has further concluded that it is best to minimize any variations therefrom with respect to the Disclosure Statement requirements. Accordingly, the final rule continues to require only that the pro forma statements included in the Disclosure Statement correspond with those that would be required under the Form S–4. If a Constituent Bank and its attorneys and accountants conclude that the Form S–4 would require inclusion of only historical pro forma information in a particular case, then it should provide that information in the Disclosure Statement.

However, in order to approve any merger application under § 1278.5 of the final rule, the Director must be provided with information to establish that the Continuing Bank will be viable and will be able to serve its members effectively immediately following the merger and for some period thereafter. The agency also recognizes that the longer the time period covered by a pro forma forecast, the less accurate the forecast is likely to be. With this in mind, the agency has decided to revise § 1278.4(a)(7) to require the Banks to include forward looking pro forma financial statements for the Continuing Bank for each of at least two years following the date of the most recently filed quarterly statement of condition for the Constituent Banks. In order to establish a baseline for these forecasts, final paragraph (a)(7) also requires that the merger application include pro forma financial statements for the Continuing Bank as of the date of the most recently filed quarterly statement of condition for the Constituent Banks. FHFA requires Banks to provide two-year forward looking pro forma statements when they apply for approval of amendments to their capital structure plans,[18] and a similar approach is warranted in the case of a merger. The agency retains the right to request pro forma forecasts covering a longer period under § 1278.4(b) if it concludes that this information is necessary to assess the merger application.

Section 1278.4(b) of the proposed rule would have authorized FHFA to require the Constituent Banks to submit any additional information that the agency determined was necessary to assess a particular merger. Under the proposed rule, if the agency had determined a merger application to be complete under § 1278.4(c), FHFA could have required the Constituent Banks to submit additional information only with respect to matters derived from or prompted by the materials already submitted, or matters of a material nature that were not reasonably apparent previously. Under proposed § 1278.4(b), FHFA would have been permitted to use a Constituent Bank's failure to provide the required information in a timely manner as grounds to deny a merger application. No commenters objected to these provisions and § 1278.4(b) has been adopted as proposed.

Section 1278.4(c) of the proposed rule addressed the timing for determining whether a merger application is complete. As proposed, FHFA would have had 30 days after the receipt of a merger application to determine whether it was complete or whether any additional information was required. The proposed rule would have required FHFA to inform the Constituent Banks in writing if the agency determined that an application was complete and that it had all information necessary to evaluate the proposed merger, and also if it determined that an application was incomplete or that it required additional information. In the latter case, FHFA would have been required to specify the number of days within which the Constituent Banks must provide any additional information or materials, and within 15 days of receipt of such information or materials, to again determine whether a merger application is complete and so inform the Banks. Again, no commenters objected to this provision and it has been adopted as proposed.

E. Section 1278.5—Approval by Director

Under the proposed rule, the review and approval of a merger by the Director would have been a two-step process. The first step, addressed by proposed § 1278.5, would have encompassed a review of all substantive aspects of a proposed merger, followed by either a preliminary approval or a denial of the merger application. Merger transactions that had been granted preliminary approval, and which had been ratified by the members of each Constituent Bank, would then have been subject to a final review and approval under § 1278.7 of the proposed rule. At the final review step, the Director would have been permitted to deny final approval of a merger only for limited reasons.

The Banks opposed this two-step process as being overly lengthy and burdensome. They recommended that the rule be revised to provide for a process similar to that which they asserted is employed by the federal depository institution regulators—*i.e.,* a single approval is granted prior to the member ratification vote, but is made subject to written conditions that must be met and certified to the agency before the merger may be consummated. FHFA has adopted this suggestion and has revised the rule to provide for a single-step approval process. However, as discussed below, § 1278.7 of the final rule continues to provide that no merger may be consummated until the Director accepts the organization certificate of the Continuing Bank pursuant to the receipt of satisfactory evidence that the conditions of the approval under § 1278.5 have been met.

Final § 1278.5(a), which establishes standards for approving a merger, has been adopted as proposed and provides that, in deciding whether to approve or deny a merger application, the Director must take into consideration the financial and managerial resources of each of the Constituent Banks, the future prospects of the Continuing Bank, and the effect of the proposed merger on the safety and soundness of the Continuing Bank and the Bank System. These standards are similar to those used by the federal depository institution regulators in considering mergers and acquisitions of federally insured depository institutions.[19] No commenters objected to the use of these standards as the basis for merger decisions made by the Director under the rule and § 1278.5(a) has been adopted substantially as proposed, save for a minor wording change made for better clarity and consistency.

Section 1278.5(b) of the proposed rule addressed procedural aspects of the merger application process. As proposed, § 1278.5(b) would have permitted the Director 30 days after determining the merger application to be complete to consider the information and materials provided in the application and either grant or deny preliminary approval of the merger. The

[18] *See* Federal Housing Finance Board Advisory Bulletin 03–4 (Mar. 18, 2003).

[19] *See* 12 U.S.C. 1467a(e)(2) (acquisitions of savings associations); 12 U.S.C. 1817(j)(7)(C),(D) (bank change in control); 12 U.S.C. 1828(c)(5) (bank mergers).

proposed provision would have required that FHFA provide written notice to each Constituent Bank, as well as to each other Bank and the Office of Finance in the case of either a preliminary approval, or a denial, of the merger application. A notice of preliminary approval would have been required to set forth any conditions to the approval, while a notice of denial would have been required to state the reasons for the denial.

In the final rule, § 1278.5(b) has been revised, and a new § 1278.5(c) has been added, to reflect the new one-step approval process. Final § 1278.5(b) continues to require that, within 30 days of FHFA's determination that a merger application is complete, the Director either approve or deny the merger application. This section has been revised to provide that an approval of a merger application may include any conditions the Director determines to be appropriate. While FHFA has not included in the final rule a requirement that the Banks must submit their Disclosure Statements to the agency for review prior to sending the document to their members, the Director will have the ability to require such a review as a condition of approval.

Final § 1278.5(b) also provides that, in every case, approval will be conditioned on each Constituent Bank demonstrating that it has obtained the members' ratification of the merger agreement in accordance with the requirements of § 1278.6 by submitting to FHFA: (1) A certified copy of the members' resolution ratifying the merger agreement, on which the members cast their votes; and (2) a certification of the member vote from the Bank's corporate secretary or from an independent third party. These materials, as well as any others necessary to prove that all conditions of approval have been met, must be provided to FHFA before the Director may effect the consummation of the merger by accepting the organization certificate of the Continuing Bank under § 1278.7 of the rule (discussed below).

Final § 1278.5(c) contains the same notice requirements that appeared in § 1278.5(b) of the proposed rule. Thereunder, FHFA must provide written notice to each Constituent Bank, as well as to each other Bank and the Office of Finance, in the case of either an approval or a denial. As in the proposed rule, a notice of approval must set forth any conditions to that approval and a notice of denial must state the reasons for the denial.

F. Section 1278.6—Ratification by Bank Members

Section 1278.6 of the proposed rule addressed the requirements for the ratification of a merger agreement by vote of the Constituent Banks' member institutions. This section has been adopted substantially as proposed, with the exceptions discussed below.

Proposed § 1278.6(a) would have required that no merger of Banks be consummated unless the merger agreement had been ratified by the members of each Constituent Bank in a voting process meeting the requirements of paragraphs (a)(1) through (a)(4) of that section. As proposed, paragraph (a)(1) would have required that each Constituent Bank deliver a ballot and a Disclosure Statement to each of its members. As defined in § 1278.1 of the proposed rule, a Disclosure Statement would have been required to contain all of the items that the Constituent Bank providing the statement would be required to include in a Form S–4 Registration Statement promulgated by the SEC under the Securities Act of 1933 (or any successor form promulgated by the SEC governing disclosure required for securities issued in business combination transactions) when prepared as a prospectus as directed in Part I of the Form. In addition, proposed paragraph (a)(1) would have required that the Disclosure Statement establish a closing date for the Bank's receipt of completed ballots that was no earlier than 30 days after the date that the ballot and Disclosure Statement were delivered to its members.

In the final rule, paragraph (a)(1) has been revised slightly to require that the enumerated items be delivered to ''each institution that was a member as of the Record Date,'' as opposed to merely ''its members.'' This change was made to reflect the fact that the eligibility of an institution to participate in the merger vote is to be determined as of the record date established by the Constituent Bank's board of directors (discussed in more detail below) and that, consequently, it is the institutions that are so eligible that must receive the ballot and the Disclosure Statement.

In addition, the definition of ''Disclosure Statement'' has been modified slightly in the final rule. In their joint comment letter, the Banks agreed that the Form S–4 is a useful and widely-accepted model for comprehensive shareholder disclosure in a merger transaction. However, the Banks asserted that a number of the Form S–4 requirements are clearly not applicable to the Banks, and requested that the rule make clear that the Form S–4 prospectus information needs to be included only to the extent applicable. Similarly, the Banks asserted that, pursuant to various statutory provisions and SEC no-action letters, the Banks are not required to comply with certain requirements that would otherwise apply in the preparation of their Annual Reports on Form 10–K. They requested that the rule also make clear that, to the extent that these Form 10–K requirements are also Form S–4 requirements, these items need not be included in the Disclosure Statement.

FHFA recognizes that, due to the unique corporate and capital structure of the Banks, certain items regarding the Banks or the transactions that are required to be disclosed in the Form S–4 will be inapplicable. The agency also recognizes that the Banks have been exempted by statute and through SEC no-action letters from a number of disclosure requirements that would otherwise be applicable. The Form S–4 and the SEC regulations that are cross-referenced therein make clear in several places that information need only be furnished to the extent appropriate.[20] However, for clarity, the definition of ''Disclosure Statement'' in § 1278.1 of the final rule has been revised to refer to a written document that contains, ''to the extent applicable,'' all of the items that a Bank would be required to include in a Form S–4. This additional clause is intended to make clear that, the Form S–4 requirements notwithstanding, a Bank need not include in its Disclosure Statement information that is not appropriate given the unique structure of the Banks or that they are not required to provide as part of their disclosures made under the Exchange Act. FHFA will provide formal or informal guidance as necessary with regard to the preparation of the Disclosure Statement.

In discussing proposed § 1278.6 in the Supplementary Information to the proposed rule, FHFA stated that, under the terms of the Form S–4, the Banks would be permitted to supply much of the required information through incorporation by reference of their Form 10–Ks and other periodic SEC filings. The Banks supported this option, but pointed out that the incorporation by reference into a Form S–4 is permitted under the SEC's regulatory authority, which would not extend to the Disclosure Statement. They therefore

[20] *See, e.g.,* Form S–4, General Instruction D.2 (stating that where the Form directs the registrant to furnish information required by Regulation S–K and the item of Regulation S–K so provides, information need only be furnished to the extent appropriate).

requested that the rule state expressly that such filings may be incorporated by reference in the Disclosure Statement. FHFA has declined to make the suggested change to the final rule. The final rule requires that a Constituent Bank follow the Form S–4 requirements, to the extent applicable, in preparing its Disclosure Statement. The Form S–4 permits the incorporation by reference of various SEC filings, including the Form 10–K, under certain circumstances. Therefore, where those circumstances apply and the referenced filing is one that the Bank is required to prepare, the Bank is permitted under the final rule to incorporate that filing by reference in the manner prescribed by the Form S–4.

Paragraph (a)(2) of proposed § 1278.6 addressed the voting rights of shareholders of the Constituent Banks and the requirements for the casting of ballots. With respect to the latter, proposed paragraph (a)(2) would have required that each voting entity cast all of its votes either for or against the ratification of the merger agreement or to abstain with respect to all of its votes, and that each entity's vote be made by resolution of its governing body, either authorizing the specific vote or delegating to an individual the authority to vote. Both of these requirements, which mirror requirements that apply to the election of Bank directors, have been carried over unchanged in the final rule.[21]

However, the approach to the determination of the voting rights of each member of a Constituent Bank in a vote to ratify a merger agreement has been modified from that which appeared in the proposed rule. As proposed, paragraph (a)(2) stated that each member of each Constituent Bank would be entitled to cast the same number of votes that the member may cast in that year's election of Bank directors. By statute, in the election of Bank directors, a member is entitled to cast one vote for each share of Bank stock the member was required to hold as of the record date (set by statute at December 31 of the prior year in the case of elections for Bank directors [22]), subject to a cap which is equal to the average number of shares of Bank stock required to be held by all members located in the same state.

Most commenters supported tying members' merger voting rights closely to those that apply to the election of Bank directors, although one requested that the rule permit each Bank to amend its bylaws to govern members' merger voting rights in a way that the Bank's board believes is appropriate. One commenter expressly supported the application of the cap on the number of shares that a member may vote, explaining that this will ensure that small members will continue to have a voice in Bank governance. Another commenter supported the voting cap in theory, but opined that in the case of a district-wide merger vote the cap should be applied uniformly for all of the members within the Bank's district and not on a state-by-state basis, as is done in the case of the election of directors.

FHFA has considered these comments and believes, on balance, that the requirements for the merger voting process should be closely tied to those that are established by statute for the election of Bank directors. This is because the voting process enshrined in the Bank Act is the only manifestation of general Congressional intent on the subject of member voting, and because it is consistent with the cooperative structure of the Bank System and will reduce the possibility that a few large stockholders will control the outcome of a vote on a merger. However, in the light of the comments received, the agency has reconsidered the application of the vote cap and has determined that because a merger ratification vote would be a district-wide ''at large'' election, the cap on the number of votes that may be cast by a member institution should be calculated based upon the average number of shares held by all members in the Bank's district, as opposed to the average number held by all members within the state in which that member institution is located.

FHFA recognizes that this will result in certain large Bank members being eligible to cast more or fewer votes—in some cases by significant margins—than the member would be eligible to cast in the election of directors. However, it is the agency's view that, as a matter of equity and appropriate corporate governance, the final rule should not permit a result where one Bank member is authorized to vote a materially different number of shares than another similarly-sized member that is located within a different state in the same Bank district. Therefore, paragraph (a)(2) has been revised in the final rule to provide that each member of each Constituent Bank shall be entitled to cast one vote for each share of Bank stock that the member was required to own as of the Record Date, provided that the number of votes that any member may cast shall not exceed the average number of shares of Bank stock required to be held by all members of that Bank, calculated on a district-wide basis, as of the Record Date.

In the Supplementary Information to the proposed rule, FHFA explained that the effect of applying the statutory and regulatory requirements governing the election of Bank directors to the merger ratification vote is that not all Bank stock would carry the right to vote in such an election. For example, stock controlled by a non-member institution as a result of the acquisition of a Bank member, and stock held by a member in excess of the statutory cap applicable to that member's state, could not be voted in a director election and, therefore, could not have been voted in a merger election under the proposal. In their joint comment letter, the Banks expressed concern about both of those examples, pointing out that the long-standing policy of both FHFA and the former Federal Housing Finance Board (Finance Board) has been that: (1) If a non-member institution acquires a Bank member after the record date, but prior to the election, the acquiring non-member may vote the acquired member's shares, despite the fact that it is not a Bank member; and (2) if a member that is subject to the statutory cap in a particular state acquires another member in the same state subsequent to the record date, but prior to the election, the acquiring member is permitted to cast the eligible votes for the acquired member, as well as its own votes, in that year only.[23]

FHFA did not intend to imply in the Supplementary Information to the proposed rule that these policies would not apply also to a merger vote under part 1278. The counter-examples given by the Banks apply to particular situations that may occur due to the fact that voting rights are determined as of the record date (December 31 in the case of director elections), whereas the vote itself may not occur until many months later. During the interim, stock that is eligible to be voted by a member as of the record date may be transferred to another entity—which could be a member or non-member—through the acquisition of the member by the other entity. In these cases, the acquiring entity may vote the shares that were deemed eligible as of the record date as the successor to the disappearing member. Because these voting rights are those of the disappearing member, the status of the acquirer as a non-member or the fact the acquirer may be a member whose own voting power is limited by the vote cap have no bearing

[21] *See* 12 CFR 1261.8.

[22] *See* 12 U.S.C. 1427(b)(1).

[23] *See* 63 FR 65683, 65685–86 (Nov. 30, 1998) (Supplementary Information to final rule governing the election of Bank directors).

on its ability to vote the shares of the acquired member. For the same reasons, these policies would apply also to merger ratification votes undertaken pursuant to final part 1278. That is, the determinative factor will be whether the stock was owned by a member as of the Record Date established by the board of directors of the Constituent Bank. If so, the stock will have voting rights that may be exercised by the current holder, regardless of the holder's membership status or whether all of the shares held by the holder would currently be eligible to be voted.

Paragraph (a)(3) of proposed § 1278.6 addressed the Constituent Banks' handling of ballots and the determination of the results of the ratification vote. It would have prohibited each Constituent Bank from reviewing any ballot until after the closing date of the election, counting any ballot received after the closing date, or disclosing how any member voted, while requiring each to tabulate the ballots immediately after the closing date and to retain all ballots for at least two years after the date of the election. Importantly, as proposed, paragraph (a)(3) provided that a merger agreement would be considered to be ratified if a majority of votes cast in the election have been cast in favor of the merger. One commenter, while otherwise supporting the parallel to the director election process, advocated requiring the approval of a supermajority of members for any proposed merger. FHFA has declined to adopt that suggestion because it interprets section 26(b) of the Bank Act as having the purpose of facilitating the ability of the Banks to voluntarily merge, and the imposition of a supermajority requirement would not further that purpose. Accordingly, paragraph (a)(3) has been adopted as proposed.

Paragraph (a)(4) of proposed § 1278.6 would have required that, within 10 calendar days of the election closing date, a Constituent Bank deliver to its members, to each Constituent Bank with which it proposes to merge, and to FHFA a statement of: the total number of eligible votes; the number of members voting in the election; and the total number of votes cast both for and against ratification of the merger agreement, as well as those that were eligible to be cast by members that abstained and by members who failed to return completed ballots. No commenters objected to any aspect of this provision, and it has been adopted as proposed.

Section 1278.6(b) of the proposed rule stated that, in connection with a proposed merger, no Bank, or any director, officer, or employee thereof, shall make any statement, written or oral, which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statement not false or misleading, or necessary to correct any earlier statement that has become false or misleading. No commenter objected to this provision, and it has also been adopted as proposed.

G. Section 1278.7—Consummation of the Merger

Section 1278.7 of the final rule governs the process for the consummation of a merger after the members of each Constituent Bank have voted to ratify the merger agreement. As proposed, § 1278.7 would have governed the second step of the preliminary/final approval process that was provided for in the proposed rule. The proposed provision would have required that the Director grant a second, final, approval prior to consummation of the merger, and would have provided the Director with limited authority to deny approval of the merger in cases where: the member vote was not carried out in accordance with the requirements of § 1278.6; one or more Constituent Banks failed to fulfill a condition of the preliminary approval; or an event had occurred since the time of the preliminary approval that would have had a significant adverse impact on the future viability of the Continuing Bank.

For the reasons discussed above, the final rule now requires only one approval by the Director to be obtained, prior to the member votes under § 1278.6. However, because this approval is conditional, § 1278.7 has been retained in revised form as a procedural mechanism to ensure that the merger cannot be consummated until the Director has received satisfactory evidence that the conditions of the approval have been met. Section 1278.7 has also been revised to provide for greater certainty as to the time that the merger becomes effective.

Section 1278.7(a) of the final rule addresses the materials that the Constituent Banks are required submit after their respective member institutions have voted to ratify the merger. Final § 1278.7(a)(1) requires that the Constituent Banks submit to FHFA evidence acceptable to the Director that all conditions imposed in connection with the approval of the merger application have been satisfied, which shall in all cases include for each Bank a certified copy of its members' resolution ratifying the merger agreement and a certification of the member votes from the corporate secretary or from an independent third party. Final § 1278.7(a)(2) requires that the Constituent Banks also submit an organization certificate for the Continuing Bank, ''in such form as FHFA may specify'' that has been executed by the individuals who will constitute the board of directors of the Continuing Bank. Although FHFA currently has no regulations or guidelines governing the form of a Bank's organization certificate, final § 1278.4(a)(3) requires that the Constituent Banks submit a proposed organization certificate as part of the merger application, and the agency anticipates that it will provide appropriate guidance as to the form and content of the final certificate as part of the merger approval process.[24]

Final § 1278.7(b) governs the method of acceptance and timing of the effectiveness of the Continuing Bank's organization certificate. Under the proposed rule, after obtaining the Director's final approval, the Constituent Banks would have been required to submit to FHFA an organization certificate for the Continuing Bank and, upon its acceptance by the agency, the corporate existence of the Continuing Bank would have commenced ''as of the Effective Date.'' This approach lacked clarity in a number of respects. First, as discussed above, the proposed rule defined ''Effective Date'' to mean ''the date on which the Constituent Banks consummate the merger,'' but left unclear what actions were required for the Banks to consummate the merger. In addition, while the proposed rule would have required FHFA to provide notice of its final approval to all of the Banks, it neither specified any particular overt action to be taken by FHFA to signify ''acceptance'' of the Continuing Bank's organization certificate, nor provided for any prior or subsequent notice of the fact or timing of such acceptance, or of

[24] Section 12(a) of the Bank Act requires each Bank to make and file with the Director an ''organization certificate'' upon the establishment of the Bank, but leaves the form and content of the certificate to the discretion of the Director. *See* 12 U.S.C. 1432(a). Of the 12 existing Banks, eight are still operating under their original 1932 organization certificates and four are operating under more recent versions. All of these certificates (the contents of which are set forth in the Banks' respective Form 10–12g Registration Statements filed with the SEC) follow the same format and FHFA expects that it would require any organization certificate that becomes effective in the future to be substantially similar to those currently in effect.

the Effective Date of the new organization certificate.

Final § 1278.7(b) is intended to provide the specificity that the proposed rule lacked. It states that, upon determining that all conditions of the Director's approval have been satisfied and that the organization certificate has been properly executed and is in the required form, the Director shall accept the organization certificate by endorsing it with the date of acceptance and the Effective Date. Paragraphs (1) and (2) of § 1278.7(b) govern the method by which the Director shall determine the Effective Date. If the merger agreement states a proposed Effective Date (whether expressed in terms of a specific date or a specific number of days after a particular event) and that date has not passed, the Director shall establish that date as the Effective Date. If the merger agreement sets forth a proposed range of dates within which the Effective Date may occur (*e.g.,* ''within thirty days of the ratification of the merger by the members of both Constituent Banks'') and that range of dates has not expired, the Director shall establish an Effective Date that is within that range of dates. If the Effective Date set forth in the merger agreement (in whatever form it is expressed) has passed, the Director shall establish the tenth business day following the date of acceptance as the Effective Date. However, if the merger agreement provides that the agreement will terminate if the merger has not become effective by a particular date, and that termination date is fewer than 10 business days following the date of acceptance, the Director shall establish the latest possible business-day prior to the date on which the merger agreement will terminate as the Effective Date.

Final §§ 1278.7(c)(1) and (2) provide that, after the Director has accepted the organization certificate as provided under § 1278.7(b), the Continuing Bank shall, as of the commencement of the Effective Date specified on the certificate, become or remain a body corporate (depending on the type of transaction) operating under such organization certificate with all powers granted to a Bank under the Bank Act, and shall succeed to all rights, titles, powers, privileges, books, records, assets, and liabilities of the Constituent Bank or Banks, as provided in the merger agreement. In the proposed rule, § 1278.7(b) stated that, after acceptance of the organization certificate, the Continuing Bank would ''be a body corporate operating under the new organization certificate.'' The Banks expressed concern about this phrasing because they believed that such language may imply that a new corporate entity has been formed even in the case of a traditional merger (where an existing Bank absorbs a disappearing Bank). In response, FHFA has specifically provided in final § 1278.7(c) that, after acceptance of the organization certificate, the Continuing Bank shall ''become or remain a body corporate (depending on the type of transaction) operating under such organization certificate.'' This phrasing is intended to address both those business combinations where the Continuing Bank is a continuation of one of the existing Constituent Banks, as well as those where the Continuing Bank is considered to be an entirely new entity. Regardless of the form of the transaction, FHFA will not consider the merger to have been legally consummated until the new or revised organization certificate becomes effective.

In addition, final § 1278.7(c)(3) provides that the corporate existence of any Constituent Bank that is not a Continuing Bank shall cease as of the Effective Date of the organization certificate of the Continuing Bank, except as provided in the merger agreement. The latter clause is intended to provide for those cases in which it may be useful or necessary for a disappearing Constituent Bank to continue in existence for a short period following the consummation of a merger—for example, where a ''shell'' Bank that has transferred its territory and most of its assets and liabilities to another Bank may need time wind down its affairs, or where the disappearing Bank is being acquired by two or more other Banks and the transactions are not to be consummated simultaneously. Section 25 of the Bank Act provides that each Bank shall have succession until dissolved by the Director (or by Act of Congress) and final § 1278.7(c)(3) is intended to make clear that the Director's approval of the merger application and endorsement of the new organization certificate are sufficient to dissolve any non-Continuing Banks without further action in cases where the merger agreement does not provide for the temporary continuation of a disappearing Constituent Bank. In the case of a shell Bank that is winding down its affairs, the Director will issue a separate order of dissolution at the appropriate time. Under the rule, any Constituent Bank that is a party to a merger (as that term is broadly defined in the rule) that continues in existence after the consummation of the merger without specific provision for its eventual disposition (either through dissolution or another merger) will be considered to be a Continuing Bank and will be subject to all applicable requirements.

Final § 1278.7(d) provides that, after the Director accepts the organization certificate for the Continuing Bank, FHFA shall provide prompt written notice of that fact to the Constituent Banks, as well as to each other Bank and the Office of Finance. This notice must include the date of acceptance and the Effective Date of the organization certificate for the Continuing Bank.

III. Paperwork Reduction Act

The final rule does not contain any collections of information pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Therefore, FHFA has not submitted any information to the Office of Management and Budget for review.

IV. Regulatory Flexibility Act

The final rule applies only to the Banks, which do not come within the meaning of small entities as defined in the Regulatory Flexibility Act (RFA). *See* 5 U.S.C. 601(6). Therefore in accordance with section 605(b) of the RFA, FHFA certifies that this final rule will not have significant economic impact on a substantial number of small entities.

List of Subjects in 12 CFR Part 1278

Banks, banking, Federal home loan banks, mergers.

For the reasons stated in the Supplementary Information, the Federal Housing Finance Agency hereby amends chapter XII of title 12 of the Code of Federal Regulations by adding new part 1278 to subchapter D to read as follows:

PART 1278—VOLUNTARY MERGERS OF FEDERAL HOME LOAN BANKS

Sec.

Authority: 12 U.S.C. 1432(a), 1446, 4511.

§ 1278.1 Definitions.

Bank, written in title case, means a Federal Home Loan Bank established under section 12 of the Bank Act (12 U.S.C. 1432).

Bank Act means the Federal Home Loan Bank Act, as amended (12 U.S.C. 1421 through 1449).

Constituent Bank means a Bank that is proposing to merge with one or more

other Banks. Each Bank entering into a merger is a Constituent Bank, regardless of whether it is also a Continuing Bank.

Continuing Bank means a Bank that will exist as the result of a merger of two or more Constituent Banks, and when used in the singular shall include the plural.

Director, written in title case, means the Director of FHFA or his or her designee.

Disclosure Statement means a written document that contains, to the extent applicable, all of the items that a Bank would be required to include in a Form S–4 Registration Statement under the Securities Act of 1933 (or any successor form promulgated by the United States Securities and Exchange Commission governing disclosure required for securities issued in business combination transactions) when prepared as a prospectus as directed in Part I of the form, if the Bank were required to provide such a prospectus to its shareholders in connection with a merger.

Effective Date means the date on which the organization certificate of the Continuing Bank becomes effective as provided under § 1278.7.

FHFA means the Federal Housing Finance Agency.

Financial Statements means statements of condition, income, capital, and cash flows, with explanatory notes, in such form as the Banks are required to include in their filings made under the Securities and Exchange Act of 1934.

GAAP means accounting principles generally accepted in the United States as in effect from time to time.

Merge or *Merger* means:

(1) A merger of one or more Banks into another Bank;

(2) A consolidation of two or more Banks resulting in a new Bank;

(3) A purchase of substantially all of the assets, and assumption of substantially all of the liabilities, of one or more Banks by another Bank or Banks; or

(4) Any other business combination of two or more Banks into one or more resulting Banks.

Office of Finance means the Office of Finance, a joint office of the Banks established under part 1273 of this chapter.

Record Date means the date established by a Bank's board of directors for determining the members that are entitled to vote on the ratification of the merger agreement and the number of ballots that may be cast by each in the election.

§ 1278.2 Authority.

Any two or more Banks may merge voluntarily under authority of section 26(b) of the Bank Act, provided that each of the following requirements has been satisfied:

(a) The Constituent Banks have executed a written merger agreement that satisfies all requirements of § 1278.3;

(b) The Constituent Banks have jointly filed a merger application with FHFA that satisfies all requirements of § 1278.4;

(c) The Director has approved the merger application in accordance with the requirements of § 1278.5;

(d) The members of each Constituent Bank have ratified the merger agreement as provided under § 1278.6; and

(e) The Director has determined that the Constituent Banks have satisfied all conditions imposed in connection with the approval of the merger application, and has accepted the properly executed organization certificate of the Continuing Bank, as provided under § 1278.7.

§ 1278.3 Merger agreement.

A merger of Banks under the authority of § 1278.2 shall require a written merger agreement that:

(a) Has been authorized by the affirmative vote of a majority of a quorum of the board of directors of each Constituent Bank at a meeting on the record and has been executed by authorized signing officers of each Constituent Bank; and

(b) Sets forth all material terms and conditions of the merger, including, without limitation, provisions addressing each of the following matters—

(1) The proposed Effective Date and the proposed acquisition date for purposes of accounting for the transaction under GAAP, if that date is to be different from the Effective Date;

(2) The proposed organization certificate and bylaws of the Continuing Bank;

(3) The proposed capital structure plan for the Continuing Bank;

(4) The proposed size and structure of the board of directors for the Continuing Bank;

(5) The formula to be used to exchange the stock of the Constituent Banks for the stock of the Continuing Bank, and a provision prohibiting the issuance of fractional shares of stock;

(6) Any conditions that must be satisfied prior to the Effective Date, which must include approval by the Director and ratification by the members of the Constituent Banks;

(7) A statement of the representations or warranties, if any, made or to be made by any Constituent Bank;

(8) A description of the legal or accounting opinions or rulings, if any, that are required to be obtained or furnished by any party in connection with the proposed merger; and

(9) A statement that the board of directors of a Constituent Bank may terminate the merger agreement before the Effective Date upon a determination that:

(i) The information disclosed to members contained material errors or omissions;

(ii) Material misrepresentations were made to members regarding the impact of the merger;

(iii) Fraudulent activities were used to obtain members' approval; or

(iv) An event occurred subsequent to the members' vote that would have a significant adverse impact on the future viability of the Continuing Bank.

§ 1278.4 Merger application.

(a) *Contents of application.* Any two or more Banks that wish to merge shall submit to FHFA a merger application that addresses all material aspects of the proposed merger. As provided in § 1202.8 of this chapter, a Bank may submit separately any portions of the application that it believes contain confidential or privileged trade secrets or commercial or financial information, which portions will be handled in accordance with FHFA's Freedom of Information Act regulations set forth in part 1202 of this chapter. The application shall include, at a minimum, the following:

(1) A written statement that includes—

(i) A summary of the material features of the proposed merger;

(ii) The reasons for the proposed merger;

(iii) The effect of the proposed merger on the Constituent Banks and their members;

(iv) The proposed Effective Date, the proposed acquisition date for purposes of accounting for the transaction under GAAP, if that date is to be different from the Effective Date (including the reasons for designating a different acquisition date), and the Record Date established by each Constituent Bank's board of directors;

(v) If the Constituent Banks contemplate that the proposed merger will be one of two or more related transactions, a summary of the material features of any related transactions and the bearing that the consummation of, or failure to consummate, the related transactions is expected to have upon the proposed merger;

(vi) If not addressed by the merger agreement, the Banks' proposal for the ultimate size and composition of the board of directors for the Continuing Bank and their plan for reducing the board to its ultimate size and composition, as well as the names of the persons proposed to serve as directors and senior executive officers of the Continuing Bank immediately after the merger;

(vii) A description of all proposed material operational changes including, but not limited to, reductions in the existing staffs of the Constituent Banks (to the extent such information is known), whether and how Bank operations will be combined, and whether any Constituent Bank will continue to operate as a branch of the Continuing Bank;

(viii) Information demonstrating that the Continuing Bank will comply with all applicable capital requirements after the Effective Date;

(ix) A statement explaining all officer and director indemnification provisions; and

(x) An undertaking that the Constituent Banks will continue to disclose all material information, and update all items of the application, as appropriate;

(2) A copy of the executed merger agreement and a certified copy of the resolution of the board of directors of each Constituent Bank authorizing the merger agreement;

(3) A copy of the proposed organization certificate of the Continuing Bank;

(4) A copy of the proposed bylaws of the Continuing Bank;

(5) A copy of the proposed capital structure plan of the Continuing Bank;

(6) The most recent annual audited Financial Statements, and any interim quarterly financial statements for the year-to-date, for each Constituent Bank; and

(7) Pro forma Financial Statements for the Continuing Bank as of the date of the most recent statement of condition supplied under paragraph (a)(6) of this section, and forecasted pro forma Financial Statements for each of at least two years following such date.

(b) *Additional information.* FHFA may require the Constituent Banks to submit any additional information FHFA deems necessary to evaluate the proposed merger. If FHFA has determined a merger application to be complete as provided in paragraph (c) of this section, FHFA may require the Constituent Banks to submit additional information only with respect to matters derived from or prompted by the materials already submitted, or matters of a material nature that were not reasonably apparent previously, including matters concealed by the Constituent Banks or relating to developments that arose after the determination of completeness. If the Constituent Banks fail to provide the additional information in a timely manner, the Director may deem the failure to provide the required information as grounds to deny the application.

(c) *Completion of application.* Within 30 days of the receipt of a merger application, FHFA shall determine whether the application is complete and whether FHFA has all information necessary for the Director to evaluate the proposed merger.

(1) If FHFA determines that the application is complete and that it has all information necessary to evaluate the proposed merger, it shall so inform the Constituent Banks in writing.

(2) If FHFA determines that the application is incomplete, or that it requires additional information in order to evaluate the application, it shall so inform the Constituent Banks in writing, and shall specify the number of days within which the Constituent Banks must provide any additional information or materials. Within 15 days of receipt of the additional information or materials, FHFA shall inform the Constituent Banks in writing whether the merger application is complete.

§ 1278.5 Approval by Director.

(a) *Standards.* In determining whether to approve a merger of Banks under the authority of § 1278.2, the Director shall take into consideration the financial and managerial resources of the Constituent Banks, the future prospects of the Continuing Bank, and the effect of the proposed merger on the safety and soundness of the Continuing Bank and the Bank system.

(b) *Determination by Director.* After FHFA determines that a merger application is complete, as provided in § 1278.4(c), the Director shall, within 30 days, either approve or deny the merger application. An approval of a merger application may include any conditions the Director determines to be appropriate, and shall in all cases be conditioned on each Constituent Bank demonstrating that it has obtained its members' ratification of the merger agreement in accordance with the requirements of § 1278.6 by submitting to FHFA:

(1) A certified copy of the members' resolution ratifying the merger agreement, on which the members cast their votes; and

(2) A certification of the member vote from the Bank's corporate secretary or from an independent third party.

(c) *Notice.* If the Director approves the merger application, FHFA shall provide written notice of the approval and any conditions to each Constituent Bank, as well as to each other Bank and the Office of Finance. If the Director denies the merger application, FHFA shall provide written notice of the denial to each Constituent Bank, as well as to each other Bank and the Office of Finance, and the notice to the Constituent Banks shall include a statement of the reasons for the denial.

§ 1278.6 Ratification by Bank Members.

(a) *Requirements for member vote.* No merger of Banks under the authority of § 1278.2 may be consummated unless a merger agreement meeting the requirements of § 1278.3 has been ratified by the affirmative vote of the members of each Constituent Bank in a voting process that meets the following requirements:

(1) *Notice of vote.* Each Constituent Bank shall submit the authorized merger agreement to its members for ratification by delivering to each institution that was a member as of the Record Date—

(i) A ballot that permits the member to vote for or against the ratification of the merger agreement, or to abstain from such vote; and

(ii) A Disclosure Statement that establishes a closing date for the Bank's receipt of completed ballots that is no earlier than 30 days after the date that the ballot and Disclosure Statement are delivered to its members.

(2) *Voting rights and requirements.* In the vote to ratify the merger agreement, each member of each Constituent Bank shall be entitled to cast one vote for each share of Bank stock that the member was required to own as of the Record Date, provided that the number of votes that any member may cast shall not exceed the average number of shares of Bank stock required to be held by all members of that Bank, calculated on a district-wide basis, as of the Record Date. A member must cast all of its votes either for or against the ratification of the merger agreement, or may abstain with respect to all of its votes. Each member's vote shall be made by resolution of its governing body, either authorizing the specific vote, or delegating to an individual the authority to vote.

(3) *Determination of result.* No Constituent Bank shall review any ballot until after the closing date established in the Disclosure Statement or include in the tabulation any ballot received after the closing date. A Constituent

Bank shall tabulate the votes cast immediately after the closing date. The members of a Constituent Bank shall be considered to have ratified a merger agreement if a majority of votes cast in the election have been cast in favor of the ratification of the merger agreement. The Constituent Bank, or the Continuing Bank, as appropriate, shall retain all ballots received for at least two years after the date of the election, and shall not disclose how any member voted.

(4) *Notice of result.* Within 10 days of the closing date, a Constituent Bank shall deliver to its members, to each Constituent Bank with which it proposes to merge, and to FHFA a statement of—

(i) The total number of eligible votes;

(ii) The number of members voting in the election; and

(iii) The total number of votes cast both for and against ratification of the merger agreement, as well as those that were eligible to be cast by members that abstained and by members who failed to return completed ballots.

(b) *False and misleading statements.* In connection with a proposed merger, no Bank, nor any director, officer, or employee thereof, shall make any statement, written or oral, which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statement not false or misleading, or necessary to correct any earlier statement that has become false or misleading.

§ 1278.7 Consummation of the merger.

(a) *Post-approval submissions.* After the members of each Constituent Bank have voted to ratify the merger agreement, the Constituent Banks shall submit to FHFA:

(1) Evidence acceptable to the Director that all conditions imposed in connection with the approval of the merger application under § 1278.5 have been satisfied, including the items specified in §§ 1278.5(b)(1) and (2); and

(2) An organization certificate for the Continuing Bank, in such form as FHFA may specify, that has been executed by the individuals who will constitute the board of directors of the Continuing Bank.

(b) *Acceptance of organization certificate.* Upon determining that all conditions have been satisfied and that the organization certificate meets the requirements of § 1278.7(a)(2), the Director shall accept the organization certificate of the Continuing Bank by endorsing thereon the date of acceptance and the Effective Date, which date shall be:

(1) The proposed Effective Date set forth in the merger agreement or, if the merger agreement expresses the proposed Effective Date in terms of a range of dates, a date within the applicable range of dates; or

(2) If the proposed Effective Date set forth in the merger agreement has passed, the earlier of:

(i) The 10th business day following the date of acceptance of the organization certificate by the Director; or

(ii) The last business day preceding any date specified in the merger agreement by which the merger agreement will terminate if the merger has not become effective.

(c) *Effectiveness of merger.* After the Director has accepted the organization certificate of the Continuing Bank as provided in § 1278.7(b), and as of the commencement of the Effective Date specified on such organization certificate:

(1) The Continuing Bank shall become or remain a body corporate (depending on the type of transaction) operating under such organization certificate with all powers granted to a Bank under the Bank Act;

(2) The Continuing Bank shall succeed to all rights, titles, powers, privileges, books, records, assets, and liabilities of the Constituent Banks, as provided in the merger agreement; and

(3) The corporate existence of any Constituent Bank that is not a Continuing Bank shall cease, unless otherwise provided in the merger agreement.

(d) *Notice.* After accepting the organization certificate for the Continuing Bank, the Director shall provide to the Constituent Banks, and to each other Bank and the Office of Finance, prompt written notice of that fact, which shall include the date of acceptance and the Effective Date of the organization certificate.

Dated: November 17, 2011.

Edward J. DeMarco,

Acting Director, Federal Housing Finance Agency.

[FR Doc. 2011–30487 Filed 11–25–11; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0376; Airspace Docket No. 10–AEA–11]

RIN 2120–AA66

Amendment and Establishment of Air Traffic Service Routes; Northeast United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction

SUMMARY: This action corrects a final rule published by the FAA in the **Federal Register** on September 19, 2011, that amends and establishes nine Air Traffic Service Routes (ATS) in the Northeast United States. This action provides more accurate latitude/longitude coordinates for one waypoint (WP) in the description of area navigation (RNAV) route Q–480.

DATES: Effective date 0901 UTC, December 15, 2011. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

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

SUPPLEMENTARY INFORMATION:

Background

On September 19, 2011, the FAA published a final rule in the **Federal Register** amending and establishing nine ATS routes in the northeast United States (76 FR 57902). Subsequent to publication a more accurate alignment was calculated for the establishment of the CANDR WP position of RNAV route Q–480. The refined coordinates result in a minor change of the CANDR position that is 0.28 nautical miles (NM) north of the original location. This equates to a move of approximately 1,700 feet which is well within the standard 8 NM width of RNAV routes. Since the coordinates in air traffic service route descriptions are rounded to the nearest second, the amended CANDR position is listed as ''lat. 40°58′16″ N., long. 74°57′35″ W.''

Area Navigation Routes are published in paragraph 2006 of FAA Order 7400.9V, dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR

71.1. The RNAV route listed in this document will be published subsequently in the Order.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the coordinates for the CANDR waypoint as published in the **Federal Register** on September 19, 2011 (76 FR 57902) (FR Doc. 2011–23839) for RNAV route Q–480, is corrected under the description as follows:

Paragraph 2006—United States Area Navigation Routes

* * * * *

Q–480 [Corrected]

On page 57905, line 38, Remove ''CANDR, NJ WP (lat. 40°57′59″ N., long. 74°57′29″ W.)''and insert ''CANDR, NJ WP (lat. 40°58′16″ N., long. 74°57′35″ W.)

Issued in Washington, DC, on November 16, 2011.

Gary A. Norek,

Acting Manager, Airspace, Regulations and ATC Procedures Group.

[FR Doc. 2011–30500 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2010–1328; Airspace Docket No. 10–AEA–26]

Amendment of Class D and Class E Airspace; Baltimore, MD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class D and Class E airspace at Baltimore, MD, as the Martin Non-Directional Beacon (NDB) has been decommissioned and new Standard Instrument Approach Procedures have been developed at Martin State Airport. This action also updates the geographic coordinates of the Baltimore VORTAC and makes a minor adjustment to the geographic coordinates of the airport. This action enhances the safety and airspace management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, February 9, 2012. The Director of the **Federal Register** approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

History

On August 31, 2011, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend Class D and E airspace at Martin State Airport, Baltimore, MD (76 FR 54153). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Subsequent to publication, the FAA found that the geographic coordinates for Martin State Airport and navigation aid needed to be adjusted. This action makes that adjustment. Class D and E airspace designations are published in paragraph 5000, 6002, and 6004 respectively of FAA Order 7400.9V dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 amends Class D airspace and Class E surface airspace and Class E airspace designated as an extension to Class D surface area. Airspace reconfiguration is necessary due to the decommissioning of the Martin NDB and cancellation of the NDB approach, and for continued safety and management of IFR operations at the airport. The geographic coordinates for the Baltimore VORTAC and Martin State Airport also are adjusted to coincide with the FAA's aeronautical database.

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

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends controlled airspace at Martin State Airport, Baltimore, MD.

Lists of Subjects in 14 CFR Part 71:

Airspace, Incorporation by reference, Navigation (Air).

Adoption of the Amendment:

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, effective September 15, 2011, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

AEA MD D Baltimore, Martin State Airport, MD [Amended]

Martin State Airport, Baltimore, MD
(Lat. 39°19′54″ N., long. 76°24′83″ W.)
Baltimore VORTAC
(Lat. 39°10′12″ N., long. 76°39′30″ W.)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 5.2-mile radius of Martin State Airport and within 4.4 miles each side of a 14.7-mile radius arc of the Baltimore VORTAC extending clockwise from the Baltimore VORTAC 030° radial to the VORTAC 046° radial, excluding that airspace within the Washington Tri-Area Class B

airspace area and Restricted Areas R–4001A and R–4001B when they are in effect. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6002 Class E Airspace Designated as Surface Areas

* * * * *

AEA MD E2 Baltimore, Martin State Airport, MD [Amended]

Martin State Airport, MD
(Lat. 39°19′54″ N., long. 76°24′83″ W.)
Baltimore VORTAC
(Lat. 39°10′12″ N., long. 76°39′30″ W.)

Within a 5.2-mile radius of Martin State Airport and within 4.4 miles each side of a 14.7-mile radius arc of the Baltimore VORTAC extending clockwise from the Baltimore VORTAC 030° radial to the VORTAC 046° radial, excluding that airspace within the Washington Tri-Area Class B airspace area and Restricted Areas R–4001A and R–4001B when they are in effect. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6004 Class E Airspace Designated as an Extension to a Class D Surface Area.

* * * * *

AEA MD E4 Baltimore, Martin State Airport, MD [Amended]

Martin State Airport, MD
(Lat. 39°19′54″ N., long. 76°24′83″ W.)

That airspace extending upward from the surface within 4 miles each side of a 134° bearing from Martin State Airport extending from the 5.2-mile radius of Martin State Airport to 9.2 miles southeast of the airport, excluding that airspace within the Washington Tri-Area Class B airspace area and Restricted Areas R–4001A and R–4001B when they are in effect. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Issued in College Park, Georgia, on November 17, 2011.

Mark D. Ward,

Manager, Operations Support Group, Easter Service Center, Air Traffic Organization.

[FR Doc. 2011–30489 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0785; Airspace Docket No. 11–AEA–20]

Amendment of Class E Airspace; Luray, VA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E Airspace at Luray, VA, to accommodate the new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures serving Luray Caverns Airport. This action enhances the safety and airspace management of Instrument Flight Rules (IFR) operations within the National Airspace System. This action also makes a minor adjustment to the geographic coordinates of the airport.

DATES: Effective 0901 UTC, February 9, 2012. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

History

On August 22, 2011, the FAA published in the **Federal Register** a notice of proposed rulemaking to amend Class E airspace at Luray, VA (76 FR 52292). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Subsequent to publication, the FAA found that the geographic coordinates of the airport needed to be adjusted. This action makes that adjustment. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9V dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 amends Class E airspace extending upward from 700 feet above the surface at Luray, VA, to provide the controlled airspace required to accommodate the new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures developed for Luray Caverns Airport. This action also adjusts the geographic coordinates of the airport to be in concert with the FAAs aeronautical database. This action is necessary for the safety and management of IFR operations at the airport.

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

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends controlled airspace at Luray Caverns Airport, Luray, VA.

Lists of Subjects in 14 CFR Part 71:

Airspace, Incorporation by reference, Navigation (Air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, effective September 15, 2011, is amended as follows:

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

* * * * *

AEA VA E5 Luray, VA [Amended]

Luray Caverns Airport, VA
(Lat. 38°40′01″ N., long. 78°30′02″ W.)

That airspace extending upward from 700 feet above the surface within a 14.5-mile radius of Luray Caverns Airport.

Issued in College Park, Georgia, on November 17, 2011.

Barry A. Knight,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2011–30492 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1068]

Drawbridge Operation Regulation; City Waterway Also Known as Thea Foss Waterway, Tacoma, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Thirteenth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the South 11th Street (''Murray Morgan'') Bridge across City Waterway also known as the Thea Foss Waterway, mile 0.6, at Tacoma, WA. The deviation is necessary to perform extensive maintenance and repair work on the bridge, including but not limited to removal and replacement of the roadway surface and the underlying steel stringer substructure as part a major bridge rehabilitation project. This deviation allows the bridge to remain in the closed position during construction activities.This deviation is effective from 8 a.m. on November 14, 2011 through 6 p.m. April 30, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–1068 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–1068 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 rule, call or email the Bridge Administrator, Coast Guard Thirteenth District; telephone (206) 220–7282 email *randall.d.overton@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The City of Tacoma has requested to place the South 11th Street ''Murray Morgan'' Bridge in the closed or down position and to not open the bridge for vessel traffic to facilitate a major rehabilitation project on the bridge. The South 11th Street Bridge crosses City Waterway mile 0.6 at Tacoma, WA. The South 11th Street Bridge is also known as the Murray Morgan Bridge and City Waterway is also known as Thea Foss Waterway. The South 11th Street Bridge is a vertical lift bridge. During this deviation the bridge will be placed in the close or down position. There will be a debris containment system attached to the underside of the bridge for the duration of construction activities. A minimum vertical clearance of 57 feet above mean high water will be provided beneath the bridge and the attached debris containment system, at all time during the deviation period. Vessels which do not require a bridge opening may continue to transit beneath the bridge during this closure period. Under normal operations the bridge operates under 33 CFR 117.1061 which requires a two hour notice for an opening and allows the bridge to not open during morning and afternoon rush hours. This current deviation states the lift span of the 11th Street South Bridge (Murray Morgan Bridge) across City Waterway (Thea Foss Waterway), mile 0.6, need not open from 8 a.m. November 14, 2011 through 6 p.m. April 30, 2012; except as otherwise outlined in this article and through ongoing coordination with waterway users. The bridge will be able to open during this maintenance period for emergent situations provided 12 hours of advance notification of an opening is given. The bridge will be placed in the open position: November 24–27, 2011; December 24, 2011 through January 1, 2012, and either April 14–15, 2012 or April 21–22, 2012, to be coordinated with the local waterway users. The bridge will also be opened during an additional weekend in January, February, and March to be determined in coordination with local waterway users.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 14, 2011.

Randall D. Overton,

Bridge Administrator.

[FR Doc. 2011–30513 Filed 11–25–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–1058]

RIN 1625–AA00

Safety Zone; Truman-Hobbs Alteration of the Elgin Joliet & Eastern Railroad Drawbridge; Illinois River, Morris, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Illinois River near Morris, Illinois. This zone is intended to restrict vessels from a portion of the Illinois River due to the Truman-Hobbs alteration of the Elgin Joliet & Eastern Railroad Drawbridge. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards associated with the removal of the Elgin Joliet & Eastern Railroad Drawbridge's old bridge piers and pier protection cells.

DATES: This rule is effective in the CFR from November 28, 2011 until December 9, 2011. It is effective for purposes of enforcement from 7 a.m. on November 16, 2011 until 7 a.m. on December 9, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–1058 and are available online by going to *http://www.regulations.gov*, inserting USCG–2011–1058 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, contact or email BM1 Adam Kraft, U.S. Coast Guard Sector Lake Michigan, at (414) 747–7148 or *Adam.D.Kraft@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 an agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 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 there is insufficient time for the Coast Guard to wait for a notice and comment period to run. The Coast Guard only recently learned that the bridge project described below will take longer than previously planned and consequently, will continue beyond the expiration of the Coast Guard safety zone previously established. Thus, waiting for a notice and comment period to run would be impracticable and contrary to the public interest in that it would prevent the Coast Guard from protecting the public and vessels on navigable waters from the hazards associated with this ongoing bridge construction project.

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**. For the reasons discussed in the preceding paragraph, a 30-day notice period would be impracticable and contrary to the public interest.

Background and Purpose

The Truman-Hobbs alteration of the Elgin Joliet & Eastern Railroad Drawbridge, which consists of the removal of the bridges old piers and pier protection cells had originally scheduled to finish by November 16, 2011. However, it has fallen behind schedule and will now go until December 9, 2011. The falling debris associated with the removal of the bridge's piers and protection cells poses a serious risk of injury to persons and property. As such, the Captain of the Port, Sector Lake Michigan, has determined that the alteration project of the Elgin Joliet & Eastern Railroad Drawbridge poses significant risks to public safety and property and that a safety zone is necessary.

Discussion of Rule

Because of the aforementioned hazards, the Captain of the Port, Sector Lake Michigan, has determined that a safety zone is necessary to protect people and vessels. The safety zone will encompass all U.S. navigable waters of the Illinois River in the vicinity of the Elgin Joliet & Eastern Railroad Drawbridge between Mile Marker 270.1 and Mile Marker 271.5 of the Illinois River in Morris, IL. [DATUM: NAD 83].

All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port, Sector Lake Michigan, or his or her designated representative. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port, Sector Lake Michigan, or his or her designated representative. The Captain of the Port, Sector Lake Michigan, or his or her designated representative may be contacted via VHF–FM Channel 16 or at (414) 747–7182.

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. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS). We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone around the bridge project will be relatively small and exist for relatively short duration. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port or his or her designated representative.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule will 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 will affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor on a portion of the Illinois River at various times between 7 a.m. on November 16, 2011 and 7 a.m. on December 9, 2011.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule will only be enforced while unsafe conditions exist. Recreational Vessel traffic will be minimal due to the time of year and Commercial traffic is well aware of this project since it has been active since October 6, 2011. This rule will simply extend the duration of the safety zone that originally was set to expire at 7 a.m. on November 16, 2011.

In the event that this temporary safety zone affects shipping, commercial vessels may request permission from the Captain of The Port, Sector Lake Michigan, or his or her designated representative to transit through the safety zone. The Captain of the Port or his or her representative can be contacted via VHF–FM Channel 16 or at (414) 747–7182. The Coast Guard will give notice to the public via a Broadcast to Mariners that the regulation is in effect.

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

Taking of Private Property

This rule will not affect 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 concern 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 proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant 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 the establishment of a safety zone and is therefore categorically excluded under paragraph 34(g) of the Instruction.

A final environmental analysis checklist and 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, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–1058 to read as follows

§ 165.T09–1058 Safety Zone; Truman-Hobbs alteration of the Elgin Joliet & Eastern Railroad Drawbridge, Morris, Illinois

(a) *Location.* The safety zone will encompass all U.S. navigable waters of the Illinois River in the vicinity of the Elgin Joliet & Eastern Railroad Drawbridge between Mile Marker 270.1 and Mile Marker 271.5 of the Illinois River in Morris, IL. [DATUM: NAD 83].

(b) *Effective and Enforcement Period.* This rule is effective and will be enforced from 7 a.m. on November 16, 2011 until 7 a.m. on December 9, 2011. If the alteration project is completed

before December 9, 2011, the Captain of the Port, Sector Lake Michigan, or his or her designated representative, may suspend the enforcement of this safety zone.

(c) *Regulations.*

(1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port, Sector Lake Michigan, or his or her designated representative.

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

(3) The ''designated representative'' of the Captain of the Port, Sector Lake Michigan, is any Coast Guard commissioned, warrant, petty officer, or District 8 Bridge Branch Member who has been designated by the Captain of the Port, Sector Lake Michigan, to act on his or her behalf. The designated representative of the Captain of the Port, Sector Lake Michigan, will be reachable via VHF–FM Channel 16 or by calling (414) 747–7182.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port, Sector Lake Michigan, or his or her designated representative to obtain permission to do so. The Captain of the Port, Sector Lake Michigan, or his or her designated representative may be contacted via VHF Channel 16 or at (414) 747–7182. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port, Sector Lake Michigan, or his or her designated representative.

Dated: November 14, 2011.

M. W. Sibley,

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

[FR Doc. 2011–30519 Filed 11–25–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0958]

RIN 1625–AA00

Safety Zones; New Year's Eve Fireworks Displays within the Captain of the Port St. Petersburg Zone, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing four temporary safety zones during New Year's Eve fireworks displays on certain navigable waterways in Naples, St. Petersburg, Cape Coral, and Sarasota, Florida. These safety zones are necessary to protect the public from the hazards associated with launching fireworks over navigable waters of the United States. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within any of the four safety zones unless authorized by the Captain of the Port St. Petersburg or a designated representative.

DATES: This rule is effective from 7 p.m. on December 31, 2011 until 1 a.m. on January 1, 2012.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0958 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0958 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 final rule, call or email Marine Science Technician First Class Nolan L. Ammons, Sector St. Petersburg Prevention Department, Coast Guard; telephone (813) 228–2191, email *D07-SMB-Tampa-WWM@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 the Coast Guard did not receive necessary information regarding the fireworks displays until October 6, 2011. As a result, the Coast Guard did not have sufficient time to publish an NPRM and to receive public comments prior to the fireworks displays. Any delay in the effective date of this rule would be contrary to the public interest because immediate action is needed to minimize potential danger to the public during the fireworks displays.

Basis and Purpose

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

The purpose of the rule is to protect the public from the hazards associated with the launching of fireworks over navigable waters of the United States.

Discussion of Rule

Multiple fireworks displays are planned for New Year's Eve celebrations throughout the Captain of the Port St. Petersburg Zone. The fireworks will be launched from land, piers, or barges. Whether launched from land, pier, or barge, such fireworks will explode over navigable waters of the United States.

The Coast Guard is establishing four temporary safety zones for New Year's Eve fireworks displays on navigable waters of the United States that are located in the Captain of the Port St. Petersburg Zone. The safety zones are listed below.

1. *Naples, Florida.* All waters within a 280 yard radius of position 26°07′53″ N, 81°48′32″ W. This safety zone will be enforced from 7 p.m. until 8:30 p.m. on December 31, 2011.

2. *St. Petersburg, Florida.* All waters within a 375 yard radius of position 27°46′31″ N, 82°37′38″ W. This safety zone will be enforced from 8:30 p.m. on December 31, 2011 until 12:30 a.m. on January 1, 2012.

3. *Cape Coral, Florida.* All waters within a 235 yard radius of position 26°32′15″ N, 81°59′57″ W. This safety zone will be enforced from 11:30 p.m. on December 31, 2011 until 12:30 a.m. on January 1, 2012.

4. *Sarasota, Florida.* All waters within a 235 yard radius of position 27°19′55″ N, 82°32′48″ W. This safety zone will be enforced from 11:30 p.m. on December 31, 2011 until 12:30 a.m. on January 1, 2012.

Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within any of the safety zones unless authorized by the Captain of the Port St. Petersburg or

a designated representative. Persons and vessels desiring to enter, transit through, anchor in, or remain within any of the safety zones may contact the Captain of the Port St. Petersburg by telephone at (727) 824–7524, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the any of the safety zones is granted by the Captain of the Port St. Petersburg or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port St. Petersburg or a designated representative. The Coast Guard will provide notice of the safety zones by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

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

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

The economic impact of this rule is not significant for the following reasons: (1) The safety zones will be enforced for only six hours; (2) vessel traffic in the areas will be minimal during the enforcement periods; (3) although persons and vessels will not be able to enter, transit through, anchor in, or remain within any of the safety zones without authorization from the Captain of the Port St. Petersburg or a designated representative, they may operate in the surrounding areas during the enforcement periods; (4) persons and vessels may still enter, transit through, anchor in, or remain within the safety zones during the enforcement periods if authorized by the Captain of the Port St. Petersburg or a designated representative; and (5) the Coast Guard will provide advance notification of the safety zones to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

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 may be small entities: The owners or operators of vessels intending to enter, transit through, anchor in, or remain within any of the four safety zones established by this regulation during the respective enforcement period. For the reasons discussed in the Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

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 that 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 four temporary safety zones, as described in paragraph 34(g) of the Instruction, that will be enforced for a total of six hours. 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 a temporary § 165.T07–0958 to read as follows:

§ 165.T07–0958 Safety Zones; New Year's Eve Fireworks Displays within the Captain of the Port St. Petersburg, FL Zone.

(a) *Regulated Areas.* The following regulated areas are safety zones, with the specific enforcement period for each safety zone. All coordinates are North American Datum 1983.

(1) *Naples, FL.* All waters within a 280 yard radius of position 26°07′53″ N., 81°48′32″ W. This regulated area will be enforced from 7 p.m. until 8:30 p.m. on December 31, 2011.

(2) *St. Petersburg, FL.* All waters within a 375 yard radius of position 27°46′31″ N., 82°37′38″ W. This regulated area will be enforced from 8:30 p.m. on December 31, 2011 until 12:30 a.m. on January 1, 2012.

(3) *Cape Coral, FL.* All waters within a 235 yard radius of position 26°32′15″ N., 81°59′57″ W. This regulated area will be enforced from 11:30 p.m. on December 31, 2011 until 12:30 a.m. on January 1, 2012.

(4) *Sarasota, FL.* All waters within a 235 yard radius of position 27°19′55″ N., 82°32′48″ W. This regulated area will be enforced from 11:30 p.m. on December 31, 2011 until 12:30 a.m. on January 1, 2012.

(b) *Definition.* The term ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port St. Petersburg in the enforcement of the regulated areas.

(c) *Regulations.*

(1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated areas unless authorized by the Captain of the Port St. Petersburg or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within any of the regulated areas may contact the Captain of the Port St. Petersburg by telephone at (727) 824–7524, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within any of the regulated areas is granted by the Captain of the Port St. Petersburg or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port St. Petersburg or a designated representative.

(3) The Coast Guard will provide notice of the regulated areas by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Effective Date.* This rule is effective from 7 p.m. on December 31, 2011 until 1 a.m. on January 1, 2012.

Dated: November 8, 2011.

S.L. Dickinson,

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

[FR Doc. 2011–30509 Filed 11–25–11; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2010–0017–201014(a) & EPA–R04–OAR–2010–0018–201001(a); FRL–9495–7]

Approval and Promulgation of Air Quality Implementation Plans: South Carolina; Negative Declarations for Groups I, II, III and IV Control Techniques Guidelines; and Reasonably Available Control Technology

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve several State Implementation Plan (SIP) revisions submitted by the South Carolina Department of Health and Environmental Control (SC DHEC). These revisions establish reasonably available control technology (RACT) requirements for the three major sources located in the portion of York County, South Carolina that is within the bi-state

Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina 1997 8-hour ozone nonattainment area that either emit volatile organic compounds (VOC), nitrogen oxides (NO_X) or both. The bi-state Charlotte-Gastonia-Rock Hill 1997 8-hour ozone nonattainment area is hereinafter referred to as the ''bi-state Charlotte Area.'' In addition, South Carolina's SIP revisions include negative declarations for certain source categories for which EPA has control technique guidelines (CTG), meaning that SC DHEC has concluded that no such sources are located in that portion of the nonattainment area. EPA has evaluated the proposed revisions to South Carolina's SIP, and has concluded that they are consistent with statutory and regulatory requirements and EPA guidance.

DATES: This rule is effective on January 27, 2012 without further notice, unless EPA receives relevant adverse comment by December 28, 2011. If EPA receives such comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2010–0017 and EPA–R04–OAR–2010–0018, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: benjamin.lynorae@epa.gov.*
3. *Fax:* (404) 562–9019.
4. *Mail:* ''EPA–R04–OAR–2010–0017'' for comments regarding the RACT demonstration and the negative declarations for Groups I and I CTG. ''EPA–R04–OAR–2010–0018'' for comments regarding the negative declarations for Groups III and IV CTG. Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960.
5. *Hand Delivery or Courier:* Lynorae Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. ''EPA–R04–OAR–2010–0017'' and ''EPA–R04–OAR–2010–0018.'' 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 through *http://www.regulations.gov* or email, information that you consider to be CBI or otherwise protected. 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 email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

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 at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Zuri Farngalo, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Zuri Farngalo may be reached by phone at (404) 562–9152 or by electronic mail address *farngalo.zuri@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

On April 30, 2004, EPA designated the bi-state Charlotte Area as a moderate nonattainment area with respect to the 1997 8-hour ozone National Ambient Air Quality Standard (NAAQS). *See* 69 FR 23858. In addition to six full counties and one partial county in North Carolina, the bi-state Charlotte Area also includes the portion of York County, South Carolina that falls within the Rock Hill-Fort Mill Area Transportation Study Metropolitan Planning Organization Area (the ''Rock Hill-Fort Mill Area'').[1] As a result of this designation, North Carolina and South Carolina were required to amend their SIPs for their respective portions of the bi-state Charlotte area to satisfy the requirements of section 182 of the Clean Air Act (CAA or Act). Today's action specifically addresses the Rock Hill-Fort Mill Area in South Carolina. The requirements for the North Carolina portion of the bi-state Charlotte Area will be addressed in separate rulemaking.

A. Statutory Requirements

Section 183(e) of the CAA directs EPA to: (1) List for regulation those categories of products that account for at least 80 percent of the VOC emissions, on a reactivity-adjusted basis, from consumer and commercial products in ozone nonattainment areas; and (2) divide the list of categories to be regulated into four groups. EPA published the initial list in the **Federal Register** on March 23, 1995 (60 FR 15264), and has revised the list several times. *See* 71 FR 28320 (May 16, 2006), 70 FR 69759 (November 17, 2005), 64 FR 13422 (March 18, 1999), 63 FR 48792

[1] Prior to 2004, the Rock Hill-Fort Mill Area was designated as an attainment area for the 1-hour ozone NAAQS, and thus South Carolina was not required to meet CTG requirements for this Area for the 1-hour ozone NAAQS.

(September 11, 1998). As authorized by CAA section 183(e)(3)(C), EPA chose to issue Control Technique Guidelines (CTGs) in lieu of regulations for each listed product category. *See* 73 FR 58481 (October 7, 2008) (Group IV CTG); 72 FR 57215 (October 9, 2007) (Group III CTG); and 71 FR 58745 (October 5, 2006) (Group II CTG).

The primary purpose of the CTGs is to satisfy the requirement in CAA section 182(b)(2) that states adopt RACT rules for all areas designated nonattainment for ozone and classified as moderate or above. The three parts to the section 182(b)(2) RACT requirement are: (1) RACT for sources covered by an existing CTG (*i.e.,* a CTG issues prior to enactment of the 1990 amendments to the CAA); (2) RACT for sources covered by a post-enactment CTG; and (3) all major sources not covered by a CTG (*i.e.,* non-CTG sources).

A CTG is a guidance document issued by EPA which, in combination with CAA section 182(b)(2), triggers a responsibility for states to submit RACT rules for stationary sources of VOC that are covered by the CTG as part of their SIPs. EPA defines RACT as ''the lowest emission limit that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility.'' 44 FR 53761 (September 17, 1979). Each CTG includes a ''presumptive norm'' or ''presumptive RACT'' that EPA believes satisfies the definition of RACT.

If a state submits a RACT rule that is consistent with the presumptive RACT, the state does not need to submit additional support to demonstrate that the rule meets the CAA's RACT requirement. However, if the state decides to submit an alternative emission limit or level of control for a source or source category for which there is a presumptive RACT, the state must submit independent documentation as to why the rule meets the statutory RACT requirement.

Section 182(b)(2) of the CAA addresses moderate and above areas for the 1-hour ozone standard. Further clarification of the RACT requirements for areas classified as moderate or above for the 1997 8-hour ozone NAAQS is provided in EPA's regulations. Specifically, 40 CFR 51.912, entitled ''What requirements apply for reasonably available control technology (RACT) and reasonably available control measures (RACM) under the 8-hour NAAQS?'' provides the pertinent RACT requirements for areas classified as moderate or above for the 1997 8-hour ozone NAAQS, stating:

> (1) For each area subject to subpart 2 in accordance with 51.903 of this part and classified moderate or higher, the State shall submit a SIP revision that meets the nitrogen oxides (NO_X) and VOC RACT requirements in sections 182(b)(2) and 182(f) of the Act.
>
> (2) The State shall submit the RACT SIP for each area no later than 27 months after designation for the 8-hour ozone NAAQS, except that for a State subject to the requirements of the Clean Air Interstate Rule, the State shall submit NO_X RACT SIPs for electrical generating units (EGUs) no later than the date by which the areas' attainment demonstration is due (prior to any reclassification under section 181(b)(3)) for the 8-hour ozone national ambient air quality standard, or July 9, 2007, whichever comes later.
>
> (3) The State shall provide for implementation of RACT as expeditiously as practicable but no later than the first ozone season or portion thereof which occurs 30 months after the RACT SIP is due.

The CTGs established by EPA are guidance to the states and provide recommendations only. A state can develop its own strategy for what constitutes RACT for the various CTG categories, and EPA will review that strategy in the context of the SIP process and determine whether it meets the RACT requirements of the CAA and its implementing regulations. If no major sources of VOC or NO_X emissions (which should be considered separately) in a particular source category exist in an applicable nonattainment area, a state may submit a negative declaration for that category.

B. Regulatory Schedule for Implementing CTGs

CTGs that were established in 1978 ultimately were required to be adopted by the States by 1990 (see schedule below for details). CAA Section 182(b)(2) provides that a CTG issued after 1990 must specify the date by which a state must submit a SIP revision in response to the CTG. States were required to have the pre-1990 CAA CTG categories and post–1990 CAA CTG categories for applicable areas addressed in their SIPs according to the following schedule:

Group	**Federal Register** published	SIP due
I	Pre-CAA CTG	Pre-CAA Amendment CTG
	As of January 1978 the first 15 CTG categories were established. Ten additional CTG were issued in 1978 (1 of those (vegetable oil) was rescinded).	The first 25 CTG categories were due to be adopted by the states by 1980. EPA initially approved most of these rules into the state SIPs. Subsequently, EPA reviewed these state rules to see if they were technically adequate and if they met national standards for national consistency. Based on this review, EPA issued the RACT fix-ups in 1987 (see general preamble (57 FR 13498, April 16, 1992)). In 1988, EPA published a technical document to address technical inadequacies found in these state adopted rules and to address minimum standards of national consistency. States were required to adopt revised rules by 1990. Congress established CTG statutory requirements in the 1990 CAA. Outstanding CTG requirements were due in 1992 (CAA Section 182(b)(2)(C).).
	Post-CAA CTG	September 15, 2006 (40 CFR 51.912, RACT SIPs due for the 1997 8-hour ozone NAAQS).
	The group of CTG established in 60 FR 15264, March 23, 1995, were broken into subsets called ''Group I, II, III and IV'' (some of these CTG are updates of previously established CTG)).	
II	71 FR 58745, October 5, 2006	October 5, 2007.
III	72 FR 57215, October 9, 2007	October 9, 2008.
IV	73 FR 58481, October 7, 2008	October 7, 2009.

II. Analysis of the State's Submittals

Following the April 2004 designation of the bi-state Charlotte Area as a moderate ozone nonattainment area, South Carolina had until June 15, 2007, to submit an attainment demonstration, RACT submission (addressing the applicable CTG), and a reasonable further progress plan for the Rock Hill-

Fort Mill Area portion of the nonattainment area. Subsequently, South Carolina was required to provide SIP revisions to address Group II CTG requirements in the Rock Hill-Fort Mill Area by October 5, 2007, and to address Group III and Group IV CTG requirements by October 9, 2008, and October 7, 2009, respectively.

South Carolina provided SIP revisions addressing Groups I and II CTG, on August 31, 2007. Subsequent to South Carolina's August 31, 2007, SIP revision, South Carolina provided SIP revisions to address Group III CTG on February 23, 2009, and Group IV CTG on July 9, 2009, for the Rock Hill Fort-Mill Area. Today's action relates to South Carolina's SIP revisions for the Rock Hill-Fort Mill Area regarding Groups, I, II, III and IV CTG requirements, and South Carolina's RACT demonstration for major non-CTG sources in the Rock Hill-Fort Mill Area.

As part of its analysis to support the negative declarations for Groups I, II, III and IV CTG, South Carolina reviewed its permits files and emissions inventory information. After this review, South Carolina determined that there are no stationary sources or emitting facilities located in Rock Hill-Fort Mill Area that are subject to Groups I, II, III and IV CTG. In accordance with CAA requirements, South Carolina prepared SIP revisions with these negative declarations and provided the public with an opportunity to review and provide comment regarding South Carolina's analyses. EPA has reviewed South Carolina's SIP revisions in support of the negative declarations for Groups I, II, III and IV CTG, and has concluded that the Rock Hill-Fort Mill Area in York County, South Carolina has met all the statutory and regulatory requirements for making a negative declaration regarding Groups I, II, III and IV CTG. Further, EPA has determined that South Carolina's August 31, 2007, February 23, 2009, and July 7, 2009, SIP revisions meet the applicable requirements of the CAA and EPA regulations.

With regard to RACT for non-CTG sources, South Carolina identified three major non-CTG sources within the Rock Hill-Fort Mill Area subject to RACT requirements. The three sources are Bowater, Inc., Cytec Carbon Fibers, LLC, and Georgia Pacific Wood Products, LLC. South Carolina determined what constitutes RACT for these facilities using the top-down process used for prevention of significant deterioration and nonattainment new source review. The top-down process provides that all available control technologies be ranked in descending order of control effectiveness. The most stringent technology is analyzed based on the following criteria: Technical considerations, along with energy, environmental, and economic impact. After this analysis is complete a determination is made as to whether the technology is achievable. The most stringent technology may be eliminated in this fashion and then the next most stringent alternative is considered, and so on.

A report submitted by the three facilities concluded that emission control devices would not be economically feasible, and thus, that RACT for these facilities should consist only of work practice requirements. SC DHEC evaluated the RACT analyses submitted by the three facilities which are further discussed below.

Bowater Coated Paper Division (Bowater) produces bleached pulp and paper products and is a major source for both NO_X and VOC. There are fifteen types of affected sources at the facility. These sources are subject to federal regulations that already require strict NO_X and VOC control. Many Bowater sources are currently meeting other federal requirements and these types of controls meet RACT for these units. Bowater has various NO_X sources. The 4110 Paper Mill-Coating unit requires Best Available Control Technology (BACT) standards and BACT meets RACT for this unit. Number 5105 No. 1 Recover Furnace and Number 2723 No. 2 Lime Kiln require Lowest Achievable Emissions Rate (LAER) standards and for these units LAER meets RACT. The RACT analysis determined that the remaining NO_X sources either meet NO_X SIP Call Control or additional controls are not feasible. All of the Bowater VOCs are Hazardous Air Pollutants (HAPs.) For the VOC units either the Maximum Available Control Technology (MACT) standards satisfy RACT or the RACT analysis for those units shows that additional controls are not feasible. SC DHEC concluded in its evaluation of Bowater's RACT analysis for each of the units that either the existing MACT standard for the affected unit was adequate or that the remaining technically feasible emission control devices would not be economically feasible to apply at the facility. SC DHEC noted that in general, good combustion results in low VOC emissions. Furthermore, SC DHEC noted that proper operation and/or good combustion practices are the only practical control techniques for biomass combustion sources identified in the RACT/BACT/LAER Clearinghouse. Thus, SC DHEC concluded that RACT for this facility will consist of work practice requirements. See Appendix R of the South Carolina RACT submittal for details of the RACT assessment including technology restrictions.

Cytec Carbon Fibers LLC (Cytec) is a title V facility that operates a carbon fiber manufacturing process and is a major source for NO_X. Therefore, SC DHEC completed a RACT analysis for their NO_X sources. Cytec is not a major source for VOC so a VOC RACT determination was not performed for this facility. Most of Cytec's NO_X emissions come from the conversion of the raw material into carbon fibers. A RACT analysis was done for their three oxidation ovens, the pre-carbonization (pre-carb) oven burner, and the carbonization ovens with the associated thermal oxidizer. SC DHEC has concluded there are no technically and economically feasible add-on control options for NO_X emissions reduction. However, Cytec's operating permit will include a work practice standard for reduction of NO_X emissions during product changes. Cytec estimates that this work practice could lower actual annual NO_X emissions. SC DHEC concluded that this fully meets RACT. See Appendix R of the South Carolina RACT submittal for details of the RACT assessment including technology restrictions.

Georgia Pacific—Catawba Hardboard Plant is a major source for VOC but not for NO_X. Therefore, SC DHEC completed a RACT analysis for VOC emissions from the facility from the cooker, dryers, and press equipment at the plant. All but 3 of the VOCs emitted from the plant are HAP VOCs. The non-HAP VOCs are Hexanal (1.4184 tons per year (tpy)), CFC–11 (0.0005 tpy), and Methyl Ethyl Ketone (0.0825 tpy). For GA Pacific, the RACT analysis determined that the only feasible control options (before determining economic feasibility) are regenerative thermal oxidizer (RTO), regenerative catalytic oxidizer (RCO), thermal catalytic oxidizer (TCO) and Biofilter. The RACT analysis went on to show that it would cost $8 million to install RTO, RCO or TCO and would cost $3.5 million annually to operate. These technologies have a cost effectiveness of $14,553 per ton. The RACT analysis also showed that it would cost $5 million to install the Biofilter technology and cost $700,000 to operate annually with a cost effectiveness of $5,483 per ton. The analysis concluded that it is not economically feasible to apply add-on controls to these units. Furthermore, SC DHEC noted that these units are already subject to the MACT requirements set forth at the 40 CFR part 63, subpart DDD. South Carolina also stated in its

evaluation that Georgia Pacific Wood Products LLC, will comply with MACT requirements set forth at 40 CFR 63, Subpart DDDD. See Appendix R of the South Carolina RACT submittal for details of the RACT assessment including technology restrictions.

III. Final Action

Pursuant to section 110 of the CAA, EPA is approving the revision to South Carolina's SIP revisions addressing negative declarations for applicability of Groups I, II, III and IV CTG for the Rock Hill-Fort Mill Area; and concerning the RACT requirements related to the 1997 8-hour ozone NAAQS for the Rock Hill-Fort Mill Area which is the portion of York County, South Carolina that is included in the bi-state Charlotte-Gastonia-Rock Hill 1997 8-hour ozone nonattainment area. EPA has evaluated South Carolina's August 31, 2007, February 23, 2009, and July 9, 2009, SIP revisions, and has determined that they meet the applicable requirements of the CAA and EPA regulations, and are consistent with EPA policy for negative declarations for Groups I, II, III and IV CTG, and for RACT.

On March 12, 2008, EPA issued a revised ozone NAAQS. See 73 FR 16436. EPA subsequently announced a reconsideration of the 2008 NAAQS, and proposed new 8-hour ozone NAAQS in January 2010. See 75 FR 2938. In September 2011, EPA withdrew the proposed reconsidered NAAQS and began implementation of the 2008 NAAQS. The current action, however, is being taken to address requirements under the 1997 ozone NAAQS. Requirements for the bi-state Charlotte Area under the 2008 NAAQS will be addressed in the future.

EPA is publishing this rule without prior proposal because the Agency views this as a non-controversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comment be filed. This rule will be effective on January 27, 2012 without further notice unless the Agency receives adverse comment by December 28, 2011. If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. If no such comments are received, the public is advised this rule will be effective on *January 27, 2012* and no further action will be taken on the proposed rule.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. 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 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 1997 8-hour ozone RACT SIP direct final approval for the South Carolina portion of the bi-state Charlotte Area does not have tribal implications as specified by Executive Order 13175 (65 FR 67,249, November 9, 2000), because the determination does not have substantial direct effects on an Indian Tribe. The Catawba Indian Nation Reservation is located within the South Carolina portion of the bi-state Charlotte nonattainment area. Generally SIPs do not apply in Indian country throughout the United States. However, for purposes of the Catawba Indian Nation Reservation in Rock Hill, the South Carolina SIP does apply within the Reservation. Pursuant to the Catawba Indian Claims Settlement Act, S.C. Code Ann. 27–16–120, ''all state and local environmental laws and regulations apply to the [Catawba Indian Nation] and Reservation and are fully enforceable by all relevant state and local agencies and authorities.'' Pursuant to Executive Order 13175 and the EPA Policy on Consultation and Coordination with Indian Tribes, in a letter dated October 13, 2011, EPA extended the opportunity for consultation between EPA and Catawba. Consultation with the Catawba Tribe began on October 14, 2011, and ended on October 31, 2011. The views and concerns raised by the Catawba Indian Nation during consultation have been taken into account in this direct final rule. Furthermore, EPA notes today's action 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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 27, 2012. 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register,** rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: November 8, 2011.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

40 CFR part 52 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 PP—South Carolina

■ 2. Section 52.2120(e) is amended by adding new entries at the end of the table for ''Applicability of Reasonably Available Control Technology for the Portion of York County, South Carolina,'' ''Negative Declaration for Applicability of Groups I Control Techniques Guidelines for York County, South Carolina,'' ''Negative Declaration for Applicability of Group II Control Techniques Guidelines for York County, South Carolina,'' ''Negative Declaration for Applicability of Groups III Control Techniques Guidelines for York County, South Carolina,'' and ''Negative Declaration for Applicability of Group IV Control Techniques Guidelines for York County, South Carolina'' to read as follows:

§ 52.2120 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED SOUTH CAROLINA NON-REGULATORY PROVISIONS

Provision	State effective date	EPA approval date	Explanation
* * *		* *	* *
Applicability of Reasonably Available Control Technology for the Portion of York County, South Carolina.	8/31/2007	11/28/11 ..... [Insert citation of publication].	Demonstration for Bowater Coated Paper Division; for Cytec Carbon Fibers; and for Georgia-Pacific—Catawba Hardboard Plant.
Negative Declaration for Applicability of Groups I Control Techniques Guidelines for York County, South Carolina.	8/31/2007	11/28/11 ..... [Insert citation of publication].	Applicable to the 1997 8-hour Ozone boundary in York County only (Rock Hill-Fort Mill Area Transportation Study Metropolitan Planning Organization Area).
Negative Declaration for Applicability of Group II Control Techniques Guidelines for York County, South Carolina.	8/31/2007	11/28/11 ..... [Insert citation of publication].	Applicable to the 1997 8-hour Ozone boundary in York County only (Rock Hill-Fort Mill Area Transportation Study Metropolitan Planning Organization Area).
Negative Declaration for Applicability of Group III Control Techniques Guidelines for York County, South Carolina.	2/23/2009	11/28/11 ..... [Insert citation of publication].	Applicable to the 1997 8-hour Ozone boundary in York County only (Rock Hill-Fort Mill Area Transportation Study Metropolitan Planning Organization Area).
Negative Declaration for Applicability of Group IV Control Techniques Guidelines for York County, South Carolina.	7/7/2009	11/28/11 ..... [Insert citation of publication].	Applicable to the 1997 8-hour Ozone boundary in York County only (Rock Hill-Fort Mill Area Transportation Study Metropolitan Planning Organization Area).

[FR Doc. 2011–30303 Filed 11–25–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[MB Docket No. 03–185; FCC 11–110]

Digital Low Power Television, Television Translator, and Television Booster Stations and To Amend Rules for Digital Class A Television Stations

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection requirements contained in a final rule published July 27, 2011. The information collection requirements were approved on February 7, 2011, and November 17, 2011, by OMB.

DATES: The amendments to 47 CFR 73.624(g), published at 76 FR 44821, July 27, 2011, are effective on November 28, 2011.

FOR FURTHER INFORMATION CONTACT: For additional information contact Cathy Williams on (202) 418–2918 or via email to: *cathy.williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that on February 7, 2011 and November 17, 2011, OMB approved, for a period of three years, the information collection requirements contained in 47 CFR 73.624(g). The Commission publishes this document to announce the effective date of this rule section. See, In the Matter of Amendment of Parts 73 and 74 of the Commission's Rules to Establish Rules for Digital Low Power Television, Television Translator, and Television Booster Stations and to Amend Rules for Digital Class A Television Stations, MB Docket No. 03–185; FCC 11–110, 76 FR 44821, July 27, 2011.

Synopsis

As required by the Paperwork Reduction Act of 1995, (44 U.S.C. 3507), the Commission is notifying the public that it received OMB approval on February 7, 2011 and November 17, 2011, for the information collection requirements contained in 47 CFR 73.624(g). Under 5 CFR part 1320, an

agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid OMB Control Number.

The OMB Control Number is 3060–0906 and the total annual reporting burdens for respondents for this information collection are as follows:

OMB Control Number: 3060–0906.

Title: 47 CFR 73.624(g), FCC Form 317.

OMB Approval Dates: February 7, 2011 and November 17, 2011.

OMB Expiration Date: November 30, 2014.

Form Number: FCC Form 317.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for profit entities; Not for profit institutions; State, local or Tribal government.

Number of Respondents/Responses: 9,351 respondents; 18,782 responses.

Estimated Hours per Response: 2–4 hours.

Frequency of Response: Recordkeeping requirement; Annual reporting requirement.

Total Annual Burden: 56,346 hours.

Total Annual Cost: $1,408,650.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in Sections 154(i), 301, 303, 336 and 403 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Act Assessment: No impact(s).

Needs and Uses: 47 CFR 73.624(g) adds a new group of respondents to this collection (namely, ''low power television, TV translator, and Class A television station DTV licensees''). The Commission has also revised FCC Form 317 and its instructions to indicate that low power television, TV translator, and Class A television station DTV licensees are required to file FCC Form 317 and to report their ancillary and supplementary services, make the required payment to the Commission, and retain the appropriate records.

Section 73.624(g) also adds a new group of respondents to this collection (namely, ''low power television, TV translator, and Class A television station DTV stations operating pursuant to STA''). The Commission has also revised FCC Form 317 and its instructions to indicate that low power television, TV translator, and Class A television station DTV stations operating pursuant to STA are required to file FCC Form 317 (which includes reporting their ancillary and supplementary services, making the required payment to the Commission, and retaining the appropriate records).

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2011–30424 Filed 11–25–11; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 225

[FRA–2008–0136, Notice No. 4]

RIN 2130–ZA05

Adjustment of Monetary Threshold for Reporting Rail Equipment Accidents/Incidents for Calendar Year 2012

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This rule increases the rail equipment accident/incident reporting threshold from $9,400 to $9,500 for certain railroad accidents/incidents involving property damage that occur during calendar year 2012. This action is needed to ensure that FRA's reporting requirements reflect cost increases that have occurred since the reporting threshold was last published in December of 2010.

DATES: This regulation is effective January 1, 2012.

FOR FURTHER INFORMATION CONTACT: Kebo Chen, Staff Director, U.S. Department of Transportation, Federal Railroad Administration, Office of Safety Analysis, RRS–22, Mail Stop 25, West Building 3rd Floor, Room W33–314, 1200 New Jersey Ave. SE., Washington, DC 20590 (telephone (202) 493–6079); or Gahan Christenson, Trial Attorney, U.S. Department of Transportation, Federal Railroad Administration, Office of Chief Counsel, RCC–10, Mail Stop 10, West Building 3rd Floor, Room W31–204, 1200 New Jersey Ave. SE., Washington, DC 20590 (telephone (202) 493–1381).

SUPPLEMENTARY INFORMATION:

Background

A ''rail equipment accident/incident'' is a collision, derailment, fire, explosion, act of God, or other event involving the operation of railroad on-track equipment (standing or moving) that results in damages to railroad on-track equipment, signals, tracks, track structures, or roadbed, including labor costs and the costs for acquiring new equipment and material, greater than the reporting threshold for the year in which the event occurs. 49 CFR 225.19(c). Each rail equipment accident/incident must be reported to FRA using the Rail Equipment Accident/Incident Report (Form FRA F 6180.54). 49 CFR 225.19(b) and (c). As revised, effective in 1997, paragraphs (c) and (e) of 49 CFR 225.19 provide that the dollar figure that constitutes the reporting threshold for rail equipment accidents/incidents will be adjusted, if necessary, every year in accordance with the procedures outlined in appendix B to part 225 to reflect any cost increases or decreases.

New Reporting Threshold

Approximately one year has passed since the rail equipment accident/incident reporting threshold was revised. 75 FR 75911 (December 7, 2010). Consequently, FRA has recalculated the threshold, as required by § 225.19(c), based on increased costs for labor and increased costs for equipment. FRA has determined that the current reporting threshold of $9,400, which applies to rail equipment accidents/incidents that occur during calendar year 2011, should increase by $100 to $9,500 for equipment accidents/incidents occurring during calendar year 2012, effective January 1, 2012. The specific inputs to the equation set forth in appendix B (*i.e., Tnew* = *Tprior* * [1 + 0.4(*Wnew*− *Wprior*)/*Wprior* + 0.6(*Enew*− *Eprior*)/100]) to part 225 are:

Tprior	Wnew	Wprior	Enew	Eprior
$9,400	$24.92646	$24.73606	186.36666	184.56666

Where: *Tnew* = New threshold; *Tprior* = Prior threshold (with reference to the threshold, ''prior'' refers to the previous threshold rounded to the nearest $100, as reported in the **Federal Register**); *Wnew* = New average hourly wage rate, in dollars; *Wprior* = Prior average hourly wage rate, in dollars; *Enew* = New equipment average Producer Price Index (PPI) value; *Eprior* = Prior equipment average PPI value. Using the above figures, the calculated new threshold, (Tnew) is $9,530.47, which is rounded to the nearest $100 for a final new reporting threshold of $9,500.

Notice and Comment Procedures

In this rule, FRA has recalculated the monetary reporting threshold based on the formula discussed in detail and adopted, after notice and comment, in the final rule published December 20, 2005, 70 FR 75414. FRA has found that both the current cost data inserted into this pre-existing formula and the original cost data that they replace were obtained from reliable Federal government sources. FRA has found that this rule imposes no additional burden on any person, but rather provides a benefit by permitting the valid comparison of accident data over time. Accordingly, finding that notice and comment procedures are either impracticable, unnecessary, or contrary to the public interest, FRA is proceeding directly to the final rule.

Regulatory Impact

Executive Orders 12866 and 13563 and DOT Regulatory Policies and Procedures

This rule has been evaluated in accordance with existing policies and procedures, and determined to be non-significant under both Executive Order 12866 and 13563 in addition to DOT policies and procedures (44 FR 11034 (Feb. 26, 1979)).

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612) requires a review of proposed and final rules to assess their impact on small entities, unless the Secretary certifies that the rule will not have a significant economic impact on a substantial number of small entities. Pursuant to Section 312 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), FRA has issued a final policy that formally establishes ''small entities'' as including railroads that meet the line-haulage revenue requirements of a Class III railroad. 49 CFR part 209, app. C. For other entities, the same dollar limit in revenues governs whether a railroad, contractor, or other respondent is a small entity. *Id.*

About 721 of the approximately 754 railroads in the United States are considered small entities by FRA. FRA certifies that this final rule will have no significant economic impact on a substantial number of small entities. To the extent that this rule has any impact on small entities, the impact will be neutral or insignificant. The frequency of rail equipment accidents/incidents, and therefore also the frequency of required reporting, is generally proportional to the size of the railroad. A railroad that employs thousands of employees and operates trains millions of miles is exposed to greater risks than one whose operation is substantially smaller. Small railroads may go for months at a time without having a reportable occurrence of any type, and even longer without having a rail equipment accident/incident. For example, current FRA data indicate that 3,000 rail equipment accidents/incidents were reported in 2006, with small railroads reporting 379 of them. Data for 2007 show that 2,694 rail equipment accidents/incidents were reported, with small railroads reporting 368 of them. Data for 2008 show that 2,478 rail equipment accidents/incidents were reported, with small railroads reporting 296 of them. In 2009, 1,905 rail equipment accidents/incidents were reported, and small railroads reported 272 of them. In 2010, 1,888 rail equipment accidents/incidents were reported, with small railroads reporting 258 of them. On average for those five calendar years, small railroads reported about 13% (ranging from 12% to 14%) of the total number of rail equipment accidents/incidents. FRA notes that these data are accurate as of the date of issuance of this final rule, and are subject to minor changes due to additional reporting. Absent this rulemaking (*i.e.,* any increase in the monetary reporting threshold), the number of reportable accidents/incidents would increase, as keeping the 2011 threshold in place would not allow it to keep pace with the increasing dollar amounts of wages and rail equipment repair costs. Therefore, this rule will be neutral in effect. Increasing the reporting threshold will slightly decrease the recordkeeping burden for railroads over time. Any recordkeeping burden will not be significant and will affect the large railroads more than the small entities, due to the higher proportion of reportable rail equipment accidents/incidents experienced by large entities.

Paperwork Reduction Act

There are no new information collection requirements associated with this final rule. Therefore, no estimate of a public reporting burden is required.

Federalism Implications

Executive Order 13132, entitled, ''Federalism,'' signed on August 4, 1999, requires that each agency ''in a separately identified portion of the preamble to the regulation as it is to be issued in the Federal Register, provide[] to the Director of the Office of Management and Budget a federalism summary impact statement, which consists of a description of the extent of the agency's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of the State and local officials have been met * * *.'' This rulemaking action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132. This rule will not have a substantial direct effect on States, on the relationship between the National Government and the States, or on the distribution of power and the responsibilities among the various levels of government, as specified in the Executive Order 13132. Accordingly, FRA has determined that this rule will not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism assessment. Accordingly, a federalism assessment has not been prepared.

Environmental Impact

FRA has evaluated this regulation in accordance with its ''Procedures for Considering Environmental Impacts'' (FRA's Procedures) (64 FR 28545 (May 26, 1999)) as required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), other environmental statutes, Executive Orders, and related regulatory requirements. FRA has determined that this regulation is not a major FRA action (requiring the preparation of an environmental impact statement or environmental assessment) because it is categorically excluded from detailed environmental review pursuant to section 4(c)(20) of FRA's Procedures. 64 FR 28545, 28547 (May 26, 1999). In accordance with section 4(c) and (e) of FRA's Procedures, the agency has further concluded that no extraordinary circumstances exist with respect to this regulation that might trigger the need for a more detailed environmental review. As a result, FRA finds that this

regulation is not a major Federal action significantly affecting the quality of the human environment.

Unfunded Mandates Reform Act of 1995

Pursuant to Section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531), each Federal agency ''shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law).'' Section 202 of the Act (2 U.S.C. 1532) further requires that ''before promulgating any general notice of proposed rulemaking that is likely to result in the promulgation of any rule that includes any Federal mandate that may result in expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of [$140,800,000 or more (as adjusted for inflation)] in any one year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement'' detailing the effect on State, local, and Tribal governments and the private sector. The final rule will not result in the expenditure, in the aggregate, of $140,800,000 or more in any one year, and thus preparation of such a statement is not required.

Energy Impact

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' 66 FR 28355 (May 22, 2001). Under the Executive Order, a ''significant energy action'' is defined as any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: That (1)(i) is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. FRA has evaluated this final rule in accordance with Executive Order 13211. FRA has determined that this final rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Consequently, FRA has determined that this regulatory action is not a ''significant energy action'' within the meaning of Executive Order 13211.

Privacy Act

Anyone is able to search the electronic form of all our 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 you may visit *http://www.regulations.gov*.

List of Subjects in 49 CFR Part 225

Investigations, Penalties, Railroad safety, Reporting and recordkeeping requirements.

The Rule

In consideration of the foregoing, FRA amends part 225 of chapter II, subtitle B of title 49, Code of Federal Regulations, as follows:

PART 225—[AMENDED]

■ 1. The authority citation for part 225 continues to read as follows:

Authority: 49 U.S.C. 103, 322(a), 20103, 20107, 20901–02, 21301, 21302, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.49.

■ 2. Amend § 225.19 by revising the first sentence of paragraph (c) and revising paragraph (e) to read as follows:

§ 225.19 Primary groups of accidents/incidents.

* * * * *

(c) *Group II—Rail equipment.* Rail equipment accidents/incidents are collisions, derailments, fires, explosions, acts of God, and other events involving the operation of on-track equipment (standing or moving) that result in damages higher than the current reporting threshold (*i.e.,* $6,700 for calendar years 2002 through 2005, $7,700 for calendar year 2006, $8,200 for calendar year 2007, $8,500 for calendar year 2008, $8,900 for calendar year 2009, $9,200 for calendar year 2010, $9,400 for calendar year 2011 and $9,500 for calendar year 2012) to railroad on-track equipment, signals, tracks, track structures, or roadbed, including labor costs and the costs for acquiring new equipment and material. * * *

* * * * *

(e) The reporting threshold is $6,700 for calendar years 2002 through 2005, $7,700 for calendar year 2006, $8,200 for calendar year 2007, $8,500 for calendar year 2008, $8,900 for calendar year 2009, $9,200 for calendar year 2010, $9,400 for calendar year 2011 and $9,500 for calendar year 2012. The procedure for determining the reporting threshold for calendar years 2006 and beyond appears as paragraphs 1–8 of appendix B to part 225.

* * * * *

Issued in Washington, DC, on November 21, 2011.

Joseph C. Szabo,

Administrator.

[FR Doc. 2011–30540 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–06–P

Proposed Rules

Federal Register
Vol. 76, No. 228
Monday, November 28, 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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1254; Directorate Identifier 2010–NM–178–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede an existing airworthiness directive (AD) that applies to certain Model 737–300, –400, and –500 series airplanes. The existing AD currently requires repetitive external detailed inspections or non-destructive inspections to detect cracks in the fuselage skin along the chem-mill steps at stringers S–1 and S–2R, between station (STA) 400 and STA 460, and repair if necessary. Since we issued that AD, we have received reports of additional crack findings of the fuselage skin at the chem-mill steps. This proposed AD would add inspections for cracking in additional fuselage skin locations, and repair if necessary. This proposed AD would also reduce the inspection thresholds and repetitive intervals for certain airplanes. We are proposing this AD to detect and correct fatigue cracking of the fuselage skin panels at the chem-mill steps, which could result in sudden fracture and failure of the fuselage skin panels, and consequent rapid decompression of the airplane.

DATES: We must receive comments on this proposed AD by January 12, 2012.

ADDRESSES: You may send comments by any of the following methods:

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Wayne Lockett, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; phone: (425) 917–6447; fax: (425) 917–6590; email: *wayne.lockett@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1254; Directorate Identifier 2010–NM–178–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

On September 11, 2008, we issued AD 2008–19–03, Amendment 39–15670 (73 FR 56958, October 1, 2008), for certain Model 737–300, –400, and –500 series airplanes. That AD requires repetitive external detailed inspections or non-destructive inspections to detect cracks in the fuselage skin along the chem-mill steps at stringers S–1 and S–2R, between STA 400 and STA 460, and repair if necessary. That AD resulted from reports of cracks in the fuselage skin common to stringers S–1 and S–2R, between STA 400 and STA 460. We issued that AD to detect and correct fatigue cracking of the fuselage skin panels at the chem-mill steps, which could result in sudden fracture and failure of the fuselage skin panels, and consequent rapid decompression of the airplane.

Actions Since Existing AD Was Issued

Since we issued AD 2008–19–03, Amendment 39–15670 (73 FR 56958, October 1, 2008), we received reports of new findings of cracking in the fuselage skin at the chem-mill steps adjacent to the Air Traffic Control antenna. One reported crack was on the inboard side of S–2R at STA 451; the crack measured one inch long. That airplane had accumulated 52,207 total flight cycles. Another reported crack was on the left-hand side of stringer S–1 at STA 431. That airplane had accumulated 43,565 total flight cycles. Other cracks were located on the left-hand side of stringer S–1, between STA 400 and STA 460 on certain airplanes. The cause of the cracking was fatigue due to high-tension stresses and local bending at the edge of the chem-mill pockets of the bonded skin. It was also determined that the detailed inspection alone (one method required by the existing AD) is not adequate to detect the cracking.

Relevant Service Information

We reviewed Boeing Alert Service Bulletin 737–53A1293, Revision 1,

dated July 7, 2010; and Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011. (Boeing Alert Service Bulletin 737–53A1293, dated August 13, 2008, was referred to for accomplishing the actions in AD 2008–19–03, Amendment 39–15670 (73 FR 56958, October 1, 2008)).

Boeing Alert Service Bulletin 737–53A1293, Revision 1, dated July 7, 2010, adds an ultrasonic phased array inspection to the options for non-destructive inspections (NDI) specified in Boeing Alert Service Bulletin 737–53A1293, dated August 13, 2008, and combines the detailed inspection and the NDI in lieu of doing either Option 1 (a detailed inspection) or Option 2 (an NDI). Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011, clarifies repair instructions for specific findings.

The initial inspection compliance times range between the following, depending on configuration: (1) Before the accumulation 33,000 total flight cycles, or within 500 flight cycles after the date on this service bulletin, whichever is later; and (2) before the accumulation of 35,000 total flight cycles, or within 1,800 flight cycles after the date on this service bulletin, whichever is later.

The repetitive inspection intervals range between 500 and 2,400 flight cycles, depending on the inspection option and configuration.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would retain certain requirements of AD 2008–19–03, Amendment 39–15670 (73 FR 56958, October 1, 2008). This proposed AD would also require accomplishing the actions specified in Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011, except as discussed under ''Differences Between the AD and the Service Information.''

Differences Between the AD and the Service Information

Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011, specifies contacting the manufacturer for instructions on how to repair a certain condition, but this AD requires repairing that condition in one of the following ways:

- Using a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization whom we have authorized to make those findings.

The post-repair inspection specified in Tables 4 and 6 of paragraph 1.E., ''Compliance,'' of Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011, is not required by this proposed AD.

Interim Action

We consider this proposed AD interim action. If final action is identified later, we might consider further rulemaking then.

Costs of Compliance

We estimate that this proposed AD affects 596 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections (required actions in AD 2008–19–03, Amendment 39–15670 (73 FR 56958, October 1, 2008).	5 work-hours × $85 per hour = $425 per inspection cycle.	N/A	$425 per inspection cycle	$253,300 per inspection cycle.
New inspections (proposed action).	Between 7 and 15 work-hours, depending on airplane configuration = between $595 and $1,275 per inspection cycle.	N/A	Between $595 and $1,275 per inspection cycle.	Between $354,620 and $759,900 per inspection cycle.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2008–19–03, Amendment 39–15670 (73 FR 56958, October 1, 2008), and adding the following new AD:

The Boeing Company: Docket No. FAA–2011–1254; Directorate Identifier 2010–NM–178–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by January 12, 2012.

Affected ADs

(b) This AD supersedes AD 2008–19–03, Amendment 39–15670 (73 FR 56958, October 1, 2008).

Applicability

(c) This AD applies to Model 737–300, –400, and –500 series airplanes, certificated in any category; as identified in Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011.

Subject

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

Unsafe Condition

(e) This AD was prompted by reports of additional crack findings of the fuselage skin at the chem-mill steps. We are issuing this AD to detect and correct fatigue cracking of the fuselage skin panels at the chem-mill steps, which could result in sudden fracture and failure of the fuselage skin panels, and consequent rapid decompression of the airplane.

Compliance

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

Repetitive Inspections

(g) At the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011, except as provided by paragraph (j) and (k) of this AD: Do both a detailed inspection and a nondestructive inspection (NDI) (medium frequency eddy current, magneto optical imaging, C-scan, or ultrasonic phased array) to detect cracks in the fuselage skin along the chem-mill steps at stringers S–1 and S–2R, between station (STA) 400 and STA 460, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011. Repeat the applicable inspections thereafter at intervals not to exceed those specified in paragraph 1.E., ''Compliance,'' of Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011.

Repair

(h) If any crack is found during any inspection required by paragraph (g) of this AD, before further flight, repair in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011; except as provided by paragraph (i) of this AD. Installation of a repair that meets the conditions specified in paragraph 1.E., ''Compliance,'' of Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011, terminates the repetitive inspections required by paragraph (g) of this AD for the repaired area only.

(i) If any crack is found during any inspection required by paragraph (g) of this AD and Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011, specifies to contact Boeing for repair: Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (n) of this AD.

Exceptions to Service Bulletin

(j) Where Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011, specifies a compliance time relative to the date on that service bulletin, this AD requires compliance within the specified compliance time after the effective date of this AD.

(k) Where the Condition column of paragraph 1.E., ''Compliance,'' of Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011, specifies a condition based on whether an airplane has or has not been inspected, this AD bases the condition on whether an airplane has or has not been inspected as of the effective date of this AD.

(l) The post-repair inspection specified in Tables 4 and 6 of paragraph 1.E., ''Compliance,'' of Boeing Service Bulletin 737–53A1293, Revision 2, August 10, 2011, is not required by this AD.

Note 1: The damage tolerance inspections specified in Tables 4 and 6 of paragraph 1.E., ''Compliance,'' of Boeing Service Bulletin 737–53A1293, Revision 2, August 10, 2011, may be used in support of compliance with section 121.1109(c)(2) or 129.109(c)(2) of the Federal Aviation Regulations (14 CFR 121.1109(c)(2) or 14 CFR 129.109(c)(2)).

Credit for Actions Accomplished in Accordance With Previous Service Information

(m) Actions done before the effective date of this AD in accordance with Boeing Alert Service Bulletin 737–53A1293, Revision 1, July 7, 2010, are acceptable for compliance with the corresponding actions required by this AD.

Alternative Methods of Compliance (AMOCs)

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

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

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

(4) AMOCs approved for AD 2008–19–03, Amendment 39–15670 (73 FR 56958, October 1, 2008), are approved as AMOCs for the corresponding requirements in this AD.

Related Information

(o) For more information about this AD, contact Wayne Lockett, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; phone: (425) 917–6447; fax: (425) 917–6590; email: *wayne.lockett@faa.gov*.

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

Issued in Renton, Washington, on November 16, 2011.

John P. Piccola,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–30559 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1251; Directorate Identifier 2011–NM–017–AD]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 190 airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

It has been found the occurrence of damage on the rod end of the Main Landing Gear (MLG) retraction actuator. The ANAC [Agência Nacional de Aviação Civil] is issuing this AD to prevent breakage of the MLG retracting actuator rod, which may result in MLG extension with no hydraulic damping and consequent damage to the locking mechanism and collapse of the MLG.

* * * * *

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by January 12, 2012.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), Technical Publications Section (PC 060), Av. Brigadeiro Faria Lima, 2170–Putim–12227–901 São Jose dos Campos–SP–BRASIL; telephone +55 12 3927–5852 or +55 12 3309–0732; fax +55 12 3927–7546; email *distrib@embraer.com.br;* Internet *http://www.flyembraer.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call (425) 227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Cindy Ashforth, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2768; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1251; Directorate Identifier 2011–NM–017–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

The Agencia Nacional De Aviacao Civil—Brazil (ANAC), which is the airworthiness authority for Brazil, has issued Brazilian Airworthiness Directive 2011–02–01, dated February 12, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

It has been found the occurrence of damage on the rod end of the Main Landing Gear (MLG) retraction actuator. The ANAC [Agência Nacional de Aviação Civil] is issuing this AD to prevent breakage of the MLG retracting actuator rod, which may result in MLG extension with no hydraulic damping and consequent damage to the locking mechanism and collapse of the MLG.

* * * * *

Required actions include performing a one-time general visual inspection to determine if a certain part number is installed on the left-hand and right-hand MLG retraction actuator, and if necessary, performing a general visual inspection for discrepancies (such as cracks, damage, and movement) between the actuator rod end and shock strut lug of the MLG retraction actuator. The corrective action includes, if any discrepancy is found during any inspection, including any movement between the actuator rod-end and shock strut lug, replacing the MLG retraction actuator, and as applicable the anti-rotation pin and the attachment bolt with a new pin and bolt; and replacing the actuator with new actuator having a certain part number, and modifying the attachment points. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

EMBRAER has issued Service Bulletin 190–32–0036, dated October 4, 2010; and Service Bulletin 190–32–0037, dated October 6, 2010. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

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

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a Note within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 73 products of U.S. registry.

We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $6,205, or $85 per product.

In addition, we estimate that any necessary follow-on actions would take about 6 work-hours and require parts costing $0, for a cost of $510 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Empresa Brasileira de Aeronautica S.A. (EMBRAER): Docket No. FAA–2011–1251; Directorate Identifier 2011–NM–017–AD.

Comments Due Date

(a) We must receive comments by January 12, 2012.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 190–100 STD, –100 LR, –100 ECJ, and –100 IGW airplanes; and Model ERJ 190–200 STD, –200 LR, and –200 IGW airplanes; certificated in any category; all serial numbers.

Subject

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

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

It has been found the occurrence of damage on the rod end of the Main Landing Gear (MLG) retraction actuator. The ANAC [Agência Nacional de Aviação Civil] is issuing this AD to prevent breakage of the MLG retracting actuator rod, which may result in MLG extension with no hydraulic damping and consequent damage to the locking mechanism and collapse of the MLG.

* * * * *

Compliance

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

Actions

(g) Within 30 days after the effective date of this AD, do a one-time general visual inspection to determine if part number (P/N) 190–70980–403 is installed on the left-hand and right-hand MLG retraction actuator. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number of the MLG retraction actuator can be conclusively determined from that review.

Note 1: For the purpose of this AD, a general visual inspection (GVI) is: ''A visual examination of an interior or exterior area, installation or assembly to detect obvious damage, failure or irregularity. This level of inspection is made from within touching distance, unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight or droplight, and may require removal or opening of access panels or doors. Stands, ladders or platforms may be required to gain proximity to the area being checked.''

(1) No further action is required by paragraph (g) of this AD if no MLG retraction actuator having P/N 190–70980–403 is found.

(2) If any MLG retraction actuator having P/N 190–70980–403 is found, do a GVI of the actuator and bolt (P/N 2821–0028) for discrepancies (such as cracks, damage, and movement between the actuator rod end and shock strut lug of the MLG retraction actuator), in accordance with ''Part I'' of the Accomplishment Instructions of EMBRAER Service Bulletin 190–32–0036, dated October 4, 2010, within the applicable compliance time specified in paragraphs (g)(2)(i) and (g)(2)(ii) of this AD. Repeat the inspection, thereafter, at intervals not to exceed 3,500 flight cycles, until the actions required by paragraph (j) of this AD are done.

(i) For any MLG retraction actuator that has accumulated fewer than 3,500 total flight cycles as of the effective date of this AD, do the GVI of the actuator before the accumulation of 4,500 total flight cycles on the MLG retraction actuator.

(ii) For any MLG retraction actuator that has accumulated 3,500 total flight cycles or more as of the effective date of this AD, do the GVI of the actuator within 1,000 flight cycles after the effective date of this AD.

(h) If any discrepancy is found during any inspection required by paragraph (g)(2) of this AD, including any movement between the actuator rod-end and shock strut lug, before further flight, replace the MLG retraction actuator, and as applicable the anti-rotation pin and the attachment bolt, in accordance with ''Part II'' and ''Part III,'' as applicable, of EMBRAER Service Bulletin 190–32–0036, dated October 4, 2010; except where EMBRAER Service Bulletin 190–32–0036, dated October 4, 2010, specifies to contact the manufacturer, before further flight repair in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, or Agência Nacional de Aviação Civil (or its delegated agent).

(i) Before any MLG retraction actuator having P/N 190–70980–403 accumulates

12,000 total flight cycles or within 1,000 flight cycles after the effective date of this AD, whichever occurs later, replace the actuator with a new actuator having P/N 190–70980–405, and modify the attachment points, in accordance with ''Part I'' and ''Part II,'' as applicable, of the Accomplishment Instructions of EMBRAER Service Bulletin 190–32–0037, dated October 6, 2010.

(j) For all actuators: Within 20,000 flight cycles or within 96 months after the effective date of this AD, whichever occurs first, do the replacement and modification, as applicable, in accordance with ''Part III'' of EMBRAER Service Bulletin 190–32–0037, dated October 6, 2010. Doing the actions in this paragraph is a terminating action for the requirements specified in paragraphs (g), (h), and (i) of this AD.

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows: Brazilian Airworthiness Directive 2011–02–01, dated February 12, 2011, requires replacing the MLG retraction actuator, and as applicable, the anti-rotation pin and attachment bolt within the next 500 flight cycles if any discrepancy is found. However, if any discrepancy is found, this AD requires replacing the MLG retraction actuator, and as applicable, the anti-rotation pin and attachment bolt, before further flight.

Other FAA AD Provisions

(k) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Cindy Ashforth, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2768; fax (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

Related Information

(l) Refer to MCAI Brazilian Airworthiness Directive 2011–02–01, dated February 12, 2011; EMBRAER Service Bulletin 190–32–0036, dated October 4, 2010; and EMBRAER Service Bulletin 190–32–0037, dated October 6, 2010; for related information.

Issued in Renton, Washington, on November 10, 2011.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–30571 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1255; Directorate Identifier 2010–NM–182–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede two existing airworthiness directives (AD) that apply to Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. The first existing AD currently requires, for certain airplanes, repetitive inspections of the Station (STA) 348.2 frame to detect cracking under the stop fittings and intercostal flanges at stringers S–14L, S–15L, and S–16L, and corrective action if necessary. The second existing AD currently requires repetitive inspections to detect cracking of the intercostal webs, attachment clips, and stringer splice channels, and corrective action if necessary. Since we issued those ADs, we have received reports of cracking of the STA 348.2 frame above the two outboard fasteners attaching the frame inner chord and door stop fittings, and in the outboard chord at stringer S–16L. We have also received reports of missing fasteners in the STA 348.2 frame inner chord. This proposed AD would require additional airplanes to do the inspection for cracking under the stop fittings; extend the repetitive interval for certain airplanes; add a one-time inspection to detect missing fasteners; and update or add certain inspection and repair instructions. This proposed AD would also require, for certain airplanes, repetitive inspections of the cargo barrier net fitting for cracking and repair if necessary. This proposed AD would also add, for certain airplanes, repetitive inspections for cracking of the S–15L aft intercostal, and repair if necessary. We are proposing this AD to detect and correct fatigue cracking of the intercostals on the forward and aft sides of the forward entry door cutout, which could result in loss of the forward entry door and rapid decompression of the airplane.

DATES: We must receive comments on this proposed AD by January 12, 2012.

ADDRESSES: You may send comments by any of the following methods:

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (*phone:* (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Alan Pohl, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; *phone:* (425) 917–6450; *fax:* (425) 917–6590; *email: Alan.Pohl@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1255; Directorate Identifier 2010–NM–182–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

On April 20, 2004, we issued AD 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004), for all Boeing Model 737–200C series airplanes. That AD requires repetitive inspections of the Station (STA) 348.2 frame to detect cracking under the stop fittings and intercostal flanges at Stringers S–14L, S–15L, and S–16L; and corrective action if necessary. That AD resulted from a report of cracks in the STA 348.2 frame on a Boeing Model 737–200C series airplane. We issued that AD to detect and correct fatigue cracking of the intercostals on the forward and aft sides of the forward entry door cutout, which could result in the loss of the forward entry door and rapid decompression of the airplane.

On July 23, 2009, we issued AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009), for certain Boeing Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. That AD requires repetitive inspections of the intercostal webs, attachment clips, and stringer splice channels for cracks; and corrective action if necessary. That AD resulted from reports of fatigue cracks on several Boeing Model 737–200 series airplanes. We issued that AD to detect and correct fatigue cracking of the intercostals on the forward and aft sides of the forward entry door, which could result in loss of the forward entry door and rapid decompression of the airplane.

Actions Since Existing ADs Were Issued

Since we issued AD 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004), we have received reports of cracking above the two outboard fasteners attaching the frame inner chord and door stop fitting of the STA 348.2 frame at S–15L. The cracking was reported on seven airplanes that had accumulated between 19,185 and 64,800 flight cycles (AD 2004–09–09 applies only to Model 737–200C airplanes). Cracking has also been found in the outboard chord at S–16L. In addition, we have received reports of 10 airplanes with missing fasteners in the STA 348.2 frame inner chord at S–7L through S–15L.

In addition, the requirement to inspect the intercostal on the aft side at S–14L to S–16L is common to both AD 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004), and AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009). Service history indicates that the repetitive inspection interval of 6,000 flight cycles for that area, as required by AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009), is adequate to ensure continued operational safety. The repetitive interval required by AD 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004), is 4,500 flight cycles.

Boeing Commercial Airplanes has received a Organization Designation Authorization (ODA). We have revised paragraph (h) of this proposed AD to delegate the authority to approve an alternative method of compliance for any repair required by this AD to the Boeing Commercial Airplanes ODA rather than a Designated Engineering Representative (DER).

Relevant Service Information

We reviewed Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010. The procedures in Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010, differ from those in 737–53A1204, Revision 1, dated March 26, 2007 (the appropriate source of service information for AD 2009–16–14 (74 FR 38901, August 5, 2009)), as follows:

- Repetitive detailed and high frequency eddy current (HFEC) inspections for cracking of the S–15L aft intercostal between body station (BS) 348.2 and BS 360 and a detailed inspection of the cargo barrier net fitting at the intercostal are added for Model 737–200C airplanes.
- New repair instructions are added for cracking found at the S–14L, S–15L, and S–16L intercostals. The repair includes either doing actions specified in Boeing Alert Service Bulletin 737–53A1240, Revision 1, dated June 29, 2010 (described below), or, if a crack is at the S–15L aft intercostal or the damage at other intercostal locations is outside certain parameters covered in Boeing Alert Service Bulletin 737–53A1240, Revision 1, Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010, specifies contacting Boeing for repair instructions.

We also reviewed Boeing Alert Service Bulletin 737–53A1240, Revision 1, dated June 29, 2010. The procedures in Boeing Alert Service Bulletin 737–53A1240, Revision 1, dated June 29, 2010, differ from those in Boeing Alert Service Bulletin 737–53A1240, dated April 10, 2003 (the appropriate source of service information for AD 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004)), as follows:

- All Model 737–100, –200, –300, –400, and –500 series airplanes (i.e., line numbers 1 through 3132) are added to the effectivity. For these airplanes, the service bulletin specifies procedures for inspecting under the stop fitting by doing HFEC and surface eddy current inspections for cracking of the frame, HFEC inspections for cracking of the reinforcement angle and shear web, and doing a detailed inspection for cracking of the STA 348.2 frame outer chord, inner chord, and reinforcement angle, and corrective actions if necessary. The corrective actions include replacing certain cracked parts with new parts, and if a crack is found in the frame outer chord, contacting Boeing for repair instructions and doing the repair.
- For Model 737–200C airplanes, the repetitive interval for the HFEC inspection of the STA 348.2 frame is extended from 4,500 flight cycles to 6,000 flight cycles.
- For Model 737–100, –200, –300, –400, and –500 series airplanes, a one-time detailed inspection is added to detect missing fasteners of the STA 348.2 frame inner chord at S–7L through S–15L. If any fastener is missing, the service bulletin specifies to contact Boeing for repair instructions.
- For all airplanes, intercostal inspections for cracking between STA 348.2 and STA 360 are now specified in Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010. Previously, for the intercostals at S–14 through S–16L, this inspection was common to both Boeing Alert Service Bulletin 737–53A1204 and Boeing Alert Service Bulletin 737–53A1240 for Model 737–200C airplanes.
- For Group 3 airplanes, instructions are added for repair of the STA 348.2 frame inner chord, reinforcement angle, and shear web; and of the door stop intercostals at S–14L through S16L.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would retain certain requirements of AD 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004) and AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009). This proposed AD would add airplanes to the applicability for the HFEC inspection for cracking of the stop fittings at the shear web at STA 348.2 frame; extend the repetitive interval for the HFEC inspection of the STA 348.2 frame for Model 737–200C airplanes; add an inspection to detect missing fasteners of the STA 348.2 frame inner chord; and update or add certain inspection and repair instructions. This proposed AD would also require accomplishing the actions specified in the service information described previously.''

Changes to Existing ADs

Since those ADs were issued, the AD format has been revised, and certain paragraphs have been rearranged. As a result, the corresponding paragraph identifiers have changed in this proposed AD, as listed in the following tables:

REVISED PARAGRAPH IDENTIFIERS

Requirement in AD 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004)	Corresponding requirement in this proposed AD
paragraph (a)	paragraph (g)
paragraph (b)	paragraph (h)

Requirement in AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009)	Corresponding requirement in this proposed AD
paragraph (f)	paragraph (i)
paragraph (g)	paragraph (j)
paragraph (h)	paragraph (k)
paragraph (i)	paragraph (l)
paragraph (j)	paragraph (m)
paragraph (k)	paragraph (n)
paragraph (l)	paragraph (o)

Costs of Compliance

We estimate that this proposed AD affects 581 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections for cracking under the stop fittings and intercostal flanges [retained from AD 2004–09–09, Amendment 39-13598 (69 FR 23646, April 30, 2004)].	18 work-hours × $85 per hour = $1,530 [per inspection cycle].	$0	$1,530 [per inspection cycle].	$888,930 [per inspection cycle].
Inspection of areas forward of the aft entry door [retained from AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009)].	2 work-hours × $85 per hour = $170 [per inspection cycle].	$0	$170 [per inspection cycle].	$98,770 [per inspection cycle].
Inspection of areas aft of the forward entry door [retained from AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009)].	1 work-hour × $85 per hour = $85 [per inspection cycle].	$0	$85 [per inspection cycle].	$49,385 [per inspection cycle].
Inspection for missing fasteners [new proposed action].	1 work-hour × $85 per hour = $85.	$476	$561	$325,941.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair of cracking if done in accordance with a method approved by the FAA	Unknown	Unknown	Unknown.
Repair of cracking if done in accordance with Boeing Alert Service Bulletin 737–53A1240	24 work-hours	$11,856	$13,896.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004), and AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009), and adding the following new AD:

The Boeing Company: Docket No. FAA–2011–1255; Directorate Identifier 2010–NM–182–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by January 12, 2012.

Affected ADs

(b) This AD supersedes AD 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004); and AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009).

Applicability

(c) This AD applies to all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes, certificated in any category.

Subject

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

Unsafe Condition

(e) This AD was prompted by reports of cracking of the STA 348.2 frame above the two outboard fasteners attaching the frame inner chord and door stop fittings, and in the outboard chord at stringer S–16L. We have also received reports of missing fasteners in the STA 348.2 frame inner chord. We are issuing this AD to detect and correct fatigue cracking of the intercostals on the forward and aft sides of the forward entry door cutout, which could result in loss of the forward entry door and rapid decompression of the airplane.

Compliance

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

Restatement of the Requirements of AD 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004) With Revised Service Information and Extended Repetitive Intervals

Initial and Repetitive Inspections at STA 348.2 for Model 737–200C Series Airplanes

(g) For Model 737–200C series airplanes: Except as provided by paragraph (h) of this AD, prior to the accumulation of 46,000 total flight cycles, or within 2,250 flight cycles after June 4, 2004 (the effective date of AD 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004)), whichever occurs later, do detailed and eddy current inspections of the STA 348.2 frame for cracking under the stop fittings and intercostal flanges at Stringers 14L, 15L, and 16L by accomplishing paragraphs 3.A. and 3.B.1. through 3.B.7. of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1240, dated April 10, 2003, or by accomplishing Part 1 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1240, Revision 1, dated June 29, 2010. Do the actions in accordance with Boeing Alert Service Bulletin 737–53A1240, dated April 10, 2003; or Revision 1, dated June 29, 2010. Any applicable repair must be accomplished prior to further flight. Repeat the inspections thereafter at intervals not to exceed 6,000 flight cycles. As of the effective date of this AD, only Boeing Alert Service Bulletin 737–53A1240, Revision 1, dated June 29, 2010, may be used.

Corrective Action for Paragraph (g) of This AD

(h) If any crack is found during any inspection required by paragraph (g) of this AD, and Boeing Alert Service Bulletin 737–53A1240, dated April 10, 2003; or Revision 1, dated June 29, 2010; specifies to contact Boeing for appropriate action: Before further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or using a method approved in accordance with the procedures specified in paragraph (t) of this AD.

Restatement of the Requirements of AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009) With Revised Service Information

Initial Compliance Time

(i) For all Model 737–100, –200, –200C, –300, –400, and –500 series airplanes, as identified in Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007: Before the accumulation of 15,000 total flight cycles, or within 4,500 flight cycles after November 1, 2005 (the effective date of AD 2005–20–03, Amendment 39–14296 (70 FR 56361, September 27, 2005)), whichever occurs later: Do the inspections required by paragraphs (k) and (l) of this AD.

(j) For all Model 737–200C series airplanes, as identified in Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007: Before the accumulation of 15,000 total flight cycles, or within 4,500 flight cycles after September 9, 2009 (the effective date of AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009)), whichever occurs later, do the inspection required by paragraph (m) of this AD.

Initial Inspection for Group 1 Configuration Airplanes

(k) For Group 1 airplanes identified in Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007: Perform a detailed inspection for cracking of the intercostal web, attachment clips, and stringer splice channels; and a high frequency eddy current (HFEC) inspection for cracking of the stringer splice channels located forward and aft of the forward entry door; and do all applicable corrective actions before further flight; in accordance with Parts 1 and 2 of the Work Instructions of Boeing Special Attention Service Bulletin 737–53–1204, dated June 19, 2003; or Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007; or in accordance with Parts 1, 2, 4, and 5 of the Work Instructions of Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010. After September 9, 2009 and until the effective date of this AD, Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007; or Revision 2, dated June 24, 2010; may be used. As of the effective date of this AD, only Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010, may be used.

Initial Inspection for Cargo Configuration Airplanes (Forward of the Forward Entry Door)

(l) For Group 2 cargo airplanes identified in Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007: Perform a detailed inspection for cracking of the intercostal webs and attachment clips located forward of the forward entry door, and do all applicable corrective actions before further flight, in accordance with Part 3 of the Work Instructions of Boeing Special Attention Service Bulletin 737–53–1204, dated June 19, 2003; or Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007; or in accordance with Part 3 of Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010. After September 9, 2009 and until the effective date of this AD, Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007; or Revision 2, dated June 24, 2010; may be used. As of the effective date of this AD, only Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010, may be used.

Initial Inspection for Cargo Configuration Airplanes (Aft of the Forward Entry Door)

(m) For Group 2 cargo airplanes identified in Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007: Perform a detailed inspection for cracking of the intercostal webs and attachment clips located aft of the forward entry door, and do all applicable corrective actions before further flight, in accordance with Part 4 of the Work Instructions of Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007; or in accordance with Part 3 of Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010. As of the effective date of this AD, only Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010, may be used.

Repeat Inspections

(n) Repeat the inspections required by paragraphs (k), (l), and (m) of this AD thereafter at intervals not to exceed 6,000 flight cycles after the previous inspection, or within 3,000 flight cycles after September 9, 2009, whichever occurs later.

Exceptions to Boeing Special Attention Service Bulletin 737–53A1204

(o) Do the actions required by paragraphs (i), (j), (k), (l), (m), and (n) of this AD by accomplishing all the applicable actions specified in the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1204, dated June 19, 2003; Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007; or Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010; except as provided by paragraphs (o)(1) and (o)(2) of this AD. After September 9, 2009, and until the effective date of this AD, Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007; or Revision 2, dated June 24, 2010; may be used. As of the effective date of this AD, only Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010, may be used.

(1) Where Boeing Special Attention Service Bulletin 737–53–1204, dated June 19, 2003; Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007; or Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010; specifies to contact Boeing for repair instructions: Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (t) of this AD.

(2) Where Boeing Special Attention Service Bulletin 737–53–1204, dated June 19, 2003; or Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007; specifies a compliance time relative to the date of a service bulletin, this AD requires compliance relative to September 9, 2009. Where Boeing Special Attention Service Bulletin 737–53–1204, dated June 19, 2003; or Boeing Alert Service Bulletin 737–53A1204, Revision 1, dated March 26, 2007; specifies a compliance time relative to the date of the initial release of the service bulletin, this AD requires compliance relative to November 1, 2005 (the effective date of AD 2005–20–03, Amendment 39–14296 (70 FR 56361, September 27, 2005)).

New Requirements of This AD

One-Time Inspection for Missing Fasteners at STA 348.2

(p) For Groups 2 and 3 airplanes identified in Boeing Alert Service Bulletin 737–53A1240, Revision 1, dated June 29, 2010: Within 4,500 flight cycles after the effective date of this AD, do a detailed inspection to detect missing fasteners of the STA 348.2 frame, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1240, Revision 1, dated June 29, 2010, except as required by paragraph (r) of this AD. If any fastener is missing, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (t) of this AD.

Initial and Repetitive Inspections at STA 348.2 for Model 737–100, –200, –300, –400, and –500 Series Airplanes

(q) For Groups 2 and 3 airplanes identified in Boeing Alert Service Bulletin 737–53A1240, Revision 1, dated June 29, 2010: Before the accumulation of 15,000 total flight cycles or within 4,500 flight cycles after the effective date of this AD, do HFEC and surface eddy current inspections for cracking of the frame, HFEC inspections for cracking of the reinforcement angle and shear web, and a detailed inspection for cracking of the STA 348.2 frame outer chord, inner chord, and reinforcement angle, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1240, Revision 1, dated June 29, 2010, except as required by paragraph (r) of this AD. If any crack is found during any inspection required by this paragraph, before further flight, do all applicable corrective actions in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1240, Revision 1, dated June 29, 2010, except as required by paragraph (r) of this AD, and except where that service bulletin specifies to contact Boeing, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (t) of this AD. Repeat the inspections thereafter at intervals not to exceed 6,000 flight cycles.

Exception to Boeing Alert Service Bulletin 737–53A1240

(r) Where Boeing Alert Service Bulletin 737–53A1240, Revision 1, dated June 29, 2010, specifies that for the instructions identified in paragraph 3.B., Work Instructions, and the Figure(s) which give the recommended sequence of steps, the sequence of the steps to do the service bulletin can be changed; the requirements in this AD do not allow the sequence of the steps to be changed.

Initial and Repetitive Inspections of the S–15L Aft Intercostal and Cargo Barrier Net Fitting for Model 737–200C Series Airplanes

(s) For Group 2 airplanes identified in Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010: Before the accumulation of 15,000 total flight cycles, or within 4,500 flight cycles after the effective date of this AD, whichever occurs later, do initial detailed and HFEC inspections for cracking of the S–15L aft intercostal between BS 348.2 and BS 360, and do a detailed inspection of the cargo barrier net fitting at the intercostal, in accordance with Figure 3 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1204, Revision 2, dated June 24, 2010. If any cracking is found, before further flight repair using a method approved in accordance with the procedures specified in paragraph (t) of this AD. Repeat the inspections at intervals not to exceed 6,000 flight cycles.

Alternative Methods of Compliance (AMOCs)

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

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

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

(4) AMOCs approved for AD 2004–09–09, Amendment 39–13598 (69 FR 23646, April 30, 2004), are approved as AMOCs for the corresponding requirements of this AD.

(5) AMOCs approved for AD 2009–16–14, Amendment 39–15987 (74 FR 38901, August 5, 2009), are approved as AMOCs for the corresponding requirements of this AD.

Related Information

(u) For more information about this AD, contact Alan Pohl, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, Washington 98057–3356; phone (425) 917–6450; fax (425) 917–6590; email: *Alan.Pohl@faa.gov.*

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

Issued in Renton, Washington, on November 18, 2011.

John P. Piccola,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–30603 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1250; Directorate Identifier 2010–NM–031–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 707–100 long body, –200, –100B long body, and –100B short body series airplanes; Model 707–300, –300B, –300C, and –400 series airplanes; and Model 720 and 720B series airplanes. For certain airplanes, this proposed AD would require using redefined flight cycle counts, determining the type of material of the horizontal stabilizer, rear spar, upper chords, and lower chords on the inboard and outboard ends of the rear spar; repetitively inspecting for cracking of the horizontal stabilizer components; and repairing or replacing the chord, or modification of chord segments made from 7079 aluminum, if necessary. For all airplanes, this proposed AD would require inspecting certain structurally significant items, and repairing discrepancies if necessary. This proposed AD was prompted by reports of stress corrosion cracking in the chord segments made from 7079 aluminum in the horizontal stabilizer rear spar, and fatigue cracking in the chord segments made from 7075 aluminum. We are proposing this AD to detect and correct stress corrosion and/or fatigue cracking in the horizontal stabilizer, which could compromise the structural integrity of the stabilizer.

DATES: We must receive comments on this proposed AD by January 12, 2012.

ADDRESSES: You may send comments by any of the following methods:

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, Washington 98057–3356; phone: (425) 917–6577; fax: (425) 917–6590, email: *berhane.alazar@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1250; Directorate Identifier 2010–NM–031–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We have received numerous reports of stress corrosion cracking in the chord segments made from 7079 aluminum in the Model 707 horizontal stabilizer rear spar. 7079 aluminum is known to be susceptible to stress corrosion cracking. Development of stress corrosion cracking was slowed by the accomplishment of the actions specified in Boeing 707 Service Bulletin 3356, Revision 2, dated December 12, 1991; and Boeing 707 Service Bulletin 3381, Revision 2, dated January 31, 1991.

In addition, we have received three reports of fatigue cracking in the upper chords of the horizontal stabilizer rear spar near the side of the body. These chords are made from 7075 aluminum. In all three cases, the actions specified in Boeing 707/720 Service Bulletin A3313, Revision 1, dated May 27, 1977, had been incorporated. The fatigue cracking in either 7075 or 7079 material configuration has occurred early in the life of the modified structure. The fatigue cracks were generated by frequent training flights that included multiple touch-and-go cycles, which are most prevalent with military operators. These conditions, if not corrected, could result in stress corrosion and/or fatigue cracking in the horizontal stabilizer, which could compromise the structural integrity of the stabilizer.

Parts made from 7079 aluminum have also been discovered on airplanes that were not originally delivered with those parts. Therefore, to adequately address the stress corrosion cracking in the chord segments in the rear spar of the horizontal stabilizer, it is necessary to determine the chord configuration on the airplane. Furthermore, it is also necessary to carefully maintain a record of that configuration until all chord segments of the rear spar of the horizontal stabilizers that are made from 7079 aluminum have been removed from the fleet. Since horizontal stabilizers can be swapped, it is also necessary to implement the inspections for early fatigue cracking on all airplanes, regardless of their current usage.

Relevant Service Information

We have reviewed Boeing 707 Alert Service Bulletin A3515, dated December

19, 2007 (for Model 707 airplanes); and Boeing 707 Alert Service Bulletin A3516, dated April 4, 2008 (for Model 707 airplanes, and Model 720 and 720B series airplanes).

Boeing 707 Alert Service Bulletin A3515 describes procedures for the following actions:

- Counting flight-cycles to determine the compliance times.
- Determining the type of material of the horizontal stabilizer, rear spar, upper chords, and lower chords on the inboard and outboard ends of the rear spar.
- Repetitive special detailed inspections for cracking of the upper chord on the inboard end of the rear spar of the left and right side horizontal stabilizers.
- Repetitive high frequency eddy current inspections for cracking of the web flanges of the upper and lower chords of the rear spar of the left and right side horizontal stabilizers between stabilizer stations 92.55 and 272.55 for 7079 aluminum components.
- Repetitive low frequency eddy current inspections for cracking of the forward skin flanges of the upper and lower chords of the rear spar in the left and right side horizontal stabilizers from stabilizer stations –13.179 to 272.55 (for lower chords) and 92.55 to 272.55 (for upper chords) for 7079 aluminum components.
- Repetitive special detailed inspections for cracking of the upper chord of the inboard side of the rear spar in the left and right side horizontal stabilizers from stabilizer station –13.179 to 92.55 for 7079 aluminum components.
- Replacing certain chord components made from 7079 aluminum.
- Corrective actions, including replacing the chord(s) with a new chord and contacting Boeing for repair instructions and doing the repair.

Boeing 707 Alert Service Bulletin A3516 specifies one-time inspections of certain structurally significant items, and provides procedures for counting flight cycles for determining the compliance times for the inspections.

Related Rulemaking

We issued AD 85–12–01, Amendment 39–5073 (50 FR 26690, June 28, 1985), for Model 707 and 720 airplanes, as revised (AD 85–12–01 R1, Amendment 39–5439 (51 FR 36002, October 8, 1986). That AD requires structural inspections and repairs or replacement on certain high time airplanes that have exceeded their fatigue design life.

FAA's Determination and Requirements of This Proposed AD

We are proposing this AD because we evaluated all relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs. This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed below. The requirements of this proposed AD do not affect the requirements of AD 85–12–01 R1, Amendment 39–5439 (51 FR 36002, October 8, 1986).

Differences Between the Proposed AD and Service Information

Paragraph (i) of this proposed AD specifies determining the material of the structural components of the horizontal stabilizer in accordance with Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007. That service bulletin also specifies that this action be repeated. We have determined that accomplishing this action one time only will provide an adequate level of safety, provided that the component material is determined before further flight on any replaced horizontal stabilizer.

Paragraph (i) of this proposed AD specifies a special detailed inspection of the upper chords, in accordance with Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007. That service bulletin specifies a compliance time of 180 days or 500 flight cycles (after the date on the service bulletin). This proposed AD, however, would remove the 500-flight-cycle compliance time to ensure that no airplane is unintentionally grounded, because it is possible an operator might exceed the flight-cycle grace period specified in paragraph (i) of this proposed AD before completing the inspection for chord material specified in paragraph (h) of this proposed AD. Similarly, paragraph (k) of this proposed AD removes the 250- and 1000-flight-cycle compliance times (specified in Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007) for the initial inspection. This proposed AD would require these inspections within 180 days after the effective date of the AD.

Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007, specifies to contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require repairing those conditions in one of the following ways:

- Using a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Interim Action

We consider this proposed AD interim action. If final action is later identified, we might consider further rulemaking then.

Costs of Compliance

We estimate that this proposed AD would affect 10 airplanes of U.S. registry. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

TABLE—ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per product	Number of U.S.-registered airplanes	Fleet cost
Inspections	24 to 32	$85	$0	$2,040 to $2,720 per inspection cycle.	10	$20,400 to $27,200 per inspection cycle.

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

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that

section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska, and

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

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2011–1250; Directorate Identifier 2010–NM–031–AD.

Comments Due Date

(a) We must receive comments by January 12, 2012.

Affected ADs

(b) This AD affects AD 85–12–01, Amendment 39–5073 (50 FR 26690, June 28, 1985), as revised by AD 85–12–01 R1, Amendment 39–5439, (51 FR 36002, October 8, 1986).

Applicability

(c) This AD applies to The Boeing Company Model 707–100 long body, –200, –100B long body, and –100B short body series airplanes; Model 707–300, –300B, –300C, and –400 series airplanes; and Model 720 and 720B series airplanes; certificated in any category; as identified in Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007, and Boeing 707 Alert Service Bulletin A3516, dated April 4, 2008.

Subject

(d) Air Transport Association (ATA) of America Code 55: Stabilizers.

Unsafe Condition

(e) This AD was prompted by reports of stress corrosion cracking in the chord segments made from 7079 aluminum in the horizontal stabilizer rear spar, and fatigue cracking in the chord segments made from 7075 aluminum. The Federal Aviation Administration is issuing this AD to detect and correct stress corrosion and/or fatigue cracking in the horizontal stabilizer, which could compromise the structural integrity of the stabilizer.

Compliance

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

Flight Cycle Counting Procedure

(g) Flight cycles, as used in this AD, must be counted as defined in Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007 (for Model 707 airplanes); or Boeing 707 Alert Service Bulletin A3516, dated April 4, 2008 (for Model 707 airplanes, and Model 720 and 720B series airplanes).

Determine Material of the Components of the Horizontal Stabilizer

(h) For airplanes identified in Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007: At the earlier of the times specified in paragraphs (h)(1) and (h)(2) of this AD, determine the type of material of the horizontal stabilizer, rear spar, upper chords, and lower chords on the inboard and outboard ends of the rear spar, in accordance with Part 2 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007.

(1) Within 180 days after the effective date of this AD.

(2) Before further flight after any horizontal stabilizer is replaced after the effective date of this AD.

Repetitive Inspections of 7075 Aluminum Components

(i) For airplanes with horizontal stabilizer components made from 7075 aluminum, as determined during the inspection required by paragraph (h) of this AD: Within 180 days after the effective date of this AD, and before further flight after any replacement of the horizontal stabilizer, do a special detailed inspection for cracking of the upper chord on the inboard end of the rear spar in the left and right side horizontal stabilizers, from stabilizer station −13.179 to 92.55, in accordance with Part 3 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007. Repeat the inspections thereafter at intervals not to exceed 500 flight cycles, and before further flight after any replacement of the horizontal stabilizer, except as provided by paragraph (j) of this AD. If any cracking is found, before further flight, either repair the cracking in accordance with Part 3 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007, except as required by paragraph (n) of this AD; or replace the chord with a new chord, in accordance with Part 6 of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007.

Note 1: For the purposes of this AD, a special detailed inspection is ''an intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. The examination is likely to make extensive use of specialized inspection techniques and/or equipment. Intricate cleaning and substantial access or disassembly procedure may be required.

(j) For airplanes on which the chord is replaced with a new chord in accordance with Part 6 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007: Within 4,000 flight cycles after the chord replacement, do the inspections required by paragraph (i) of this AD, and repeat the inspections thereafter at the times specified in paragraph (i) of this AD.

Repetitive Inspections of 7079 Aluminum Components

(k) For airplanes with horizontal stabilizers that have components of the chords of the rear spar made from 7079 aluminum, as determined during the inspection required by paragraph (h) of this AD: Within 180 days after the effective date of this AD, do the actions required by paragraphs (k)(1), (k)(2), and (k)(3) of this AD, and repeat those actions at the applicable intervals specified in paragraphs (k)(1), (k)(2), and (k)(3) of this AD.

(1) Do a special detailed inspection for cracking of the upper chord of the inboard side of the rear spar in the left and right side horizontal stabilizers from stabilizer station −13.179 to 92.55, in accordance with Part 3 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007. Repeat the inspection thereafter at intervals not to exceed 250 flight cycles or 180 days, whichever occurs first. If any cracking is found during any inspection required by this paragraph, before further flight, either repair the cracking, in accordance with Part 3 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007, except as required by paragraph (n) of this AD; or replace the chord with a new chord, in accordance with Part

6 of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007.

(2) Do a high frequency eddy current inspection for cracking of the web flanges of the upper and lower chords of the rear spar in the left and right side horizontal stabilizers from stabilizer stations 92.55 to 272.55, in accordance with Part 4 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007. Repeat the inspection thereafter at intervals not to exceed 1,000 flight cycles or 180 days, whichever occurs first. If any cracking is found during any inspection required by this paragraph, before further flight, do the actions specified in paragraph (k)(2)(i) or (k)(2)(ii) of this AD.

(i) Determine whether the cracking meets the limits specified in Part 4 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007, and whether a previous repair has been done; determine if all 7079 upper and lower chord segments installed on the horizontal stabilizer have had the Part II, Group 1, Preventative Modification specified in Boeing 707 Service Bulletin 3356 done; and do all applicable repairs and modifications, in accordance with Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007. Do the actions required by this paragraph in accordance with Part 4 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007, except as required by paragraph (n) of this AD. Do all applicable repairs and modifications before further flight.

(ii) Replace the chord with a new chord, in accordance with Part 6 of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007.

(3) Do low frequency eddy current (LFEC) inspections for cracking of the forward skin flanges of the upper and lower chords of the rear spar in the left and right side horizontal stabilizers from stabilizer stations −13.179 to 272.55 (for lower chords) and 92.55 to 272.55 (for upper chords), in accordance with Part 5 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007. Repeat the inspections thereafter at intervals not to exceed 1,000 flight cycles or 180 days, whichever occurs first. If any cracking is found during any inspection required by this paragraph, before further flight, do the actions specified in either paragraph (k)(3)(i) or paragraph (k)(3)(ii) of this AD.

(i) Repair cracking, and determine whether all 7079 upper and lower chord segments installed on the horizontal stabilizer have had the Part II—Preventative Modification specified in Boeing 707 Service Bulletin 3381 done, and do all applicable modifications, in accordance with Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007. Do the actions required by this paragraph in accordance with Part 5 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007, except as required by paragraph (n) of this AD. Do all applicable modifications before further flight.

(ii) Replace the chord with a new chord, in accordance with Part 6 of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007.

Modification/Chord Replacement

(l) For airplanes identified in Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007, with horizontal stabilizers that have rear spar chord components made from 7079 aluminum and have not had embodied the modification of Part II of Boeing 707 Service Bulletin 3381, dated July 25, 1980; or Revision 1, dated July 31, 1981: Before further flight after determining the type of material in accordance with paragraph (h) of this AD, modify all 7079 chord segments still installed on the horizontal stabilizer, in accordance with Part 5 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007; or replace the chord, in accordance with Part 6 of the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007.

Supplemental Structural Inspection Document Inspections

(m) For all airplanes: Within 180 days or 1,000 flight cycles after the effective date of this AD, whichever occurs first, do the inspections of the applicable structurally significant items specified in and in accordance with the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3516, dated April 4, 2008. If any cracking is found, before further flight, repair in accordance with the procedures specified in paragraph (q) of this AD. The inspections required by AD 85–12–01 R1, Amendment 39–5439 (51 FR 36002, October 8, 1986), are still required, except, as of the effective date of this AD, the flight-cycle interval for the repetitive inspections specified in paragraph 1.E., ''Compliance,'' of Boeing 707 Alert Service Bulletin A3516, dated April 4, 2008, must be counted in accordance with the requirements of paragraph (g) of this AD.

Exceptions to the Service Information

(n) If any cracking is found during any inspection required by this AD, and Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007, specifies to contact Boeing for appropriate action: Before further flight, repair the cracking using a method approved in accordance with the procedures specified in paragraph (q) of this AD.

(o) Where Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007, specifies that operators ''refer to'' NDT procedures, the procedures must be done in accordance with the service information identified in paragraphs (o)(1), (o)(2), and (o)(3) of this AD, as applicable.

(1) Subject 51–00–00, ''Structures-General,'' Figure 20, ''Electrical Conductivity Measurement for Aluminum,'' of Part 6–Eddy Current, of the Boeing 707/720 Nondestructive Test Manual, Document D6–48023, Revision 118, dated July 15, 2011.

(2) Subject 55–10–07, ''Horizontal Stabilizer,'' of Part 6–Eddy Current, of the Boeing 707/720 Nondestructive Test Manual, Document D6–48023, Revision 118, dated July 15, 2011.

(3) Subject 51–01–00, ''Orientation and Preparation for Testing'' of Part 1–General, of the Boeing 707/720 Nondestructive Test Manual, Document D6–48023, Revision 118, dated July 15, 2011.

Parts Installation

(p) As of the effective date of this AD, no person may install any horizontal stabilizer assembly with any chord segment having a part number other than that identified in paragraph 2.C.2. of Boeing 707 Alert Service Bulletin A3515, dated December 19, 2007, on any airplane.

Alternative Methods of Compliance (AMOCs)

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

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

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

Related Information

(r) For more information about this AD, contact Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, Washington 98057–3356; phone: (425) 917–6577; fax: (425) 917–6590; email: *berhane.alazar@faa.gov*.

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

Issued in Renton, Washington, on November 10, 2011.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–30582 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0499; Airspace Docket No. 11–ACE–10]

Proposed Amendment of Class E Airspace; Hastings, NE

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace at Hastings, NE. Additional controlled airspace is necessary to accommodate new Standard Instrument Approach Procedures (SIAP) at Hastings Municipal Airport. The FAA is taking this action to enhance the safety and management of Instrument Flight Rules (IFR) operations for SIAPs at the airport.

DATES: Comments must be received on or before January 12, 2012.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001. You must identify the docket number FAA–2011–0499/Airspace Docket No. 11–ACE–10, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–(800) 647–5527), is on the ground floor of the building at the above address.

FOR FURTHER INFORMATION CONTACT: Scott Enander, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76137; *telephone:* (817) 321–7716.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2011–0499/Airspace Docket No. 11–ACE–10.'' The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Central Service Center, 2601 Meacham Blvd., Fort Worth, TX 76137.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking (202) 267–9677, to request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

This action proposes to amend Title 14, Code of Federal Regulations (14 CFR), part 71 by amending Class E airspace extending upward from 700 feet above the surface to accommodate new standard instrument approach procedures at Hastings Municipal Airport, Hastings, NE. Controlled airspace is needed for the safety and management of IFR operations at the airport.

Class E airspace areas are published in Paragraph 6005 of FAA Order 7400.9V, dated August 9, 2011 and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

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

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend controlled airspace at Hastings Municipal Airport, Hastings, NE.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, and effective September 15, 2011, is amended as follows:

Paragraph 6005 Class E Airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE NE E5 Hastings, NE [Amended]

Hastings Municipal Airport, NE
(Lat. 40°36′19″ N., long. 98°25′40″ W.)

That airspace extending upward from 700 feet above the surface within a 7.2-mile radius of Hastings Municipal Airport, and within 2 miles each side of the 150° bearing from the airport extending from the 7.2-mile radius to 10.4 miles southeast of the airport.

Issued in Fort Worth, TX on November 9, 2011.

Gail L. Kasson,

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

[FR Doc. 2011–30537 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0828; Airspace Docket No. 11–AGL–16]

Proposed Establishment of Class E Airspace; Boyne City, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Boyne City, MI. Controlled airspace is necessary to accommodate new Standard Instrument Approach Procedures (SIAP) at Boyne City Municipal Airport. The FAA is taking this action to enhance the safety and management of Instrument Flight Rules (IFR) operations for SIAPs at the airport.

DATES: Comments must be received on or before January 12, 2012.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001. You must identify the docket number FAA–2011–0828/Airspace Docket No. 11–AGL–16, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-(800) 647–5527), is on the ground floor of the building at the above address.

FOR FURTHER INFORMATION CONTACT: Scott Enander, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76137; *telephone:* (817) 321–7716.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2011–0828/Airspace Docket No. 11–AGL–16.'' The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Central Service Center, 2601 Meacham Blvd., Fort Worth, TX 76137.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking (202) 267–9677, to request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

This action proposes to amend Title 14, Code of Federal Regulations (14 CFR), part 71 by establishing Class E airspace extending upward from 700 feet above the surface for new standard instrument approach procedures at Boyne City Municipal Airport, Boyne City, MI. Controlled airspace is needed for the safety and management of IFR operations at the airport.

Class E airspace areas are published in Paragraph 6005 of FAA Order 7400.9V, dated August 9, 2011 and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

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

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish controlled airspace at Boyne City Municipal Airport, Boyne City, MI.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration

proposes to amend 14 CFR Part 71 as follows:

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

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

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

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, and effective September 15, 2011, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL MI E5 Boyne City, MI [New]

Boyne City Municipal Airport, MI
(Lat. 45°12′32″ N., long. 84°59′24″ W.)

That airspace extending upward from 700 feet above the surface within a 9.9-mile radius of Boyne City Municipal Airport, and within 2 miles each side of the 080 degree bearing from the airport extending from the 9.9-mile radius to 11.9 miles east of the airport.

Issued in Fort Worth, TX, on November 9, 2011.

Gail L. Kasson,

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

[FR Doc. 2011–30572 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2011–0117; Airspace Docket No. 09–AGL–31]

Proposed Establishment of Restricted Areas R–5402, R–5403A, R–5403B, R–5403C, R–5403D, R–5403E, and R–5403F; Devils Lake, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish restricted area airspace within the Devils Lake Military Operations Area (MOA), overlying Camp Grafton Range, in the vicinity of Devils Lake, ND. The new restricted areas would permit realistic training in modern tactics to be conducted at Camp Grafton Range while ensuring the safe and efficient use of the National Airspace System (NAS) in the Devils Lake, ND, area. Unlike restricted areas which are designated under Title 14 Code of Federal Regulations (14 CFR) part 73, MOAs are not rulemaking airspace actions. However, since the proposed restricted areas overlap the Devils Lake East MOA, the FAA is including a description of the Devils Lake East MOA change in this NPRM. The MOA change described herein will also be published in the National Flight Data Digest (NFDD).

DATES: Comments must be received on or before January 12, 2012.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; *telephone:* (202) 366–9826. You must identify FAA Docket No. FAA–2011–0117 and Airspace Docket No. 09–AGL–31, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov*.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2011–0117 and Airspace Docket No. 09–AGL–31) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov*.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2011–0117 and Airspace Docket No. 09–AGL–31.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Central Service Center, Operations Support Group, Federal Aviation Administration, 2601 Meacham Blvd. Fort Worth, TX 76137.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Background

Resulting from the 2005 Base Realignment and Closure Commission decisions, Grand Forks AFB was selected for a mission change from its existing aerial refueling mission to an emerging unmanned aerial system (UAS) mission. To accommodate this mission change, the United States (U.S.) Air Force is establishing an operational MQ–1, Predator, squadron at Hector International Airport, ND, with eight Predator aircraft being located at Grand Forks AFB. The launch and recovery operations and maintenance support activities for these aircraft will be accomplished at Grand Forks AFB. Additionally, the U.S. Air Force is

establishing a second Global Hawk Main Operating Base for RQ–4, Global Hawk, operations, with six to eight Global Hawk aircraft to be assigned at Grand Forks AFB as well.

The UAS aircraft programmed to arrive at Grand Forks AFB will have mission and training requirements that include employing Intelligence/Reconnaissance/Surveillance, Close Air Support, and Time Sensitive Targeting tactics. Predator laser training will be accomplished at Camp Grafton Range near Devils Lake, ND. Since the Predator onboard laser system is not eye-safe, its use during training must be contained within restricted area airspace. Restricted areas are regulatory airspace areas that are designated under 14 CFR part 73 rulemaking procedures to contain activities that may present a hazard to nonparticipating aircraft. No person may operate an aircraft within a restricted area without the advance permission of the using or controlling agency.

With the emerging UAS mission at Grand Forks AFB and associated laser training requirements at Camp Grafton Range, the existing R–5401 restricted area surrounding the range is inadequate to satisfy laser training requirements for realistic mission profiles above 5,000 feet mean sea level (MSL). In order to fully exploit the capabilities of today's UAS aircraft and provide the essential training that replicates the conditions that are encountered during wartime deployments today, it is necessary to expand the restricted airspace around Camp Grafton Range. The U.S. Air Force has proposed the FAA establish restricted areas surrounding Camp Grafton Range and R–5401 to enable realistic UAS mission profiles above 5,000 feet MSL to contain the hazardous non-eye safe laser training.

The proposed restricted areas would be established within the existing Devils Lake East MOA and would also extend beyond the MOA's southern boundary approximately 10 NM at the furthest point. Additionally, the Devils Lake East and Devils Lake West MOAs and the existing air traffic control assigned airspaces associated with the MOAs would be retained to support integrated training activities; thus, allowing Predator crews to train for real world mission scenarios with other manned aircraft. To prevent confusion and conflict of having the proposed restricted areas and the existing MOA active in the same airspace at the same time, the Devils Lake East MOA would be amended to exclude R–5401 and the proposed restricted areas when they are active.

MOAs are nonregulatory airspace areas that are established administratively and published in the NFDD. MOAs are established to separate or segregate non-hazardous military flight activities from aircraft operating in accordance with instrument flight rules (IFR), and to advise pilots flying under visual flight rules (VFR) where these activities are conducted. IFR aircraft may be routed through an active MOA only when air traffic control can provide approved separation from the MOA activity. VFR pilots are not restricted from flying in an active MOA, but are advised to exercise caution while doing so. Normally, MOA proposals are not published in an NPRM, but are advertised for public comment through a nonrule circular distributed by an FAA Service Center office to aviation interests in the affected area. When a nonrulemaking action is an integral part of a rulemaking action, FAA procedures allow for the nonrulemaking proposal to be included in the NPRM. Since R–5401 and the proposed restricted areas R–5402, R–5403A, R–5403B, R–5403C, R–5403D, R–5403E, and R–5403F all infringe on the Devils Lake East MOA, the FAA is including a description of the Devils Lake East MOA amendment in this NPRM. Comments on the proposed MOA change may also be submitted as indicated above in the ''Comments Invited'' section of this NPRM.

Proposed MOA Change

The FAA is proposing to amend the Devils Lake East MOA legal description to exclude that airspace within the proposed restricted areas R–5402, R–5403A, R–5403B, R–5403C, R–5403D, R–5403E, and R–5403F, which overlaps airspace within the MOA, when any of the restricted areas are active, respectively. The intent would be to exclude the restricted areas individually only as they are activated. Additionally, the Devils Lake East MOA amendment will retain and move the R–5401 exclusionary language contained in the altitude information of the legal description to the boundaries information. Except for moving the R–5401 exclusion information, the altitude and time of use descriptions for Devils Lake East MOA will remain unchanged. This proposed amendment will prevent airspace conflict with the overlapping existing and proposed restricted areas.

Devils Lake East MOA, ND [Amended]

By removing the current boundaries and altitudes descriptions and substituting the following:

Boundaries. Beginning at lat. 47°50′00″ N., long. 99°09′01″ W.; to lat. 47°47′00″ N., long. 99°00′01″ W.; to lat. 47°50′00″ N., long. 98°17′01″ W.; to lat. 47°35′00″ N., long. 98°07′01″ W.; to lat. 47°19′00″ N., long. 97°44′01″ W.; at lat. 47°07′00″ N., long. 98°12′01″ W.; to lat. 47°14′00″ N., long. 98°22′01″ W.; to lat. 47°25′00″ N., long. 99°15′01″ W.; to lat. 47°25′00″ N., long. 99°41′01″ W.; to the point of beginning, excluding R–5401, R–5402, R–5403A, R–5403B, R–5403C, R–5403D, R–5403E, and R–5403F when active.

Altitudes. 3,500 feet MSL to but not including FL 180.

Restricted Area Proposal

The FAA is proposing to amend 14 CFR part 73 to expand the vertical and lateral limits of restricted area airspace over Camp Grafton Range to contain hazardous non-eye safe laser training operations by an emerging UAS mission at Grand Forks Air Force Base (AFB), transforming the range into a viable non-eye safe laser training location. Camp Grafton Range currently is surrounded by R–5401; however, the lateral boundaries and altitude are insufficient to contain the laser training mission profiles and tactics flown today in combat operations. This proposal would supplement R–5401 and establish additional restricted areas, R–5402, R–5403A, R–5403B, R–5403C, R–5403D, R–5403E, and R–5403F, to provide the vertical and lateral tactical maneuver airspace needed for UAS target acquisition prior to attack, and to contain the non-eye safe laser during laser target designation training operations from medium to high altitudes.

The proposed restricted area R–5402 boundary, described in the regulatory text, would be defined by a 7 nautical mile (NM) radius around the center of R–5401, with the northern boundary adjusted to lie along the 47°45′00″ N latitude. The proposed restricted area altitude would be upward from 500 feet above ground level to, but not including 10,000 feet MSL. This new restricted area would provide a pathway for the non-eye safe laser beam to transit from the proposed R–5403A, R–5403B, or R–5403C (described below) through the existing R–5401 and onto Camp Grafton Range.

The proposed restricted areas R–5403A, R–5403B, and R–5403C would share the same lateral boundaries, overlying R–5402 and layered in ascending order. The northern boundary of these R–5403 areas, as described in the regulatory text, would share the same northern boundary as R–5402, the 47°45′00″ N latitude. The western boundary would lie approximately 14 NM west of R–5402 along the 99°15′00″ W longitude and the eastern boundary would lie approximately 7 NM east of

R–5402 along the 98°15′00″ W longitude. Finally, the southern boundary would be established to remain north of the protected airspace for V–55. The proposed restricted area altitudes, in ascending order, would be defined upward from 8,000 feet MSL to, but not including 10,000 feet MSL for R–5403A; upward from 10,000 feet MSL to, but not including 14,000 feet MSL for R–5403B; and upward from 14,000 feet MSL to, but not including Flight Level (FL) 180 for R–5403C. The additional lateral and vertical limits provided by these proposed restricted areas, in conjunction with R–5401, R–5402, R–5403D, R–5403E, R–5403F, and Camp Grafton Range, would establish the maneuvering airspace needed for UAS aircraft to practice the tactical maneuvering and standoff target acquisition training requirements necessary for the combat tactics and mission profiles flown today and to contain the hazardous non-eye safe laser, when employed, completely within restricted airspace.

The proposed restricted areas R–5403D, R–5403E, and R–5403F would also share the same lateral boundaries, adjacent to and southeast of R–5403A, R–5403B, and R–5403C, and also layered in ascending order. The northern boundary of these R–5403 areas, as described in the regulatory text, would share the same southern boundary of R–5403A, R–5403B, and R–5403C. The western boundary point would reach to the 99°15′00″ W longitude and the eastern boundary would lie along the 98°15′00″ W longitude. Finally, the southern boundary would be established to lie along the 47°30′00″ N latitude. The proposed restricted area altitudes, in ascending order, would be defined upward from 10,000 feet MSL to, but not including 12,000 feet MSL for R–5403D; upward from 12,000 feet MSL to, but not including 14,000 feet MSL for R–5403E; and upward from 14,000 feet MSL to, but not including Flight Level (FL) 180 for R–5403F. The additional lateral and vertical limits provided by these proposed restricted areas, in conjunction with R–5401, R–5402, R–5403A, R–5403B, R–5403C, and Camp Grafton Range, would establish the maneuvering airspace, standoff target acquisition, and hazardous non-eye safe laser employment training completely within restricted airspace, as noted above.

Restricted areas R–5402, R–5403A, R–5403B, R–5403C, R–5403D, R–5403E, and R–5403F will all be designated as ''joint-use'' airspace. This means that, during periods when any of the restricted airspace areas are not needed by the using agency for its designated purposes, the airspace will be returned to the controlling agency for access by other NAS users. The Minneapolis Air Route Traffic Control Center is the controlling agency for the proposed restricted areas.

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

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish restricted airspace at Camp Grafton Range near Devils Lake, ND, to enhance safety and accommodate essential military training.

Environmental Review

This proposal will be subjected to an environmental analysis in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures,'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited Areas, Restricted Areas.

The Proposed Amendment

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

PART 73—SPECIAL USE AIRSPACE

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

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

§ 73.54 [Amended]

2. § 73.54 is amended as follows:

* * * * *

R–5402 Devils Lake, ND [New]

Boundaries. Beginning at lat. 47°45′00″ N., long. 98°47′19″ W.; to lat. 47°45′00″ N., long. 98°31′25″ W.; then clockwise on a 7 NM arc centered on lat. 47°40′31″ N., long. 98°39′22″ W.; to the point of beginning, excluding the airspace within R–5401 when active, and R–5403A when active.

Designated altitudes. 500 feet AGL to, but not including, 10,000 feet MSL.

Time of designation. 0700–2200 daily, by NOTAM 4 hours in advance; other times by NOTAM.

Controlling agency. FAA, Minneapolis ARTCC.

Using agency. U.S. Air Force, 119th Operations Support Squadron, Hector International Airport, Fargo, ND.

R–5403A Devils Lake, ND [New]

Boundaries. Beginning at lat. 47°45′00″ N., long. 99°15′00″ W.; to lat. 47°45′00″ N., long. 98°15′00″ W.; to lat. 47°35′39″ N., long. 98°15′00″ W.; to lat. 47°15′00″ N., long. 99°15′00″ W.; to the point of beginning.

Designated altitudes. 8,000 feet MSL to, but not including, 10,000 feet MSL.

Time of designation. 0700–2200 daily, by NOTAM 4 hours in advance; other times by NOTAM.

Controlling agency. FAA, Minneapolis ARTCC.

Using agency. U.S. Air Force, 119th Operations Support Squadron, Hector International Airport, Fargo, ND.

R–5403B Devils Lake, ND [New]

Boundaries. Beginning at lat. 47°45′00″ N., long. 99°15′00″ W.; to lat. 47°45′00″ N., long. 98°15′00″ W.; to lat. 47°35′39″ N., long. 98°15′00″ W.; to lat. 47°15′00″ N., long. 99°15′00″ W.; to the point of beginning.

Designated altitudes. 10,000 feet MSL to, but not including, 14,000 feet MSL.

Time of designation. 0700–2200 daily, by NOTAM 4 hours in advance; other times by NOTAM.

Controlling agency. FAA, Minneapolis ARTCC.

Using agency. U.S. Air Force, 119th Operations Support Squadron, Hector International Airport, Fargo, ND.

R–5403C Devils Lake, ND [New]

Boundaries. Beginning at lat. 47°45′00″ N., long. 99°15′00″ W.; to lat. 47°45′00″ N., long. 98°15′00″ W.; to lat. 47°35′39″ N., long. 98°15′00″ W.; to lat. 47°15′00″ N., long. 99°15′00″ W.; to the point of beginning.

Designated altitudes. 14,000 feet MSL to, but not including, FL 180.

Time of designation. 0700–2200 daily, by NOTAM 4 hours in advance; other times by NOTAM.

Controlling agency. FAA, Minneapolis ARTCC.

Using agency. U.S. Air Force, 119th Operations Support Squadron, Hector International Airport, Fargo, ND.

R–5403D Devils Lake, ND [New]

Boundaries. Beginning at lat. 47°35′39″ N., long. 98°15′00″ W.; to lat. 47°15′00″ N., long. 98°15′00″ W.; to lat. 47°15′00″ N., long. 99°15′00″ W.; to the point of beginning.

Designated Altitudes. 10,000 feet MSL to, but not including, 12,000 feet MSL.

Time of designation. 0700–2200 daily, by NOTAM 4 hours in advance; other times by NOTAM.

Controlling agency. FAA, Minneapolis ARTCC.

Using agency. U.S. Air Force, 119th Operations Support Squadron, Hector International Airport, Fargo, ND.

R–5403E Devils Lake, ND [New]

Boundaries. Beginning at lat. 47°35′39″ N., long. 98°15′00″ W.; to lat. 47°15′00″ N., long. 98°15′00″ W.; to lat. 47°15′00″ N., long. 99°15′00″ W.; to the point of beginning.

Designated Altitudes. 12,000 feet MSL to, but not including, 14,000 feet MSL.

Time of designation. 0700–2200 daily, by NOTAM 4 hours in advance; other times by NOTAM.

Controlling agency. FAA, Minneapolis ARTCC.

Using agency. U.S. Air Force, 119th Operations Support Squadron, Hector International Airport, Fargo, ND.

R–5403F Devils Lake, ND [New]

Boundaries. Beginning at lat. 47°35′39″ N., long. 98°15′00″ W.; to lat. 47°15′00″ N., long. 98°15′00″ W.; to lat. 47°15′00″ N., long. 99°15′00″ W.; to the point of beginning.

Designated Altitudes. 14,000 feet MSL to, but not including, FL 180.

Time of designation. 0700–2200 daily, by NOTAM 4 hours in advance; other times by NOTAM.

Controlling agency. FAA, Minneapolis ARTCC.

Using agency. U.S. Air Force, 119th Operations Support Squadron, Hector International Airport, Fargo, ND.

Issued in Washington, DC, on November 17, 2011.

Gary A. Norek,

Acting Manager, Airspace, Regulations and ATC Procedures Group.

[FR Doc. 2011–30495 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 305

[RIN 3084–AB03]

Rule Concerning Disclosures Regarding Energy Consumption and Water Use of Certain Home Appliances and Other Products Required Under the Energy Policy and Conservation Act (''Appliance Labeling Rule'')

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Advance notice of proposed rulemaking and public meeting announcement.

SUMMARY: The Commission seeks comment on disclosures to help consumers, distributors, contractors, and installers easily determine whether a specific furnace, central air conditioner, or heat pump meets the applicable new Department of Energy efficiency standard for the regions where it will be installed. The Commission seeks comment on the content, location, and format of such disclosures. As part of this effort, the Commission staff will hold a public meeting with the Department of Energy to discuss possible disclosures.

DATES: Comments must be received by January 10, 2012. The public meeting will be held on December 16, 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 ''Regional Labeling for Heating and Cooling Equipment (16 CFR Part 305) (Project No. P114202)'' on your comment, and file your comment online at *https://public.commentworks.com/ftc/regional-disclosuresanpr,* 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 H), 600 Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome, Attorney, (202) 326–2889, Division of Enforcement, Federal Trade Commission, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Commission seeks comment on new labeling requirements and other disclosures for residential furnaces, central air conditioners, and heat pumps (*i.e.,* heating and cooling equipment) to help consumers and industry members install equipment with the efficiency rating appropriate for their location under new regional efficiency standards issued by the Department of Energy (DOE). These new standards impose minimum efficiency levels which vary by region for different types of equipment.

To facilitate the development of such disclosures, the Commission seeks comment on their appropriate content, location, and format. After considering comments, the Commission will publish specific proposed requirements for comment and then publish final disclosure requirements as amendments to the Commission's Appliance Labeling Rule (16 CFR Part 305).

II. Background

The Commission's Appliance Labeling Rule, issued pursuant to the Energy Policy and Conservation Act (EPCA),[1] requires energy labeling for major household appliances and other consumer products to help consumers compare competing models.[2] When first published in 1979,[3] the Rule applied to eight appliance categories: refrigerators, refrigerator-freezers, freezers, dishwashers, water heaters, clothes washers, room air conditioners, and furnaces. Since 1979, the Commission has expanded the Rule's coverage to include central air conditioners, heat pumps, plumbing products, lighting products, ceiling fans, certain types of water heaters, and televisions.[4] The Rule requires manufacturers to attach yellow EnergyGuide labels to all covered furnaces, central air conditioners, and heat pumps.[5] The Rule also prohibits retailers from removing these labels or rendering them illegible.[6] In addition, sellers, including retailers, must post label information on Web sites and in paper catalogs from which covered products can be ordered.[7]

The EnergyGuide labels for heating and cooling equipment contain two key disclosures: (1) The product's efficiency

[1] 42 U.S.C. 6291 *et seq.*

[2] More information about the Rule can be found at *http://www.ftc.gov/appliances.*

[3] 44 FR 66466 (Nov. 19, 1979).

[4] *See* 52 FR 46888 (Dec. 10, 1987) (central air conditioners and heat pumps); 54 FR 28031 (Jul. 5, 1989) (fluorescent lamp ballasts); 58 FR 54955 (Oct. 25, 1993) (certain plumbing products); 59 FR 25176 (May 13, 1994) (lighting products); 59 FR 49556 (Sep. 28, 1994) (pool heaters); 71 FR 78057 (Dec. 26, 2006) (ceiling fans); and 76 FR 1038 (Jan. 6, 2011) (televisions).

[5] *See* 42 U.S.C. 6302(a)(1) and 16 CFR 305.4(a)(1).

[6] *See* 42 U.S.C. 6302(a)(2) and 16 CFR 305.4(a)(2).

[7] *See* 42 U.S.C. 6296(a) and 16 CFR 305.20.

rating,[8] and (2) a ''range of comparability'' showing the highest and lowest ratings for all similar models.[9] The Rule also specifies the label's format. For example, the label must be yellow and feature the EnergyGuide headline in a specific format and type. Additionally, manufacturers cannot place any information on the label other than that specifically allowed by the Rule.

The Rule also requires manufacturers to provide distributors and installers with energy information about their furnaces, central air conditioners, and heat pumps in paper or electronic form (including internet-based access).[10] In turn, retailers, including installers, must show this information to their customers and let them read the information before purchase.

III. DOE Regional Standards for Heating and Cooling Equipment

On June 27, 2011,[11] DOE published a direct final rule notice promulgating new efficiency standards for residential furnaces, central air conditioners, and heat pumps as authorized by the Energy Independence and Security Act of 2007 (EISA).[12] DOE's direct final rule became effective on October 25, 2011.[13] Unlike existing DOE standards which impose uniform, national efficiency levels, the new standards for certain products vary by region.[14] As detailed in Tables 1 and 2, the DOE standards impose regional efficiency standards for split air conditioners, package air conditioners, and gas furnaces (non-weatherized and mobile home). The standards for other covered heating and cooling equipment are national.

TABLE 1—DOE REGIONAL EFFICIENCY STANDARDS FOR FURNACES

System type	North	Southeast	Southwest
Non-weatherized	90% AFUE	80% AFUE	80% AFUE.
Mobile home gas	90% AFUE	80% AFUE	80% AFUE.
Non-weatherized	83% AFUE	83% AFUE	83% AFUE.
Weatherized gas	81% AFUE	81% AFUE	81% AFUE.
Mobile home oil-fired	75% AFUE	75% AFUE	75% AFUE.
Weatherized oil-fired	78% AFUE	78% AFUE	78% AFUE.
Electric	78% AFUE	78% AFUE	78% AFUE.

TABLE 2—DOE REGIONAL EFFICIENCY STANDARDS FOR CENTRAL AIR CONDITIONERS AND HEAT PUMPS

System type	North	Southeast	Southwest
Split-system air	13 SEER[15]	14 SEER	14 SEER/12.2 EER[16] <45,000 Btu/h.
Split-system heat pumps	14 SEER/8.2 HSPF[17]	14 SEER/8.2 HSPF	14 SEER/8.2 HSPF.
Single package air conditioners	14 SEER	14 SEER	14 SEER/11.0 EER.
Single-Package Heat Pumps	14 SEER/8.0 HSPF	14 SEER/8.0 HSPF	14 SEER/8.0 HSPF.
Small-duct, high-velocity systems	13 SEER/7.7 HSPF	13 SEER/7.7 HSPF	13 SEER/7.7 HSPF.
Space-constrained products—air conditioners.	12 SEER	12 SEER	12 SEER.
Space-constrained products—heat pumps.	12 SEER/7.4 HSPF	12 SEER/7.4 HSPF	12 SEER/7.4 HSPF.

To promote compliance with these new standards, DOE is developing an EISA-directed enforcement plan which will specify the responsibilities of various entities (*e.g.,* installers, distributors, and manufacturers) to meet the new standards and to make any required disclosures.[18] DOE must complete this plan within 15 months after issuance of the final regional standards. To augment DOE's enforcement efforts, EISA grants states the authority to enforce the regional standards in Federal court.[19]

IV. FTC Disclosures for Heating and Cooling Equipment

To help consumers and businesses determine whether a product conforms with the regional standards promulgated by DOE, EISA directs the FTC to develop new disclosures for furnaces, central air conditioners, and heat pumps. Specifically, the law requires the Commission to ''determine the appropriate 1 or more methods for disclosing information so that consumers, distributors, contractors, and installers can easily determine whether a specific piece of equipment that is installed in a specific building is in conformance with the regional standard that applies to the building.'' [20] The statute also authorizes the Commission to modify the Energy Guide label or develop other disclosure

[8] Efficiency ratings for these products include annual fuel utilization efficiency (AFUE) for furnaces, and seasonal energy efficiency ratio (SEER) and heating performance seasonal factor (HSPF) for central air conditioners and heat pumps.

[9] 16 CFR 305.13.

[10] 16 CFR 305.14.

[11] 76 FR 37408.

[12] Public Law 110–140; 42 U.S.C. 6295(o)(6). EISA amended EPCA to authorize separate regional standards for these products.

[13] *See* 76 FR 67037 (Oct. 31, 2011). Although DOE's final standards became effective on October 25, 2011, DOE is not requiring compliance until later. Specifically, DOE will require nonweatherized gas furnaces to comply by May 1, 2013; and weatherized gas furnaces and central air conditioner and heat pump product classes to comply by January 1, 2015.

[14] 42 U.S.C. 6295(o)(6)(B). The DOE standards apply to three regions: The North, Southeast, and Southwest. For furnaces, the standards are the same for the southeastern and southwestern regions. The Northern region encompasses Alaska, Colorado, Connecticut, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, Washington, West Virginia, Wisconsin, and Wyoming. The Southeastern region encompasses Alabama, Arkansas, Delaware, Florida, Georgia, Hawaii, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and the District of Columbia. The Southwest includes Arizona, California, New Mexico, and Nevada. 76 FR 37422.

[15] Seasonal Energy Efficiency Rating.

[16] Energy Efficiency Rating.

[17] Heating Seasonal Performance Factor.

[18] 42 U.S.C. 6295(o)(6)(G).

[19] *Id.*

[20] 42 U.S.C. 6295(o)(6)(H).

''methods that make it easy for consumers and installers to use and understand at the point of installation.'' [21] The Commission must complete this effort within 15 months of DOE's final publication of the regional standards. To begin this effort, the Commission requests comment on the content, location, and format for the new disclosure requirements.

The content of the new disclosures must help consumers and industry members avoid installing equipment in violation of regional standards. The Commission seeks suggestions for the best disclosure content to meet this goal. For example, such disclosures could simply explain that a particular product may or may not be installed in certain regions:[22]

• *[For split air conditioner systems rated lower than 14 SEER]:*

Federal law prohibits installation of this unit in Alabama, Arizona, Arkansas, California, Delaware, Florida, Georgia, Hawaii, Kentucky, Louisiana, Maryland, Mississippi, New Mexico, Nevada, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, or the District of Columbia.

• *[For split air conditioner systems smaller than 45,000 Btu/h and rated lower than 12.2 EER, split air conditioner systems larger than or equal to 45,000 Btu/h and rated lower than 11.7 EER, and single-package air conditioner systems rated lower than 11.0 EER]:*

Federal law prohibits installation of this unit in Arizona, California, New Mexico, or Nevada.

• *[For non-weatherized gas furnaces (including mobile home gas furnaces) rated lower than 90% AFUE]:*

Federal law prohibits the installation of this unit in Alaska, Colorado, Connecticut, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Dakota, Ohio, Oregon, Pennsylvania Rhode Island, South Dakota, Utah, Vermont, Washington, West Virginia, Wisconsin, or Wyoming.

• *[For all other covered products]:*

Federal law allows installation of this unit in any U.S. state.

These examples represent one possible approach for providing the content of the disclosures. Other possibilities include providing more detailed explanations of the standards or using illustrations, such as a map of the U.S. to indicate where the law prohibits installation of certain equipment.[23] The Commission seeks comments on these options and other possible disclosures. Please address whether the label should include additional information that may be relevant to regional standards compliance, such as the Energy Efficiency Rating (EER) for central air conditioners.[24] Commenters should also refer to the specific questions set forth in section V.

Comments should also address the location and format for the required disclosures. For instance, the EnergyGuide label could be revised to include information about whether a specific piece of equipment meets standards for installation in a specific region. Alternatively, the manufacturer could provide the required disclosures through other means such as product nameplates, product packaging, brochures, user manuals, Web sites, or online databases. Such alternative methods might provide more space than the EnergyGuide labels for the disclosure of detailed compliance information. The disclosure format could also involve a combination of these approaches. For example, the Energy Guide label could include a QR (Quick Response) scan code to provide mobile phone access to an online database containing detailed product information in addition to disclosures on the label or elsewhere. The EPA recently adopted such an approach for new fuel economy labels on automobiles.[25] In addressing these issues, commenters should also consider the specific questions in section V.

V. Issues and Questions for Comment

The Commission seeks general comments on potential disclosure methods to help consumers, distributors, contractors, and installers easily determine whether residential heating and cooling equipment meets applicable regional efficiency standards. The Commission invites interested persons to submit written comments on any issue of fact, law or policy that may bear upon the FTC's current labeling requirements. Please provide details to support your comments. We encourage commenters to consider the questions below when preparing comments.

(1) *Content:* What information is necessary to inform consumers and industry members whether equipment complies with DOE-mandated regional energy standards in a particular region? Should the disclosures use images (*e.g.,* a map of the U.S.) to illustrate the scope of the regional standards? What changes would be required to the EnergyGuide label (*e.g.,* EER disclosures) in addition to disclosures specifically related to regional standards?

(2) *Location and Format:* Should the required disclosures appear on the label affixed to the product, on packaging, through point of sale materials, on the Internet, or through some other means? Should the disclosures appear in a combination of these formats in multiple locations? If so, which ones? Should the FTC explore the use of QR (Quick Response) scan codes to allow installers and consumers to access detailed information about the equipment through mobile phones? If the disclosures appear on the product itself, should the Commission replace the EnergyGuide label with permanent disclosure on the product nameplate or a similar location?

(3) *Separate Disclosures:* Should the Commission develop separate disclosures for furnaces, central air conditioners, and heat pumps given differences in the way these products are rated on the EnergyGuide label and how they are installed? Should the Rule require separate disclosures for industry members and consumers? Should the Rule require different disclosures or instructions for various industry members such as distributors and installers?

(4) *Installer Requirements:* What changes, if any, should the Commission make to the content and format of disclosures installers must provide to their customers?

(5) *Database Information:* Are there existing databases the Commission could use to help industry members and consumers determine whether equipment complies with the regional energy standards, including the efficiency ratings of specific compressor and coil combinations for central air conditioners?

[21] *Id.*

[22] Efficiency ratings for central air conditioner systems depend on the particular condenser and evaporator coil paired to form the system. Thousands of possible condenser and coil combinations exist. Given the impracticality of including all such combinations on a label, the current EnergyGuide label discloses a condenser's efficiency rating when paired with the coil with which it is most commonly sold. The current label appears on the condenser only.

[23] New ENERGY STAR logo specifications adopted by the Environmental Protection Agency use a U.S. map to communicate whether a product meets the energy efficiency levels for that program. *http://www.energystar.gov/ia/partners/prod_development/revisions/downloads/furnaces/Furnaces_Final_V3_and_V4_Cover_Memo.pdf.*

[24] Currently, the EnergyGuide label for these products only discloses the Seasonal Energy Efficiency Rating (SEER). The SEER reflects a model's energy performance over a range of temperature conditions while EER measures energy performance at a single, high temperature.

[25] *http://yosemite.epa.gov/opa/admpress.nsf/names/hq_2011-5-25_fueleconomylabel.*

(6) *Benefits:* What benefits, if any, will the new disclosures provide to consumers? What evidence supports the asserted benefits? What benefits, if any, will the new disclosures provide to industry members? What is the magnitude of such benefits? What evidence supports the asserted benefits?

(7) *Costs:* What costs, if any, would the potential new disclosures impose on businesses, and in particular on small businesses such as installers? What would be the magnitude of such costs? What evidence supports the asserted costs?

(8) *Other Federal, State, or Local Requirements:* Would the new disclosures overlap or conflict with other federal, state, or local laws or regulations? If so, how?

VI. Request for Comment

The Commission invites interested persons to submit written comments on any issue of fact, law, or policy that may bear upon the proposals under consideration. Please include explanations for any answers provided, as well as supporting evidence where appropriate. After examining the comments, the Commission will determine whether to issue specific amendments.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 10, 2012. Write ''Regional Labeling for Heating and Cooling Equipment, (16 CFR Part 305) (Project No. P114202)'' 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 does not 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 does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not 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). 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 4.9(c).[26] 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, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at *https://public.commentworks.com/ftc/regional-disclosuresanpr,* 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 ''Regional Labeling for Heating and Cooling Equipment, (16 CFR Part 305) (Project No.114202)'' 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 H), 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 January 10, 2012. 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.*

VII. Public Meeting Information

The Commission and DOE staff have scheduled a public meeting to give interested parties an opportunity to provide their views on potential FTC disclosures and the DOE enforcement plan related to new regional standards for furnaces, central air conditioners, and heat pumps. The public meeting will be held on December 16, 2011 at DOE. DOE will provide details regarding time, location, attendance and participation at the meeting.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2011–30436 Filed 11–25–11; 8:45 am]

BILLING CODE 6750–01–P

[26] 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 1

[REG–109369–10]

RIN 1545–BJ33

Passive Activity Losses and Credits Limited

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations regarding the definition of an ''interest in a limited partnership as a limited partner'' for purposes of determining whether a taxpayer materially participates in an activity under section 469 of the Internal Revenue Code (Code). These proposed regulations affect individuals who are partners in partnerships.

DATES: Written or electronic comments and requests for a public hearing must be received by February 27, 2012.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–109369–10), Room 5203, 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–109369–10), 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-109369-10).*

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Michala Irons, (202) 622–3050; concerning submissions of comments and requests for public hearing, Oluwafunmilayo Taylor, (202) 622–7180 (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Background

Section 469(a)(1) limits the ability of certain taxpayers to deduct losses from passive activities. Section 469(b) permits passive losses disallowed in one year to be carried over to the next year. Section 469(c)(1) provides that a passive activity means any activity which involves the conduct of any trade or business, and in which the taxpayer does not materially participate. Section 469(h)(1) provides that a taxpayer shall be treated as materially participating in an activity only if the taxpayer is involved in the operations of the activity on a basis which is regular, continuous, and substantial. The Treasury Department and the IRS promulgated temporary regulations under section 469 in 1988. See TD 8175, 53 FR 5686 (February 25, 1988). Section 1.469–5T(a) provides that an individual taxpayer shall be treated as materially participating in an activity for the taxable year if and only if:

(1) The individual participates in the activity for more than 500 hours during such year;

(2) The individual's participation in the activity for the taxable year constitutes substantially all of the participation in such activity of all individuals (including individuals who are not owners of interests in the activity) for such year;

(3) The individual participates in the activity for more than 100 hours during the taxable year, and such individual's participation in the activity for the taxable year is not less than the participation in the activity of any other individual (including individuals who are not owners of interests in the activity) for such year;

(4) The activity is a significant participation activity (within the meaning of § 1.469–5T(c)) for the taxable year, and the individual's aggregate participation in all significant participation activities during such year exceeds 500 hours;

(5) The individual materially participated in the activity (determined without regard to § 1.469–5T(a)(5)) for any five taxable years (whether or not consecutive) during the ten taxable years that immediately precede the taxable year;

(6) The activity is a personal service activity (within the meaning of § 1.469–5T(d)), and the individual materially participated in the activity for any three taxable years (whether or not consecutive) preceding the taxable year; or

(7) Based on all of the facts and circumstances (taking into account the rules in § 1.469–5T(b)), the individual participates in the activity on a regular, continuous, and substantial basis during such year.

Section 469(h)(2) presumptively treats losses from interests in limited partnerships as passive. Section 469(h)(2) provides that, except as provided in regulations, no interest in a limited partnership as a limited partner shall be treated as an interest with respect to which a taxpayer materially participates. Section 1.469–5T(e)(2) permits an individual taxpayer to establish material participation in a limited partnership but constrains the individual taxpayer to only three of the seven regulatory tests in § 1.469–5T(a), (§ 1.469–5T(a)(1), (a)(5), or (a)(6)).

Section 1.469–5T(e)(3)(i) generally provides that a partnership interest shall be treated as a limited partnership interest if (A) such interest is either designated as a limited partnership interest in the limited partnership agreement or the certificate of limited partnership, without regard to whether the liability of the holder of such interest for obligations of the partnership is limited under applicable State law; or (B) the liability of the holder of such interest for obligations of the partnership is limited, under the law of the State in which the partnership is organized, to a determinable fixed amount (for example, the sum of the holder's capital contributions to the partnership and contractual obligations to make additional capital contributions to the partnership). However, even if the interest is characterized as a limited partnership interest under § 1.469–5T(e)(3)(i), an exception under § 1.469–5T(e)(3)(ii) applies if the individual is a general partner in the partnership at all times during the partnership's taxable year ending with or within the individual's taxable year (or portion of the partnership's taxable year during which the individual (directly or indirectly) owns such limited partnership interest) (the ''general partner exception''). If the general partner exception applies, the limited partnership interest will not be treated as such for the year in which the individual taxpayer is a general partner in the partnership. This allows the individual taxpayer to demonstrate material participation through any of the seven regulatory tests in § 1.469–5T(a).

Courts have concluded, in certain instances, that the holder of a limited liability company (LLC) interest is not treated as holding an interest in a limited partnership as a limited partner for purposes of applying the section 469 material participation tests. In *Gregg* v. *U.S.,* 186 F.Supp.2d 1123 (D. Or. 2000), an Oregon district court concluded that, in the absence of regulations to the effect that an LLC member should be treated as a limited partner, the limited partner exception in section 469(h)(2) was not applicable to LLC members. In *Garnett* v. *Comm'r,* 132 T.C. 368 (2009), the Tax Court found that the taxpayers' ownership interests in limited liability partnerships and LLCs were not interests in limited partnerships because their interests fit within the general partner exception in § 1.469–5T(e)(3)(ii). Shortly thereafter, in *Thompson* v. *U.S.,* 87 Fed. Cl. 728 (2009), the Court of Federal Claims concluded that the regulations under section 469(h)(2) require the taxpayer's ownership interest to be in a partnership under State law rather than a partnership under Federal income tax law. Accordingly, because an LLC member is not a limited partner under State law, the court concluded that section 469(h)(2) did not apply to an LLC member. Most recently, the Tax Court in *Newell* v. *Comm'r,* T.C. Memo. 2010–23, concluded that section 469(h)(2) did not apply to the managing member of an LLC and that the member fell within the general partner exception in § 1.469–5T(e)(3)(ii). On April 5, 2010, the IRS issued an Action on Decision acquiescing in the result only in *Thompson* v. *U.S.,* AOD 2010–02, 2010–14 I.R.B. 515.

Explanation of Provisions

The proposed regulations provide that an interest in an entity will be treated as an interest in a limited partnership under section 469(h)(2) if (A) the entity in which such interest is held is classified as a partnership for Federal income tax purposes under § 301.7701–3; and (B) the holder of such interest does not have rights to manage the entity at all times during the entity's taxable year under the law of the jurisdiction in which the entity was organized and under the governing agreement. Rights to manage include the power to bind the entity. The proposed regulations provide rules concerning an interest in a limited partnership based on the purposes for which section 469 was enacted, and the manner in which the provision is structured and operates within the Code. Accordingly, the rules concerning an interest in a limited partnership in the proposed regulations are provided solely for purposes of section 469 and no inference is intended that the same rules would apply for any other provisions of the Code requiring a distinction between a general partner and a limited partner.

In *Garnett v. Comm'r, supra,* the Tax Court noted that Congress enacted

section 469(h)(2) to address the limitations on a limited partner's ability to participate in the control of the partnership's business. Under the Uniform Limited Partnership Act of 1916, limited partners could lose their limited liability protection if they participated in the control of the partnership. The regulations under section 469(h)(2) were drafted with these constraints in mind. Today, many states have adopted a variation of the Revised Uniform Limited Partnership Act of 1985 (RULPA). Under RULPA, limited partners may participate in the management and control of the partnership without losing their limited liability. As a consequence, limited partners under RULPA are now more akin to general partners and LLC members with respect to their rights in the management of the entity. Under the Uniform Limited Liability Company Act of 1996, LLC members of member-managed LLCs do not lose their limited liability by participating in the management and conduct of the company's business. In *Newell* v. *Comm'r, supra,* the Tax Court noted that the managing member of the LLC at issue managed the day-to-day operations of the LLC and was the ''substantial equivalent'' of a general partner. Recognizing that the original presumptions regarding the limitations on a limited partner's participation in the activities of the entity are no longer valid today, and also recognizing the emergence of LLCs, the proposed regulations eliminate the current regulations' reliance on limited liability for purposes of determining whether an interest is an interest in a limited partnership as a limited partner under section 469(h)(2) and instead adopt an approach that relies on the individual partner's right to participate in the management of the entity.

The regulations are proposed to apply to taxable years beginning on or after the date of publication of the Treasury decision adopting these regulations as final regulations in the **Federal Register.**

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 assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. All comments will be available for public inspection and copying. A public hearing will 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 public hearing will be published in the **Federal Register.**

Drafting Information

The principal author of these proposed regulations is Michala Irons, 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 in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.469–0 is amended by:

1. Revising the entries for § 1.469–5(a), (b), (c), (d), and (e).

2. Removing the entries for § 1.469–5T(e)(1), (e)(2), and (e)(3).

The revisions read as follows:

§ 1.469–0 Table of contents.

* * * * *

§ 1.469–5 Material participation.

(a) through (d) [Reserved].

(e) Treatment of an interest in a limited partnership as a limited partner.

(1) In general.

(2) Exceptions.

(3) Interest in a limited partnership as a limited partner.

(i) In general.

(ii) Individual holding an interest other than an interest in a limited partnership as a limited partner.

(4) Effective/applicability date.

* * * * *

Par. 3. In § 1.469–5, paragraphs (a), (b), (c), (d), and (e) are revised to read as follows:

§ 1.469–5 Material participation.

(a) through (d) [Reserved].

(e) *Treatment of an interest in a limited partnership as a limited partner*—(1) *In general.* Except as otherwise provided in this paragraph (e), an individual shall not be treated as materially participating in any activity in which the individual owns an interest in a limited partnership as a limited partner (as defined in paragraph (e)(3)(i) of this section) for purposes of applying section 469 and the regulations thereunder to—

(i) The individual's share of any income, gain, loss, deduction, or credit from such activity that is attributable to an interest in a limited partnership as a limited partner; and

(ii) Any gain or loss from such activity recognized upon a sale or exchange of such an interest.

(2) *Exceptions.* Paragraph (e)(1) of this section shall not apply to an individual's share of income, gain, loss, deduction, and credit for a taxable year from any activity in which the individual would be treated as materially participating for the taxable year under paragraphs (a)(1), (a)(5), or (a)(6) of § 1.469–5T if the individual did not own an interest in a limited partnership as a limited partner (as defined in paragraph (e)(3)(i) of this section) for such taxable year.

(3) *Interest in a limited partnership as a limited partner*—(i) *In general.* Except as provided in paragraph (e)(3)(ii) of this section, for purposes of section 469(h)(2) and this paragraph (e), an interest in an entity shall be treated as an interest in a limited partnership as a limited partner if—

(A) The entity in which such interest is held is classified as a partnership for Federal income tax purposes under § 301.7701–3; and

(B) The holder of such interest does not have rights to manage the entity at all times during the entity's taxable year under the law of the jurisdiction in which the entity is organized and under the governing agreement.

(ii) *Individual holding an interest other than an interest in a limited partnership as a limited partner.* An individual shall not be treated as holding an interest in a limited partnership as a limited partner for the individual's taxable year if such

individual also holds an interest in the partnership that is not an interest in a limited partnership as a limited partner (as defined in paragraph (e)(3)(i) of this section), such as a state-law general partnership interest, at all times during the entity's taxable year ending with or within the individual's taxable year (or the portion of the entity's taxable year during which the individual (directly or indirectly) owns such interest in a limited partnership as a limited partner).

(4) *Effective/applicability date.* This section applies to taxable years beginning on or after the date of publication of the Treasury decision adopting these rules as a final regulation in the **Federal Register.**

* * * * *

Par. 4. Section 1.469–5T paragraph (e) is revised to read as follows:

§ 1.469–5T Material participation (temporary).

* * * * *

(e) *Treatment of Limited Partners.* [Reserved]. See § 1.469–5(e) for rules relating to this paragraph (e).

* * * * *

Par. 5. Section 1.469–9 paragraph (f)(1) is revised to read as follows:

§ 1.469–9 Rules for certain rental real estate activities.

* * * * *

(f) *Limited partnership interests in rental real estate activities*—(1) *In general.* If a taxpayer elects under paragraph (g) of this section to treat all interests in rental real estate as a single rental real estate activity, and at least one interest in rental real estate is held by the taxpayer as an interest in a limited partnership as a limited partner (within the meaning of § 1.469–5(e)(3)), the combined rental real estate activity of the taxpayer will be treated as an interest in a limited partnership as a limited partner for purposes of determining material participation. Accordingly, the taxpayer will not be treated under this section as materially participating in the combined rental real estate activity unless the taxpayer materially participates in the activity under the tests listed in § 1.469–5(e)(2) (dealing with the tests for determining the material participation of a limited partner).

* * * * *

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2011–30611 Filed 11–25–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

31 CFR Chapter X

RIN 1506–AB16

Financial Crimes Enforcement Network; Amendment to the Bank Secrecy Act Regulations—Imposition of Special Measure Against the Islamic Republic of Iran as a Jurisdiction of Primary Money Laundering Concern

AGENCY: Financial Crimes Enforcement Network, Treasury (''FinCEN''), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: In a notice of finding published elsewhere in this issue of the **Federal Register**, the Secretary of the Treasury, through his delegate, the Director of FinCEN, found that reasonable grounds exist for concluding that the Islamic Republic of Iran (''Iran'') is a jurisdiction of primary money laundering concern pursuant to 31 U.S.C. 5318A. FinCEN is issuing this notice of proposed rulemaking to impose a special measure against Iran.

DATES: Written comments on the notice of proposed rulemaking must be submitted on or before January 27, 2012.

ADDRESSES: You may submit comments, identified by RIN 1506–AB16, by any of the following methods:

- *Federal E-rulemaking Portal: http:/www.regulations.gov.* Follow the instructions for submitting comments. Include 1506–AB16 in the submission. Refer to Docket Number FINCEN–2011–0008.
- *Mail:* The Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Include RIN 1506–AB16 in the body of the text. Please submit comments by one method only.

Comments submitted in response to this NPRM will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

Inspection of comments: Public comments received electronically or through the U. S. Postal Service sent in response to a notice and request for comment will be made available for public review as soon as possible on *http://www.regulations.gov.* Comments received may be physically inspected in the FinCEN reading room located in Vienna, Virginia. Reading room appointments are available weekdays (excluding holidays) between 10 a.m. and 3 p.m., by calling the Disclosure Officer at (703) 905–5034 (not a toll-free call).

FOR FUTHER INFORMATION CONTACT: The FinCEN regulatory helpline at (800) 949–2732 and select Option 6.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Provisions

On October 26, 2001, the President signed into law the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (the ''USA PATRIOT Act''), Public Law 107–56. Title III of the USA PATRIOT Act amends the anti-money laundering provisions of the Bank Secrecy Act (''BSA''), codified at 12 U.S.C. 1829b and 1951–1959, and 31 U.S.C. 5311–5314, and 5316–5332, to promote the prevention, detection, and prosecution of international money laundering and the financing of terrorism. Regulations implementing the BSA appear at 31 CFR Chapter X. The authority of the Secretary of the Treasury (the ''Secretary'') to administer the BSA and its implementing regulations has been delegated to the Director of FinCEN.[1]

Section 311 of the USA PATRIOT Act (''section 311'') added section 5318A to the BSA, granting the Secretary the authority, upon finding that reasonable grounds exist for concluding that a foreign jurisdiction, institution, class of transaction, or type of account is of ''primary money laundering concern,'' to require domestic financial institutions and financial agencies to take certain ''special measures'' against the primary money laundering concern. Section 311 identifies factors for the Secretary to consider and Federal agencies to consult before the Secretary may conclude that a jurisdiction, institution, class of transaction, or type of account is of primary money laundering concern. The statute also provides similar procedures, *i.e.,* factors and consultation requirements, for selecting the specific special measures to be imposed against the primary money laundering concern.

Taken as a whole, section 311 provides the Secretary with a range of options that can be adapted to target specific money laundering and terrorist financing concerns most effectively. These options give the Secretary the authority to bring additional pressure on those jurisdictions and institutions that pose money laundering threats. Through the imposition of various special measures, the Secretary can gain more information about the jurisdictions, institutions, transactions, or accounts of concern; can more effectively monitor the respective jurisdictions, institutions,

[1] Therefore, references to the authority of the Secretary of the Treasury under section 311 of the USA PATRIOT Act apply equally to the Director of FinCEN.

transactions, or accounts; or can protect U.S. financial institutions from involvement with jurisdictions, institutions, transactions, or accounts that are of money laundering concern.

Before making a finding that reasonable grounds exist for concluding that a jurisdiction is of primary money laundering concern, the Secretary is required to consult with both the Secretary of State and the Attorney General. The Secretary is also required by section 311, as amended,[2] to consider ''such information as the Secretary determines to be relevant, including the following potentially relevant factors,'' which extend the Secretary's consideration beyond traditional money laundering concerns to issues involving, inter alia, terrorist financing and weapons proliferation:

- Evidence that organized criminal groups, international terrorists, or entities involved in the proliferation of weapons of mass destruction or missiles, have transacted business in that jurisdiction;
- The extent to which that jurisdiction or financial institutions operating in that jurisdiction offer bank secrecy or special regulatory advantages to nonresidents or nondomiciliaries of that jurisdiction;
- The substance and quality of administration of the bank supervisory and counter-money laundering laws of that jurisdiction;
- The relationship between the volume of financial transactions occurring in that jurisdiction and the size of the economy of the jurisdiction;
- The extent to which that jurisdiction is characterized as an offshore banking or secrecy haven by credible international organizations or multilateral expert groups;
- Whether the United States has a mutual legal assistance treaty with that jurisdiction, and the experience of United States law enforcement officials and regulatory officials in obtaining information about transactions originating in or routed through or to such jurisdiction; and
- The extent to which that jurisdiction is characterized by high levels of official or institutional corruption.

If the Secretary determines that reasonable grounds exist for concluding that a jurisdiction is of primary money laundering concern, the Secretary must determine the appropriate special measure(s) to address the specific money laundering risks. Section 311 provides a range of special measures that can be imposed individually, jointly, in any combination, and in any sequence.[3] The Secretary's imposition of special measures requires additional consultations to be made and factors to be considered. The statute requires the Secretary to consult with appropriate federal agencies and other interested parties[4] and to consider the following specific factors:

- Whether similar action has been or is being taken by other nations or multilateral groups;
- Whether the imposition of any particular special measures would create a significant competitive disadvantage, including any undue cost or burden associated with compliance, for financial institutions organized or licensed in the United States;
- The extent to which the action or the timing of the action would have a significant adverse systemic impact on the international payment, clearance, and settlement system, or on legitimate business activities involving the particular jurisdiction; and
- The effect of the action on United States national security and foreign policy.

B. Finding

Today, as detailed elsewhere in this part,[5] based upon a review and analysis of the administrative record in this matter, consultations with relevant Federal agencies and departments, and after consideration of the factors enumerated in section 311, the Director of FinCEN has determined that reasonable grounds exist for concluding that the Islamic Republic of Iran is a jurisdiction of primary money laundering concern.[6]

II. Imposition of Special Measure Against the Islamic Republic of Iran as a Jurisdiction of Primary Money Laundering Concern, Including the Central Bank of Iran Within the Definition of Iranian Banking Institution

As a result of that finding, and based upon the additional consultations and the consideration of all relevant factors discussed in the finding and in this notice of proposed rulemaking, the Director of FinCEN has determined that reasonable grounds exist for the imposition of the fifth special measure authorized by section 5318A(b)(5).[7] That special measure authorizes a prohibition against the opening or maintaining of correspondent accounts[8] by any domestic financial institution or agency for or on behalf of a foreign banking institution, if the correspondent account involves the targeted jurisdiction. A discussion of the section 311 factors relevant to imposing this particular special measure follows.

1. Whether Similar Actions Have Been or Will Be Taken by Other Nations or Multilateral Groups Against Iran

The United Nations Security Council has adopted multiple resolutions imposing sanctions on Iran for its refusal to comply with international nuclear obligations and proliferation sensitive activities, including United Nations Security Council resolutions (''UNSCRs'') 1696,[9] 1737,[10] 1747,[11]

[2] 31 U.S.C. 5318A was amended by section 501 of the Iran Freedom Support Act of 2006, Public Law 109–293.

[3] Available special measures include requiring: (1) Recordkeeping and reporting of certain financial transactions; (2) collection of information relating to beneficial ownership; (3) collection of information relating to certain payable-through accounts; (4) collection of information relating to certain correspondent accounts; and (5) prohibition or conditions on the opening or maintaining of correspondent or payable through accounts. 31 U.S.C. 5318A(b)(l)–(5). For a complete discussion of the range of possible countermeasures, *see* 68 FR 18917 (April 17, 2003) (proposing special measures against Nauru).

[4] Section 5318A(a)(4)(A) requires the Secretary to consult with the Chairman of the Board of Governors of the Federal Reserve System, any other appropriate Federal banking agency, the Secretary of State, the Securities and Exchange Commission (SEC), the Commodity Futures Trading Commission (CFTC), the National Credit Union Administration (NCUA), and, in the sole discretion of the Secretary, ''such other agencies and interested parties as the Secretary may find to be appropriate.'' The consultation process must also include the Attorney General, if the Secretary is considering prohibiting or imposing conditions on domestic financial institutions opening or maintaining correspondent account relationships with the designated jurisdiction.

[5] *See* the notice of this finding published elsewhere today in the **Federal Register**.

[6] Classified information used in support of a section 311 finding and measure(s) may be submitted by Treasury to a reviewing court *ex parte* and *in camera*. *See* section 376 of the Intelligence Authorization Act for fiscal year 2004, Public Law 108–177 (amending 31 U.S.C. 5318A by adding new paragraph (f)).

[7] In connection with this action, FinCEN consulted with staffs of the Federal functional regulators, the Department of Justice, and the Department of State.

[8] For purposes of the proposed rule, a correspondent account is defined as an account established to receive deposits from, or make payments or other disbursements on behalf of, a foreign bank, or handle other financial transactions related to the foreign bank.

[9] For a complete discussion of the sanctions adopted by UNSCR 1696, *see* ''Resolution 1696,'' United Nations Security Council, July 31, 2006 (*http://www.un.org/Docs/sc/unsc_resolutions06.htm*).

[10] For a complete discussion of the sanctions adopted by UNSCR 1737, *see* ''Resolution 1737,'' United Nations Security Council, December 23, 2006 (*http://www.un.org/Docs/sc/unsc_resolutions06.htm*).

[11] For a complete discussion of the sanctions adopted by UNSCR 1747, *see* ''Resolution 1747,'' United Nations Security Council, March 24, 2007 (*http://www.un.org/Docs/sc/unsc_resolutions07.htm*).

1803,[12] and 1929.[13] All resolutions were reaffirmed in 2008, 2009, and 2010 through UNSCRs 1835,[14] 1887,[15] and 1929,[16] respectively.

Iran's serious deficiencies with respect to anti-money laundering/countering the financing of terrorism (''AML/CFT'') controls have long been highlighted by numerous international bodies and government agencies. Starting in October 2007, the Financial Action Task Force (''FATF'') has issued a series of public statements expressing its concern that Iran's lack of a comprehensive AML/CFT regime represents a significant vulnerability within the international financial system. The statements further called upon Iran to address those deficiencies with urgency, and called upon FATF-member countries to advise their institutions to conduct enhanced due diligence with respect to the risks associated with Iran's deficiencies.[17]

The FATF has been particularly concerned with Iran's failure to address the risk of terrorist financing, and starting in February 2009, the FATF called upon its members and urged all jurisdictions to apply effective countermeasures to protect their financial sectors from the terrorist financing risks emanating from Iran.[18] In addition, the FATF advised jurisdictions to protect correspondent relationships from being used to bypass or evade countermeasures and risk mitigation practices, and to take into account money laundering and financing of terrorism risks when considering requests by Iranian financial institutions to open branches and subsidiaries in their jurisdictions.[19] The FATF also called on its members and other jurisdictions to advise their financial institutions to give special attention to business relationships and transactions with Iran, including Iranian companies and financial institutions.[20] Over the past three years, the FATF has repeatedly reiterated these concerns and reaffirmed its call for FATF-member countries and all jurisdictions to implement countermeasures to protect the international financial system from the terrorist financing risk emanating from Iran. In response, numerous countries, including all G7 countries, have issued advisories to their financial institutions.[21]

The FATF's most recent statement in October 2011 reiterated, with a renewed urgency, its concern regarding Iran's failure to address the risk of terrorist financing and the serious threat this poses to the integrity to the international financial system.[22] The FATF reaffirmed its February 2009 call to apply effective countermeasures to protect their financial sectors from ML/FT risks emanating from Iran, and further called upon its members to consider the steps already taken and possible additional safeguards or strengthen existing ones.[23] In addition, the FATF stated that, if Iran fails to take concrete steps to improve its AML/CFT regime, the FATF will consider calling on its members and urging all jurisdictions to strengthen countermeasures in February 2012.[24] The numerous calls by the FATF for Iran to urgently address its terrorist financing vulnerability, coupled with the extensive record of Iranian entities using the financial system to finance terrorism, proliferation activities, and other illicit activity,[25] raises significant concern over the willingness or ability of Iran to establish adequate controls to counter terrorist financing.

Although none of these actions to sanction Iran prohibit domestic financial institutions and agencies from opening or maintaining a correspondent account for or on behalf of any financial institution in Iran, or require the type of special due diligence outlined in this proposed rulemaking, FinCEN encourages other countries or multilateral groups to take similar action based on the findings contained in this rulemaking.

2. Whether the Imposition of the Fifth Special Measure Would Create a Significant Competitive Disadvantage, Including Any Undue Cost or Burden Associated With Compliance, for Financial Institutions Organized or Licensed in the United States

The fifth special measure sought to be imposed by this rulemaking would prohibit covered financial institutions from opening and maintaining correspondent accounts for, or on behalf of, Iranian banking institutions. As a corollary to this measure, covered financial institutions also would be required to take reasonable steps to apply special due diligence, as set forth below, to all of their correspondent accounts to help ensure that no such account is being used indirectly to provide services to an Iranian banking institution. FinCEN does not expect the burden associated with these requirements to be significant given that U.S. financial institutions have long been subject to sanctions regulations prohibiting the provision of correspondent account services for banking institutions in Iran. There is a minimal burden involved in transmitting a one-time notice to certain correspondent account holders concerning the prohibition on indirectly providing services to Iranian banking institutions. In addition, U.S. financial

[12] For a complete discussion of the sanctions adopted by UNSCR 1803, see ''Resolution 1803,'' United Nations Security Council, March 3, 2008 (*http://www.un.org/Docs/sc/unsc_resolutions08.htm*).

[13] For a complete discussion of the sanctions adopted by UNSCR 1929, *see* ''Resolution 1929,'' United Nations Security Council, June 9, 2010 (*http://www.un.org/Docs/sc/unsc_resolutions10.htm*).

[14] *See* ''Resolution 1835,'' United Nations Security Council, September 27, 2008 (*http://www.un.org/Docs/sc/unsc_resolutions08.htm*).

[15] *See* ''Resolution 1887,'' United Nations Security Council, September 24, 2009 (*http://www.un.org/Docs/sc/unsc_resolutions09.htm*).

[16] *See* ''Resolution 1929,'' United Nations Security Council, June 9, 2010 (*http://www.un.org/Docs/sc/unsc_resolutions10.htm*).

[17] In response to concerns raised by these FATF and IMF reports, FinCEN issued an advisory on October 16, 2007 to financial institutions regarding the heightened risk of Iranian ''money laundering, terrorist financing, and weapons of mass destruction proliferation financing.'' The advisory further cautioned institutions that there may be an increased effort by Iranian entities to circumvent international sanctions and related financial community scrutiny through the use of deceptive practices. *See* ''Guidance to Financial Institutions on the Increasing Money Laundering Threat Involving Illicit Iranian Activity,'' FinCEN, October 16, 2007 (*http://www.fincen.gov/statutes_regs/guidance/pdf/guidance_fi_increasing_mlt_iranian.pdf*). The FATF simultaneously published guidance to assist countries with implementation of UNSCRs 1737 and 1747. *See* ''Guidance Regarding the Implementation of Activity-Based Financial Prohibitions of United Nations Security Council Resolution 1737,'' October 12, 2007 (*http://www.fatf-gafi.org/dataoecd/43/17/39494050.pdf*) and ''Guidance Regarding the Implementation of Financial Provisions of the United Nations Security Council Resolutions to Counter the Proliferation of Weapons of Mass Destruction,'' September 5, 2007 (*http://www.fatf-gafi.org/dataoecd/23/16/39318680.pdf*).

[18] *See* ''FATF Statement on Iran,'' The Financial Action Task Force, February 25, 2009 (*http://www.fatf-gafi.org/dataoecd/18/28/42242615.pdf*).

[19] *Id.*

[20] *Id.*

[21] *See* ''Circular 13/2008 (GW)—Statement of the FATF of 16 October 2008,'' November 7, 2008 (*http://www.bafin.de/cln_171/nn_721228/SharedDocs/Veroeffentlichungen/EN/Service/Circulars/rs_0813_gw.html?_nnn=true*); ''February 27, 2009 FINTRAC Advisory,'' February 27, 2009 (*http://www.fintrac-canafe.gc.ca/publications/avs/2009-02-27-eng.asp*); ''HM Treasury warns businesses of serious threats posed to the international financial system,'' March 11, 2009 (*http://webarchive.nationalarchives.gov.uk/+/http://www.hm-treasury.gov.uk/press_26_09.htm*); ''Letter from French Minister of Economy,'' (*http://www2.economie.gouv.fr/directions_services/dgtpe/sanctions/sanctions iran.php*); and ''Bank of Italy Circular,'' (*http://www.dt.tesoro.it/it/prevenzione_reati_finanziari/*).

[22] *See* ''FATF Public Statement,'' The Financial Action Task Force, October 28, 2011 (*http://www.fatf-gafi.org/document/55/0,3746,en_32250379_32236992_48966519_1_1_1_1,00.html*).

[23] *Id.*

[24] *Id.*

[25] ''Update on the Continuing Illicit Finance Threat Emanating From Iran,'' FinCEN, June 22, 2010 (*http://www.fincen.gov/statutes_regs/guidance/html/fin-2010-a008.html*).

institutions generally apply some degree of due diligence in screening their transactions and accounts, often through the use of commercially available software such as that used for compliance with the economic sanctions programs administered by the Office of Foreign Assets Control (OFAC) of the Department of the Treasury. As explained in more detail in the section-by-section analysis below, financial institutions should, if necessary, be able to easily adapt their current screening procedures to comply with this special measure. Thus, the special due diligence that would be required by this rulemaking is not expected to impose a significant additional burden upon U.S. financial institutions.

3. The Extent To Which the Proposed Action or Timing of the Action Will Have a Significant Adverse Systemic Impact on the International Payment, Clearance, and Settlement System, or on Legitimate Business Activities of Iran

Banking institutions in Iran generally are not major participants in the international payment system and are not relied upon by the international banking community for clearance or settlement services. Additionally, given the preexisting OFAC and international sanctions on Iran and certain Iranian banking institutions, it is unlikely that these new measures or the timing of the new measures will have a significant impact on the international payment, clearance, and settlement system. Financial transactions between the United States and Iran pertaining to licensed agricultural and medical exports to Iran, as well as other licensed transactions or transactions exempted or not prohibited from the scope of OFAC sanctions, may continue under the rule as proposed.[26] Legitimate pre-existing personal investments held by Iranian residents in the United States that do not involve Iranian banking institutions will be unaffected. Consequently, in light of the reasons for imposing this special measure, FinCEN does not believe that it will impose an undue burden on legitimate business activities.

4. The Effect of the Proposed Action on United States National Security and Foreign Policy

The exclusion from the U.S. financial system of jurisdictions that serve as conduits for significant money laundering activity, for the financing of terrorism or weapons of mass destruction or their delivery systems, and for other financial crimes enhances U.S. national security by making it more difficult for terrorists and money launderers to access the substantial resources of the U.S. financial system. To the extent that this action serves as an additional tool in preventing Iran from accessing the U.S. financial system, the proposed action supports and upholds U.S. national security and foreign policy goals. More generally, the imposition of the fifth special measure would complement the U.S. Government's worldwide efforts to expose and disrupt international money laundering and terrorist financing.

Therefore, pursuant to the finding of the Director of FinCEN that Iran is a jurisdiction of primary money laundering concern, and after conducting the required consultations and weighing the relevant factors, FinCEN has determined that reasonable grounds exist for imposing the fifth special measure authorized by 31 U.S.C. 5318A(b)(5) against Iran.

III. Section-by-Section Analysis

The proposed rule would prohibit covered financial institutions from establishing, maintaining, or managing in the United States any correspondent account for, or on behalf of, banking institutions in Iran. As a corollary to this prohibition, covered financial institutions would be required to apply special due diligence to their correspondent accounts to guard against their improper indirect use by Iranian banking institutions. At a minimum, that special due diligence must include two elements. First, a covered financial institution must notify those correspondent account holders that the covered financial institution knows or has reason to know provide services to Iranian banking institutions, that such correspondents may not provide Iranian banking institutions with access to the correspondent account maintained at the covered financial institution. Second, a covered financial institution must take reasonable steps to identify any indirect use of its correspondent accounts by Iranian banking institutions, to the extent that such indirect use can be determined from transactional records maintained by the covered financial institution in the normal course of business. A covered financial institution should take a risk-based approach when deciding what, if any, additional due diligence measures it should adopt to guard against the improper indirect use of its correspondent accounts by Iranian banking institutions, based on risk factors such as the type of services it offers and the geographic locations of its correspondents.

A. 1010.657(a)—Definitions

1. Correspondent Account

Section 1010.657(a)(1) defines the term ''correspondent account'' by reference to the definition contained in 31 CFR 1010.605(c)(1)(ii). Section 1010.605(c)(1)(ii) defines a correspondent account to mean:

- An account established to receive deposits from, or make payments or other disbursements on behalf of, a foreign bank, or handle other financial transactions related to the foreign bank.

In the case of a U.S. depository institution, this broad definition includes most types of banking relationships between a U.S. depository institution and a foreign bank that are established to provide regular services, dealings, and other financial transactions including demand deposit, savings deposit, or other transaction or asset accounts, and credit accounts or other extensions of credit.[27]

In the case of securities broker-dealers, futures commission merchants, introducing brokers in commodities, and investment companies that are open-end companies (mutual funds), we are using the same definition of ''account'' for purposes of this rule as was established in the final rule implementing section 312 of the USA PATRIOT Act.[28]

2. Covered Financial Institution

Section 1010.657(a)(2) of the proposed rule defines ''covered financial institution'' with the same definition used in the final rule implementing section 312 of the USA PATRIOT Act,[29] which in general includes the following:

- An insured bank (as defined in section 3(h) of the Federal Deposit Insurance Act (12 U.S.C. 1813(h));
- A commercial bank;
- An agency or branch of a foreign bank in the United States;
- A federally insured credit union;
- A credit union;
- A savings association;
- A corporation acting under section 25A of the Federal Reserve Act (12 U.S.C. 611);
- A trust bank or trust company that is federally regulated and is subject to an anti-money laundering program requirements;
- A broker or dealer in securities registered, or required to be registered,

[26] For a more complete discussion of prohibited and non-prohibited transactions, *see http://www.treas.gov/ofac.*

[27] *See* 31 CFR 1010.605(c)(2)(i)(A)–(B).

[28] *See* 31 CFR 1010.605(c)(2)(ii)–(iv).

[29] *See* 31 CFR 1010.605(f)(1)–(2).

with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), except persons who register pursuant to section 15(b)(11) of the Securities Exchange Act of 1934;

- A futures commission merchant or an introducing broker registered, or required to be registered, with the Commodity Futures Trading Commission under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*), except persons who register pursuant to section 4(f)(a)(2) of the Commodity Exchange Act;
- A private banker; and
- A mutual fund.

3. Iranian Banking Institution

Section 1010.657(a)(3) of the proposed rule defines a foreign bank as that term is defined in 1010.100(u). An Iranian banking institution shall mean any foreign bank chartered by Iran, including any branches, offices, or subsidiaries of such bank operating in any jurisdiction, and any branch or office within Iran of any foreign bank licensed by Iran. In addition, the Central Bank of Iran (Bank Markazi Iran),[30] as well as any foreign bank of which more than 50 percent of the voting stock or analogous interest is owned by two or more foreign banks chartered by Iran, shall be considered an Iranian banking institution. For purposes of this rule, a subsidiary shall mean a company of which more than 50 percent of the voting stock or analogous interest is directly or indirectly owned by another company.

A covered financial institution should take commercially reasonable measures to determine whether it maintains a correspondent account for an Iranian banking institution, including a branch, office, or subsidiary of an Iranian banking institution.

B. 1010.657(b)—Requirements for Covered Financial Institutions

For purposes of complying with the proposed rule's prohibition on the opening or maintaining of correspondent accounts for, or on behalf of, Iranian banking institutions, FinCEN expects that a covered financial institution will take such steps that a reasonable and prudent financial institution would take to protect itself from loan fraud or other fraud or loss based on misidentification of a person's status.

1. Prohibition on Direct Use of Correspondent Accounts

Section 1010.657(b)(1) of the proposed rule requires all covered financial institutions to terminate any correspondent account that is established, maintained, administered, or managed in the United States for, or on behalf of, Iranian banking institutions, provided that the account is not blocked under any Executive Order issued pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA) or under 31 CFR Chapter V. The prohibition would require all covered financial institutions to review their account records to ensure that they maintain no accounts directly for, or on behalf of, an Iranian banking institution.

2. Special Due Diligence of Correspondent Accounts To Prohibit Improper Indirect Use

As a corollary to the prohibition on maintaining correspondent accounts directly for Iranian banking institutions, proposed section 1010.657(b)(2) requires a covered financial institution to apply special due diligence to its correspondent accounts [31] that is reasonably designed to guard against their improper indirect use by Iranian banking institutions. At a minimum, that special due diligence must include notifying those correspondent account holders that the covered financial institution knows or has reason to know provide services to Iranian banking institutions, that such correspondents generally may not provide Iranian banking institutions with access to the correspondent account maintained at the covered financial institution. A covered financial institution would, for example, have knowledge that the correspondents provide such access to Iranian banking institutions through transaction screening software or through the processing of Iranian transactions under OFAC licenses. A covered financial institution may satisfy this requirement by transmitting the following notice to its correspondent account holders that it knows or has reason to know provide services to Iranian banking institutions:

> Notice: Pursuant to U.S. regulations issued under section 311 of the USA PATRIOT Act, 31 CFR 1010.657, we are prohibited from establishing, maintaining, administering or managing a correspondent account for, or on behalf of, an Iranian banking institution or any of its subsidiaries. The regulations also require us to notify you that you may not provide an Iranian banking institution or any of its subsidiaries with access to the correspondent account you hold at our financial institution other than for the purpose of processing transactions that are authorized, exempt, or not prohibited pursuant to any Executive Order issued under the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) or 31 C.F.R. Chapter V. If we become aware that an Iranian banking institution or any of its subsidiaries is indirectly using the correspondent account you hold at our financial institution for transactions other than those specified above, we will be required to take appropriate steps to prevent such access, including terminating your account.

The purpose of the notice requirement is to help ensure cooperation from correspondent account holders in denying Iranian banking institutions access to the U.S. financial system. However, FinCEN does not require or expect a covered financial institution to obtain a certification from any of its correspondent account holders that indirect access will not be provided in order to comply with this notice requirement. Instead, methods of compliance with the notice requirement could include, for example, transmitting a one-time notice by mail, fax, or email to certain of the covered financial institution's correspondent account customers, informing them that they may not provide Iranian banking institutions with access to the covered financial institution's correspondent account, or including such information in the next regularly occurring transmittal from the covered financial institution to those correspondent account holders. FinCEN specifically solicits comments on the form and scope of the notice that would be required under the rule. FinCEN also requests comment as to whether a one-time notice will be sufficient to ensure cooperation from correspondent account holders in denying Iranian banking institutions access to the financial system, as well as the incremental costs that financial institutions would incur if this rule required an annual notice.

A covered financial institution also would be required under this rulemaking to take reasonable steps to identify any indirect use of its correspondent accounts by Iranian

[30] Prior regulations that have applied Section 311 special measures to jurisdictions of primary money laundering concern have not included the jurisdiction's central bank within the scope of the regulation. However, in the case of the Islamic Republic of Iran, this inclusion is justified due to the deceptive practices the Central Bank of Iran engages in and encourages among Iranian state-owned banks. This behavior is discussed in the notice of finding that the Islamic Republic of Iran is a jurisdiction of primary money laundering concern published elsewhere today in the **Federal Register**. *See* footnote 5, *supra.*

[31] Again, for purposes of the proposed rule, a correspondent account is defined as an account established to receive deposits from, or make payments or other disbursements on behalf of, a foreign bank, or handle other financial transactions related to the foreign bank.

banking institutions, to the extent that such indirect use can be determined from transactional records maintained by the covered financial institution in the normal course of business. For example, a covered financial institution would be expected to apply an appropriate screening mechanism to be able to identify a funds transfer order that on its face listed an Iranian banking institution as the originator's or beneficiary's financial institution, or otherwise referenced an Iranian banking institution in a manner detectable under the financial institution's normal screening processes. An appropriate screening mechanism could be the mechanism used by a covered financial institution to comply with various legal requirements, such as the commercially available software programs used to comply with the economic sanctions programs administered by OFAC. FinCEN specifically solicits comments on the requirement under the proposed rule that covered financial institutions take reasonable steps to screen their correspondent accounts in order to identify any indirect use of such accounts by Iranian banking institutions.

Notifying certain correspondent account holders and taking reasonable steps to identify any indirect use of its correspondent accounts by Iranian banking institutions in the manner discussed above are the minimum due diligence requirements under the proposed rule. Beyond these minimum steps, a covered financial institution should adopt a risk-based approach for determining what, if any, additional due diligence measures it should implement to guard against the improper indirect use of its correspondent accounts by Iranian banking institutions, based on risk factors such as the type of services it offers and the geographic locations of its correspondent account holders.

A covered financial institution that obtains knowledge that a correspondent account is being used by a foreign bank to provide indirect access to an Iranian banking institution must take all appropriate steps to prevent such indirect access, including the notification of its correspondent account holder per section 1010.657(b)(2)(i)(A) and, where necessary, terminating the correspondent account. However, this provision does not require financial institutions to prevent indirect access to correspondent accounts when such access is necessary to conduct transactions involving Iranian banking institutions that are: (1) Authorized pursuant to Executive Orders issued under IEEPA or pursuant to 31 CFR Chapter V, including transactions authorized by the Office of Foreign Assets Control; (2), exempted from the prohibitions of such authority; or (3) not prohibited by such authority.

A covered financial institution may afford the foreign bank a reasonable opportunity to take corrective action prior to terminating the correspondent account. Should the foreign bank refuse to comply, or if the covered financial institution cannot obtain adequate assurances that Iranian banking institutions will no longer be able to improperly access the correspondent account, the covered financial institution must terminate the account within a commercially reasonable time. This means that the covered financial institution should not permit the foreign bank to establish any new positions or execute any transactions through the account, other than those necessary to close the account. A covered financial institution may reestablish an account closed under the proposed rule if it determines that the account will not be used to provide improper indirect access to an Iranian banking institution. FinCEN specifically solicits comments on the requirement under the proposed rule that covered financial institutions prevent improper indirect access to Iranian banking institutions, once such indirect access is identified.

3. Reporting Not Required

Section 1010.657(b)(3) of the proposed rule clarifies that the rule does not impose any reporting requirement upon any covered financial institution that is not otherwise required by applicable law or regulation. A covered financial institution must, however, document its compliance with the requirement that it notify those correspondent account holders that the covered financial institution knows or has reason to know provide services to Iranian banking institutions, that such correspondents may not provide Iranian banking institutions with improper access to the correspondent account maintained at the covered financial institution.

IV. Request for Comments

FinCEN invites comments on all aspects of the proposal to prohibit the opening or maintaining of correspondent accounts for or on behalf of Iranian banking institutions, and specifically invites comments on the following matters:

1. The form and scope of the notice to certain correspondent account holders that would be required under the rule and whether a one-time notice will be sufficient to ensure cooperation from correspondent account holders in denying Iranian banking institutions access to the financial system, and the incremental costs that financial institutions would incur if this rule required an annual notice;

2. The appropriate scope of the proposed requirement for a covered financial institution to take reasonable steps to identify any indirect use of its correspondent accounts by Iranian banking institutions;

3. The appropriate steps a covered financial institution should take once it identifies an indirect use of one of its correspondent accounts by an Iranian banking institution; and

4. The impact of the proposed special measure upon legitimate transactions with Iran involving, in particular, U.S. persons and entities; foreign persons, entities, and governments; and multilateral organizations doing legitimate business with persons or entities operating in Iran.

V. Regulatory Flexibility Act

It is hereby certified that this proposed rule will not have a significant economic impact on a substantial number of small entities. Given that U.S. financial institutions have long been subject to sanctions regulations prohibiting the provision of correspondent account services for banking institutions in Iran, FinCEN assesses that the prohibition on maintaining such accounts will not have a significant impact on a substantial number of small entities. In addition, all U.S. persons, including U.S. financial institutions, currently must exercise some degree of due diligence in order to comply with various legal requirements. The tools used for such purposes, including commercially available software used to comply with the economic sanctions programs administered by OFAC, can easily be modified to monitor for the use of correspondent accounts by Iranian banking institutions. Thus, the special due diligence that would be required by this rulemaking—*i.e.,* the one-time transmittal of notice to certain correspondent account holders and the screening of transactions to identify any indirect use of correspondent accounts, is not expected to impose a significant additional economic burden upon small U.S. financial institutions. FinCEN invites comments from members of the public who believe there will be a significant economic impact on small entities.

VI. Paperwork Reduction Act

The collection of information contained in this proposed rule is being submitted to the Office of Management

and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Desk Officer for the Department of Treasury, Office of Information and Regulatory Affairs, Office of Management and Budget, Paperwork Reduction Project (1506), Washington, DC 20503 (or by email to *oira_submission@omb.eop.gov*) with a copy to FinCEN by mail or email at the addresses previously specified. Comments should be submitted by one method only. Comments on the collection of information should be received by January 27, 2012. In accordance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), and its implementing regulations, 5 CFR part 1320, the following information concerning the collection of information as required by 31 CFR 1010.657 is presented to assist those persons wishing to comment on the information collection.

The collection of information in this proposed rule is in 1010.657(b)(2)(i) and 1010.657(b)(3)(i). The notification requirement in 1010.657(b)(2)(i) is intended to ensure cooperation from correspondent account holders in denying Iranian banking institutions access to the U.S. financial system. The information required to be maintained by 1010.657(b)(3)(i) will be used by federal agencies and certain self-regulatory organizations to verify compliance by covered financial institutions with the provisions of 31 CFR 1010.657. The class of financial institutions affected by the notification requirement is identical to the class of financial institutions affected by the recordkeeping requirement. The collection of information is mandatory.

Description of Affected Financial Institutions: Banks, broker-dealers in securities, futures commission merchants and introducing brokers, and mutual funds maintaining correspondent accounts.

Estimated Number of Affected Financial Institutions: 5,000.

Estimated Average Annual Burden Hours per Affected Financial Institution: The estimated average burden associated with the collection of information in this proposed rule is one hour per affected financial institution.

Estimated Total Annual Burden: 5,000 hours.

FinCEN specifically invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the mission of FinCEN, including whether the information shall have practical utility; (b) the accuracy of FinCEN's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information required to be maintained; (d) ways to minimize the burden of the required collection of information, 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 maintain the information.

VII. Executive Order 12866

The proposed rule is not a significant regulatory action for purposes of Executive Order 12866, ''Regulatory Planning and Review.''

List of Subjects in 31 CFR Chapter X

Administrative practice and procedure, Banks and banking, Brokers, Counter-money laundering, Counter-terrorism, Foreign banking, Iran.

Authority and Issuance

For the reasons set forth in the preamble, chapter X of title 31 of the Code of Federal Regulations is proposed to be amended as follows:

Chapter X—Financial Recordkeeping and Reporting of Currency and Financial Transactions

1. The authority citation for chapter X is amended to read as follows:

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5314, 5316–5332 Title III, secs. 311, 312, 313, 314, 319, 326, 352, Pub. L. 107–56, 115 Stat. 307.

2. Subpart F of Chapter X is amended by adding new § 1010.657 under the undesignated center heading ''SPECIAL DUE DILIGENCE FOR CORRESPONDENT ACCOUNTS AND PRIVATE BANKING ACCOUNTS'' to read as follows:

§ 1010.657 Special measures against the Islamic Republic of Iran.

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

(1) *Correspondent account* has the same meaning as provided in § 1010.605(c)(1)(ii).

(2) *Covered financial institution* has the same meaning as provided in § 1010.605(f)(1)–(2).

(3) *Foreign bank* has the same meaning as 1010.100(u).

(4) *Iranian banking institution* means the following:

(i) Any foreign bank chartered by Iran, including any branches, offices, or subsidiaries of such bank operating in any jurisdiction, and any branch or office within Iran of any foreign bank licensed by Iran;

(ii) The Central Bank of Iran (Bank Markazi Iran); and

(iii) Any foreign bank of which more than 50 percent of the voting stock or analogous interest is owned by two or more foreign banks chartered by Iran.

(5) *Subsidiary* means a company of which more than 50 percent of the voting stock or analogous interest is owned by another company.

(b) *Requirements for covered financial institutions.*

(1) *Prohibition on direct use of correspondent accounts.* A covered financial institution shall terminate any correspondent account that is established, maintained, administered, or managed in the United States for, or on behalf of, an Iranian banking institution, provided that the account is not blocked under any Executive Order issued pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA) or under 31 CFR Chapter V.

(2) *Special due diligence of correspondent accounts to prohibit improper indirect use.*

(i) A covered financial institution shall apply special due diligence to its correspondent accounts that is reasonably designed to guard against their improper indirect use by Iranian banking institutions. At a minimum, that special due diligence must include:

(A) Notifying those correspondent account holders that the covered financial institution knows or has reason to know provide services to Iranian banking institutions, that such correspondents generally may not provide Iranian banking institutions with access to the correspondent account maintained at the covered financial institution; and

(B) Taking reasonable steps to identify any indirect use of its correspondent accounts by Iranian banking institutions, to the extent that such indirect use can be determined from transactional records maintained in the covered financial institution's normal course of business.

(ii) A covered financial institution shall take a risk-based approach when deciding what, if any, other due diligence measures it should adopt to guard against the improper indirect use of its correspondent accounts by Iranian banking institutions.

(iii) A covered financial institution that obtains knowledge that a correspondent account is being used by the foreign bank to provide indirect access to an Iranian banking institution, shall take all appropriate steps to prevent such indirect access, including the notification of its correspondent account holder under paragraph

(b)(2)(i)(A) of this section and, where necessary, terminating the correspondent account, except to the extent that such indirect access to the correspondent accounts is necessary to conduct transactions involving Iranian banking institutions that are: (1) Authorized pursuant to Executive Orders issued under IEEPA or pursuant to 31 CFR Chapter V, including transactions authorized by the Office of Foreign Assets Control; (2), exempted from the prohibitions of such authority; or (3) not prohibited by such authority.

(3) *Recordkeeping and reporting.*

(i) A covered financial institution is required to document its compliance with the notice requirement set forth in paragraph (b)(2)(i)(A) of this section.

(ii) Nothing in this section shall require a covered financial institution to report any information not otherwise required to be reported by law or regulation.

Dated: November 18, 2011.

James H. Freis, Jr.,

Director, Financial Crimes Enforcement Network.

[FR Doc. 2011–30331 Filed 11–25–11; 8:45 am]

BILLING CODE 4810–02–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2010–0017–201014(b) & EPA–R04–OAR–2010–0018–201001(b); FRL–9495–8]

Approval and Promulgation of Air Quality Implementation Plans: South Carolina; Negative Declarations for Groups I, II, III and IV Control Techniques Guidelines; and Reasonably Available Control Technology

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve several State Implementation Plan (SIP) revisions submitted by the South Carolina Department of Health and Environmental Control (SC DHEC). These revisions establish reasonably available control technology (RACT) requirements for the three major sources located in the portion of York County, South Carolina that is within the bi-state Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina 1997 8-hour ozone nonattainment area that either emit volatile organic compounds, nitrogen oxides or both. The bi-state Charlotte-Gastonia-Rock Hill 1997 8-hour ozone nonattainment area is hereinafter referred to as the ''bi-state Charlotte Area.'' In addition, South Carolina's SIP revisions include negative declarations for certain source categories for which EPA has control technique guidelines, meaning that SC DHEC has concluded that no such sources are located in that portion of the nonattainment area. EPA has evaluated the proposed revisions to South Carolina's SIP, and has preliminarily concluded that they are consistent with statutory and regulatory requirements and EPA guidance.

DATES: Written comments must be received on or before December 28, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2010–0017 and EPA–R04–OAR–2010–0018 by one of the following methods:

1. *http://www.regulations.gov:* Follow the online instructions for submitting comments.

2. *Email: benjamin.lynorae@epa.gov*.

3. *Fax:* (404) 562–9019.

4. *Mail:* ''EPA–R04–OAR–2010–0017'' for comments regarding the RACT demonstration and the negative declarations for Groups I and I CTG. ''EPA–R04–OAR–2010–0018'' for comments regarding the negative declarations for Groups III and IV CTG. Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960.

5. *Hand Delivery or Courier:* Lynorae Benjamin, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Zuri Farngalo, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Zuri Farngalo may be reached by phone at (404) 562–9152 or by electronic mail address *farngalo.zuri@epa.gov*.

SUPPLEMENTARY INFORMATION: On March 12, 2008, EPA issued a revised ozone NAAQS. See 73 FR 16436. EPA subsequently announced a reconsideration of the 2008 NAAQS, and proposed new 8-hour ozone NAAQS in January 2010. See 75 Fr 2938. In September 2011, EPA withdrew the proposed reconsidered NAAQS and began implementation of the 2008 NAAQS. The current action, however, is being taken to address requirements under the 1997 ozone NAAQS for a portion of York County, South Carolina. Requirements for the bi-state Charlotte Area under the 2008 NAAQS will be addressed in the future.

For additional information see the direct final rule which is published in the Rules Section of this **Federal Register.** In the Final Rules Section of this **Federal Register,** EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

Dated: November 7, 2011.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 2011–30297 Filed 11–25–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 99–325; DA 11–1832]

FM Asymmetric Sideband Operation and Associated Technical Studies

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission seeks comment on a request by certain private parties, identified below, that the Commission authorize voluntary asymmetric digital sideband power for

FM stations. This document establishes a period for public comment on this request and on two related technical reports.

DATES: Comments for this proceeding may be filed on or before December 19, 2011 and reply comments may be filed on or before January 3, 2012.

ADDRESSES: You may submit comments, identified by MM Docket No. 99–325, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web Site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *Email: ecfs@fcc.gov.* Include the docket number in the subject line of the message. See the **SUPPLEMENTARY INFORMATION** section of this document for detailed information on how to submit comments by email.
- *Mail:* 445 12th Street SW., Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: (202) 418–0530 or TTY: (202) 418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Peter H. Doyle, Chief, Media Bureau, Audio Division, at (202) 418–2700; Susan Crawford, Ann Gallagher, or Charles Miller, Media Bureau, Audio Division, at (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a summary of a Public Notice released by the Media Bureau on November 1, 2011. The full text of this document is available for public inspection and copying during regular business hours in the Commission's Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone (202) 488–5300, facsimile (202) 488–5563 or via email *FCC@BCPIWEB.com.* The full text may also be downloaded at *http://www.fcc.gov.* Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://www.fcc.gov/cbg/ecfs,* or the Federal eRulemaking Portal: *http://www.regulations.gov.* Filers should follow the instructions provided on the Web sites for submitting comments.
- *For ECFS filers, in completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket number:* MM Docket No. 99–325. Parties may also submit an electronic comment by Internet email. To get filing instructions, filers should send an email to *ecfs@fcc.gov,* and include the following words in the body of the message, ''get form.'' A sample form and instructions will be sent in response.
- *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission. The Commission's contractor will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street SW., Washington, DC 20554.
- Copies of the reports and any subsequently filed documents in this matter may be obtained electronically at *http://www.fcc.gov/e-file/ecfs.html,* and in paper form from BCPI during normal business hours in the Commission's Reference Information Center located at 445 12th Street SW., Room CY–A257, Washington, DC, 20554.
- Alternate formats of this Public Notice (computer diskette, large print, audio recording or Braille) are available to persons with disabilities by contacting the Consumer and Governmental Affairs Bureau at (202) 418–0530 or (202) 418–7365 (TTY).

Summary of Public Notice

On October 4, 2011, representatives of iBiquity Digital Corporation (iBiquity) and National Public Radio, Inc. (NPR) met with Media Bureau staff to discuss the possibility of permitting FM stations to operate with unequal digital sideband power levels. Concurrently, iBiquity filed a technical report that discusses the field performance of asymmetric digital sideband operation by FM stations. On October 24, 2011, NPR filed a report describing the results of field testing of asymmetric FM digital sidebands used in conjunction with the testing of newly-developed technology for reducing the peak-to-average power ratio in digital transmitters. Based on these reports, iBiquity and NPR requested that the Commission authorize voluntary asymmetric digital sideband power for FM stations. On November 1, 2011, the Media Bureau released the ''November 1, 2011, *Public Notice*'' soliciting comments on the iBiquity and NPR request and the two related technical reports. *Comment Sought on Request for FM Asymmetric Sideband Operation and Associated Technical Studies,* MM Docket No. 99–325, Public Notice, DA 11–1832 (MB rel. Nov. 1, 2011).

The iBiquity and NPR request and the iBiquity and NPR technical studies are available electronically from the Commission's Electronic Comment Filing System under MM Docket No. 99–235 at *http://fjallfoss.fcc.gov/ecfs/comments/view?id=6016844127* and *http://fjallfoss.fcc.gov/ecfs/document/view?id=7021717638,* respectively; or from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, 1–(800) 378–3160. The Media Bureau seeks comment on the issues identified above. The Bureau also seeks comment on the Initial Regulatory Flexibility Analysis below. This action is taken under delegated authority pursuant to §§ 0.61 and 0.283 of the Commission's rules, 47 CFR 0.61, 0.283, and the Second IBOC Order (*Digital Audio Broadcasting Systems and Their Impact on the Terrestrial Radio Broadcast Service,* Second Report and Order, First Order on Reconsideration and Second Further Notice of Proposed Rulemaking, 22 FCC Rcd 10344, 10383, para. 99 (2007)).

Paperwork Reduction Act

The Public Notice tentatively concludes that it would be expedient to modify Form 335–FM (OMB control number 3060–1034), currently used for Digital Notifications, to accommodate requests for increased digital power and/or operation with asymmetric digital sideband power. The Public Notice also seeks comment on the process by which FM stations engaging in such operations would notify the Commission and how such notifications would be maintained in the Commission's electronic databases. Thus, the proposal under consideration may result in a new or revised information collection requirement being adopted by the Commission when the final rules are adopted. If the Commission adopts any new or revised information collection requirement, the Commission will publish a separate notice in the **Federal Register** inviting the public to comment on the requirement, as required by the paper Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501–3520). In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

Ex Parte Rules

This proceeding will be treated as a ''permit-but-disclose'' proceeding subject to the ''permit-but-disclose'' requirements under § 1.1206(b) of the Commission's rules (47 CFR 1.1206(b)). *Ex parte* presentations are permissible if disclosed in accordance with Commission rules, except during the Sunshine Agenda period when presentations, *ex parte* or otherwise, are generally prohibited. Persons making oral *ex parte* presentations are reminded that a memorandum summarizing a presentation must contain a summary of the substance of the presentation and not merely a listing of the subjects discussed. More than a one- or two-sentence description of the views and arguments presented is generally required. Additional rules pertaining to oral and written presentations are set forth in 47 CFR 1.1206(b).

Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), 5 U.S.C. 603, the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the proposed rule as provided in the ''Dates'' paragraph of the item. The Commission will send a copy of the proposed rule, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the proposed rule and IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Proposed Rules

This document seeks comment on the iBiquity and NPR request that the Commission authorize voluntary asymmetric digital sideband power for FM stations. Currently, FM stations may operate only with equal power levels on the upper and lower primary digital sidebands. In the *First IBOC Order (Digital Audio Broadcasting Systems and Their Impact on the Terrestrial Radio Broadcast Service,* First Report and Order, 17 FCC Rcd 19990 (2002)), the Commission authorized FM stations to commence hybrid digital broadcasting with digital effective radiated power of one percent (-20 dBc) of the analog carrier level. In authorizing in-band-on-channel (IBOC) operation for FM stations, the Commission observed: ''The digital portion of the hybrid IBOC signal is transmitted on frequencies immediately adjacent to the main analog signal. Consequently, minimizing interference to stations on first-and, to a lesser extent, second-adjacent channels poses the most serious analog compatibility challenge.''

Early experience with FM IBOC operation showed the one-percent digital power level to be insufficient to replicate analog coverage areas. In response to a request from a group of broadcasters, the Media Bureau issued its January 29, 2010, *Order (Digital Audio Broadcasting Systems and Their Impact on the Terrestrial Radio Broadcast Service,* Order, 25 FCC Rcd 1182 (MB 2010)), which authorized most FM stations to increase their digital power up to 6 dB (to -14 dBc) upon notification to the Commission, and some stations up to 10 dB (to -10 dBc) by filing an informal application demonstrating that certain contour non-overlap conditions are met with respect to other stations operating on the upper and lower first-adjacent channels.

A significant number of FM stations are currently precluded from taking advantage of the full 10 dB digital power increase permitted by the *Order* due to the presence of a nearby station on one but not both of the two first-adjacent channels. If asymmetric digital sideband operation is permitted, such stations could presumably increase their digital power on the sideband away from the limiting station. The two technical reports include data supporting iBiquity's and NPR's contentions that such operations may improve a station's digital coverage without causing interference. By this November 1, 2011, *Public Notice* the Bureau seeks comment on the iBiquity and NPR request and the iBiquity and NPR technical reports.

B. Legal Basis

The authority for this proposed rulemaking is contained in sections 1, 2, 4(i), 301, 302, 303, 307, 308, and 309(j) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 301, 302, 303, 307, 308, and 309(j).

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

The RFA directs the Commission to provide a description of and, where feasible, an estimate of the number of small entities that will be affected by the proposed rules. The RFA generally defines the term ''small entity'' as encompassing the terms ''small business,'' ''small organization,'' and ''small governmental entity.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

Radio Stations. A radio broadcasting station is an establishment primarily engaged in broadcasting aural programs by radio to the public.[1] Included in this industry are commercial, religious, educational, and other radio stations. Radio broadcasting stations which primarily are engaged in radio broadcasting and which produce radio program materials are similarly included. The SBA has established a small business size standard for this category, which is: firms having $7 million or less in annual receipts.[2] According to BIA/Kelsey, MEDIA Access Pro Radio Analyzer Database, on

[1] U.S. Census Bureau, 2007 NAICS Code Definitions for NAICS Code 515112 Radio Stations. *http://www.census.gov/naics/2007/def/ND515111HTM#N51512.*

[2] 13 CFR 121.201, NAICS code 515112 (updated for inflation in 2008).

November 1, 2011, about 10,785 (97%) of 11,127 commercial radio stations have revenue of $7 million or less and thus qualify as small entities under the SBA definition. Therefore, the majority of such entities are small entities. We note, however, that in assessing whether a business concern qualifies as small under the above size standard, business affiliations must be included. Many radio stations are affiliated with much larger corporations having much higher revenue. Our estimate, therefore, likely overstates the number of small entities that might be affected by any ultimate changes to the rules and forms.

D. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements

In the *Second IBOC Order,* the Commission declined to establish a deadline for radio stations to convert to digital broadcasting, 22 FCC Rcd at 10351. Presently, radio stations may choose to commence IBOC digital operation pursuant to § 73.404 of the Commission's rules, 47 CFR 73.404, which requires that licensees provide notification to the Commission within 10 days of commencing IBOC digital operation. The January 29, 2010, *Order* allows eligible authorized FM stations to commence operation of FM digital facilities with digital effective radiated power (ERP) up to −14 dBc upon notice to the Commission on FCC Form 335–FM—Digital Notification. In addition, licensees must electronically notify the Media Bureau of any power increase in their FM digital ERP within 10 days of commencement using the same Form 335—Digital Notification. However, use of the Form 335–FM for notification of commencement of FM hybrid digital operation, or notification of modification of FM digital operation, is currently limited to non-super-powered FM stations with digital ERP not exceeding −14 dBc and super-powered stations with digital ERP not exceeding −20 dBc.

Non-super-powered FM stations requesting authorization to operate with digital ERP between −14 dBc and −10 dBc, or super-powered FM stations requesting digital ERP in excess of −20 dBc are required to file an informal request using the Engineering STA Form prior to commencement of the increased power FM digital operation. Licensees submitting such a request must use the simplified method set forth in the January 29, 2010, *Order* to determine the station's maximum permissible FM digital ERP. In situations where the simplified method is not applicable due to unusual terrain or other technical considerations, the Bureau will accept applications for FM digital ERP in excess of −14 dBc on a case-by-case basis, when accompanied by a showing detailing the prediction methodology, data, maps and sample calculations.

The proposed rule changes may, in some cases, impose different reporting or recordkeeping requirements on FM radio stations, insofar as they would allow certain licensees to voluntarily operate with asymmetric digital sideband power. However, the information that would be reported is already familiar to broadcasters, and is similar to the current IBOC digital operation notification or authorization reporting requirements, so any additional burdens would be minimal. The Public Notice tentatively concludes that it would be expedient to modify Form 335–FM, currently used for Digital Notifications, to accommodate requests for increased digital power and/or operation with asymmetric digital sideband power.

E. Steps Taken To Minimize Significant Impact on Small Entities, and Significant Alternatives Considered

The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities (5 U.S.C. 603(b)).

Operation of hybrid digital facilities by Commission licensees and permittees is voluntary. Likewise, use of asymmetric FM digital sideband powers would be limited to those licensees and permittees expressly seeking authorization for such operation. The proposal to permit use of asymmetric FM digital sideband powers thus would not impose any additional burden on FM broadcasters. In fact, for those FM broadcasters that choose to operate hybrid FM facilities, the proposal would confer a benefit. Currently, a significant number of FM stations are precluded from operating maximum permissible hybrid FM digital facilities. This occurs in the case of an FM station operating hybrid digital facilities that has a nearby FM station on one, but not both, of its two first-adjacent channels, thus limiting allowable digital power in both sidebands to a level that protects the sole limiting station. By permitting asymmetric FM digital sideband operation, such a station could increase to maximum permissible digital power on the sideband opposite the limiting FM station, thus achieving improved digital facilities and signal coverage. Because operation under the proposed rule is voluntary, and would only be undertaken by licensees and permittees that would realize a benefit from such operation, consideration of alternatives was not required.

F. Federal Rules Which Duplicate, Overlap, or Conflict With the Commission's Proposals

None.

Federal Communications Commission.

Kris A. Monteith,

Deputy Chief, Media Bureau.

[FR Doc. 2011–30598 Filed 11–25–11; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2011–0160]

Federal Motor Vehicle Safety Standards; Small Business Impacts of Motor Vehicle Safety

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of regulatory review; Request for comments.

SUMMARY: NHTSA seeks comments on the economic impact of its regulations on small entities. As required by Section 610 of the Regulatory Flexibility Act, we are attempting to identify rules that may have a significant economic impact on a substantial number of small entities. We also request comments on ways to make these regulations easier to read and understand. The focus of this notice is rules that specifically relate to school buses and other buses.

DATES: You should submit comments early enough to ensure that Docket Management receives them not later than January 27, 2012.

ADDRESSES: You may submit comments [identified by DOT Docket ID Number NHTSA–2011–0160] by any of the following methods:

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

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

• *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

• *Fax:* (202) 493–2251.

Instructions: For detailed instructions on submitting comments and additional information see the Comments heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

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 (65 FR 19477–78) or you may visit *http://DocketsInfo.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Juanita Kavalauskas, Office of Regulatory Analysis, Office of Regulatory Analysis and Evaluation, National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590 (telephone (202) 366–2584, fax (202) 366–3189).

SUPPLEMENTARY INFORMATION:

I. Section 610 of the Regulatory Flexibility Act

A. Background and Purpose

Section 610 of the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), requires agencies to conduct periodic reviews of final rules that have a significant economic impact on a substantial number of small business entities. The purpose of the reviews is to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the objectives of applicable statutes, to minimize any significant economic impact of the rules on a substantial number of such small entities.

B. Review Schedule

The Department of Transportation (DOT) published its Semiannual Regulatory Agenda on November 22, 1999, listing in Appendix D (64 FR 64684) those regulations that each operating administration will review under section 610 during the next 12 months. Appendix D contained DOT's 10-year review plan for all of its existing regulations. On November 24, 2008, NHTSA published in the **Federal Register** (73 FR 71401) a revised 10-year review plan for its existing regulations.

The National Highway Traffic Safety Administration (NHTSA, ''we'') has divided its rules into 10 groups by subject area. Each group will be reviewed once every 10 years, undergoing a two-stage process—an Analysis Year and a Review Year. For purposes of these reviews, a year will coincide with the fall-to-fall publication schedule of the Semiannual Regulatory Agenda. The newly revised 10-year plan will assess years 9 and 10 of the old plan in years 1 and 2 of the new plan. Year 1 (2008) began in the fall of 2008 and will end in the fall of 2009; Year 2 (2009) will begin in the fall of 2009 and will end in the fall of 2010; and so on.

During the Analysis Year, we will request public comment on and analyze each of the rules in a given year's group to determine whether any rule has a significant impact on a substantial number of small entities and, thus, requires review in accordance with section 610 of the Regulatory Flexibility Act. In each fall's Regulatory Agenda, we will publish the results of the analyses we completed during the previous year. For rules that have subparts, or other discrete sections of rules that do have a significant impact on a substantial number of small entities, we will announce that we will be conducting a formal section 610 review during the following 12 months.

The section 610 review will determine whether a specific rule should be revised or revoked to lessen its impact on small entities. We will consider: (1) The continued need for the rule; (2) the nature of complaints or comments received from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other federal rules or with state or local government rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule. At the end of the Review Year, we will publish the results of our review. The following table shows the 10-year analysis and review schedule:

NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION SECTION 610 REVIEWS

Year	Regulations to be reviewed	Analysis year	Review year
1	49 CFR 571.223 through 571.500, and parts 575 and 579	2008	2009
2	23 CFR parts 1200 and 1300	2009	2010
3	49 CFR parts 501 through 526 and 571.213	2010	2011
4	49 CFR 571.131, 571.217, 571.220, 571.221, and 571.222	2011	2012
5	49 CFR 571.101 through 571.110, and 571.135, 571.138 and 571.139	2012	2013
6	49 CFR parts 529 through 578, except parts 571 and 575	2013	2014
7	49 CFR 571.111 through 571.129 and parts 580 through 588	2014	2015
8	49 CFR 571.201 through 571.212	2015	2016
9	49 CFR 571.214 through 571.219, except 571.217	2016	2017
10	49 CFR parts 591 through 595 and new parts and subparts	2017	2018

C. Regulations Under Analysis

During Year 4, we will continue to conduct a preliminary assessment of the following: 49 CFR 571.131, 571.217, 571.220, 571.221, and 571.222.

Section	Title
571.131	School bus pedestrian safety devices.
571.217	Bus emergency exits and window retention and release.
571.220	School bus rollover protection.
571.221	School bus body joint strength.
571.222	School bus passenger seating and crash protection.

We are seeking comments on whether any requirements in 49 CFR 571.131, 571.217, 571.220, 571.221, and 571.222 have a significant economic impact on a substantial number of small entities. ''Small entities'' include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000. Business entities are generally defined as small businesses by Standard Industrial Classification (SIC) code, for the purposes of receiving Small Business Administration (SBA) assistance. Size standards established by SBA in 13 CFR 121.201 are expressed either in number of employees or annual receipts in millions of dollars, unless otherwise specified. The number of employees or annual receipts indicates the maximum allowed for a concern and its affiliates to be considered small. If your business or organization is a small entity and if any of the requirements in 49 CFR 571.131, 571.217, 571.220, 571.221, and 571.222 have a significant economic impact on your business or organization, please submit a comment to explain how and to what degree these rules affect you, the extent of the economic impact on your business or organization, and why you believe the economic impact is significant.

If the agency determines that there is a significant economic impact on a substantial number of small entities, it will ask for comment in a subsequent notice during the Review Year on how these impacts could be reduced without reducing safety.

II. Plain Language

A. Background and Purpose

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

- Have we organized the material to suit the public's needs?
- Are the requirements in the rule clearly stated?
- Does the rule contain technical language or jargon that is not clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?

If you have any responses to these questions, please include them in your comments on this document.

B. Review Schedule

In conjunction with our section 610 reviews, we will be performing plain language reviews over a ten-year period on a schedule consistent with the section 610 review schedule. We will review 49 CFR 571.131, 571.217, 571.220, 571.221, and 571.222 to determine if these regulations can be reorganized and/or rewritten to make them easier to read, understand, and use. We encourage interested persons to submit draft regulatory language that clearly and simply communicates regulatory requirements, and other recommendations, such as for putting information in tables that may make the regulations easier to use.

Comments

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number of this document in your comments.

Your comments must not be more than 15 pages long. (49 CFR 553.21.) We established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.

Please submit two copies of your comments, including the attachments, to Docket Management at the address given above under **ADDRESSES**.

Please note that pursuant to the Data Quality Act, in order for substantive data to be relied upon and used by the agency, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at *http://www.whitehouse.gov/omb/fedreg/reproducible.html.* DOT's guidelines may be accessed at *http://dmses.dot.gov/submit/DataQualityGuidelines.pdf.*

How can I be sure that my comments were received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation. (49 CFR part 512.)

Will the agency consider late comments?

We will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date.

How can I read the comments submitted by other people?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket are indicated above in the same location.

You may also see the comments on the Internet. To read the comments on the Internet, take the following steps:

(1) Go to the Federal Docket Management System (FDMS) at *http://regulations.gov.*

(2) FDMS provides two basic methods of searching to retrieve dockets and docket materials that are available in the system: (a) ''Quick Search'' to search using a full-text search engine, or (b) ''Advanced Search,'' which displays various indexed fields such as the docket name, docket identification number, phase of the action, initiating office, date of issuance, document title, document identification number, type of document, **Federal Register** reference, CFR citation, etc. Each data field in the advanced search may be searched independently or in combination with other fields, as desired. Each search yields a simultaneous display of all available information found in FDMS that is relevant to the requested subject or topic.

(3) You may download the comments. However, since the comments are

imaged documents, instead of word processing documents, the ''pdf'' versions of the documents are word searchable.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

Terry Shelton,

Associate Administrator for the National Center for Statistics and Analysis.

[FR Doc. 2011–30277 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

[Docket No. 111025652–1657–01]

RIN 0648–XA798

Endangered and Threatened Wildlife; 90-Day Finding on a Petition To List the Scalloped Hammerhead Shark as Threatened or Endangered Under the Endangered Species Act

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

ACTION: 90-day petition finding, request for information, and initiation of status review.

SUMMARY: We, NMFS, announce a 90-day finding on a petition to list the scalloped hammerhead shark (*Sphyrna lewini*) or, in the alternative, multiple distinct population segments (DPSs) of the scalloped hammerhead shark as threatened or endangered under the Endangered Species Act (ESA), and to designate critical habitat concurrently with the listing. We find that the petition and information in our files present substantial scientific or commercial information indicating that the petitioned action may be warranted. We will conduct a status review of the species to determine if the petitioned action is warranted. To ensure that the status review is comprehensive, we are soliciting scientific and commercial information pertaining to this species from any interested party.

DATES: Information and comments on the subject action must be received by January 27, 2012.

ADDRESSES: You may submit comments, information, or data, identified by ''NOAA–NMFS–2011–0261'' by any one of the following methods:

- *Electronic Submissions:* Submit all electronic comments via the Federal eRulemaking Portal *http://www.regulations.gov.* To submit comments via the e-Rulemaking Portal, first click the ''submit a comment'' icon, then enter ''NOAA–NMFS–2011–0261'' in the keyword search. Locate the document you wish to comment on from the resulting list and click on the ''Submit a Comment'' icon on the right of that line.
- *Mail or hand-delivery:* Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910.

Instructions: All comments received are a part of the public record and may be posted to *http://www.regulations.gov* without change. All personally identifiable information (for example, name, address, *etc.*) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. NMFS will accept anonymous comments. Attachments to electronic comments will be accepted in Microsoft Word, Excel, Corel WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Maggie Miller, NMFS, Office of Protected Resources, (301) 427–8403.

SUPPLEMENTARY INFORMATION:

Background

On August 14, 2011, we received a petition from WildEarth Guardians and Friends of Animals to list the scalloped hammerhead shark (*Sphyrna lewini*) as threatened or endangered under the ESA throughout its entire range, or, as an alternative, to delineate the species into five DPSs (Eastern Central and Southeast Pacific, Eastern Central Atlantic, Northwest and Western Central Atlantic, Southwest Atlantic, and Western Indian Ocean) and list any or all of these DPSs as threatened or endangered. The petitioners also requested that critical habitat be designated for the scalloped hammerhead under the ESA. Copies of the petition are available upon request (see **ADDRESSES,** above).

ESA Statutory, Regulatory, and Policy Provisions and Evaluation Framework

Section 4(b)(3)(A) of the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires, to the maximum extent practicable, that within 90 days of receipt of a petition to list a species as threatened or endangered, the Secretary of Commerce make a finding on whether that petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted, and to promptly publish such finding in the **Federal Register** (16 U.S.C. 1533(b)(3)(A)). When it is found that substantial scientific or commercial information in a petition indicates the petitioned action may be warranted (a ''positive 90-day finding''), we are required to promptly commence a review of the status of the species concerned during which we will conduct a comprehensive review of the best available scientific and commercial information. In such cases, we conclude the review with a finding as to whether, in fact, the petitioned action is warranted within 12 months of receipt of the petition. Because the finding at the 12-month stage is based on a more thorough review of the available information, as compared to the narrow scope of review at the 90-day stage, a ''may be warranted'' finding does not prejudge the outcome of the status review.

Under the ESA, a listing determination may address a species, which is defined to also include subspecies and, for any vertebrate species, any DPS that interbreeds when mature (16 U.S.C. 1532(16)). A joint NMFS–U.S. Fish and Wildlife Service (USFWS) (jointly, ''the Services'') policy clarifies the agencies' interpretation of the phrase ''distinct population segment'' for the purposes of listing, delisting, and reclassifying a species under the ESA (61 FR 4722; February 7, 1996). A species, subspecies, or DPS is ''endangered'' if it is in danger of extinction throughout all or a significant portion of its range, and ''threatened'' if it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range (ESA sections 3(6) and 3(20), respectively, 16 U.S.C. 1532(6) and (20)). Pursuant to the ESA and our implementing regulations, we determine whether species are threatened or endangered based on any one or a combination of the following five section 4(a)(1) factors: (1) The present or threatened destruction, modification, or curtailment of habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) inadequacy of existing regulatory mechanisms; and (5) any other natural or manmade factors affecting the species' existence (16 U.S.C. 1533(a)(1), 50 CFR 424.11(c)).

ESA-implementing regulations issued jointly by NMFS and USFWS (50 CFR 424.14(b)) define ''substantial information'' in the context of reviewing

a petition to list, delist, or reclassify a species as the amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted. In evaluating whether substantial information is contained in a petition, the Secretary must consider whether the petition: (1) Clearly indicates the administrative measure recommended and gives the scientific and any common name of the species involved; (2) contains detailed narrative justification for the recommended measure, describing, based on available information, past and present numbers and distribution of the species involved and any threats faced by the species; (3) provides information regarding the status of the species over all or a significant portion of its range; and (4) is accompanied by the appropriate supporting documentation in the form of bibliographic references, reprints of pertinent publications, copies of reports or letters from authorities, and maps (50 CFR 424.14(b)(2)).

Judicial decisions have clarified the appropriate scope and limitations of the Services' review of petitions at the 90-day finding stage, in making a determination that a petitioned action ''may be'' warranted. As a general matter, these decisions hold that a petition need not establish a ''strong likelihood'' or a ''high probability'' that a species is either threatened or endangered to support a positive 90-day finding.

We evaluate the petitioners' request based upon the information in the petition including its references and the information readily available in our files. We do not conduct additional research, and we do not solicit information from parties outside the agency to help us in evaluating the petition. We will accept the petitioners' sources and characterizations of the information presented if they appear to be based on accepted scientific principles, unless we have specific information in our files that indicates the petition's information is incorrect, unreliable, obsolete, or otherwise irrelevant to the requested action. Information that is susceptible to more than one interpretation or that is contradicted by other available information will not be dismissed at the 90-day finding stage, so long as it is reliable and a reasonable person would conclude it supports the petitioners' assertions. In other words, conclusive information indicating the species may meet the ESA's requirements for listing is not required to make a positive 90-day finding. We will not conclude that a lack of specific information alone negates a positive 90-day finding if a reasonable person would conclude that the unknown information itself suggests an extinction risk of concern for the species at issue.

To make a 90-day finding on a petition to list a species, we evaluate whether the petition presents substantial scientific or commercial information indicating the subject species may be either threatened or endangered, as defined by the ESA. First, we evaluate whether the information presented in the petition, along with the information readily available in our files, indicates that the petitioned entity constitutes a ''species'' eligible for listing under the ESA. Next, we evaluate whether the information indicates that the species faces an extinction risk that is cause for concern; this may be indicated in information expressly discussing the species' status and trends, or in information describing impacts and threats to the species. We evaluate any information on specific demographic factors pertinent to evaluating extinction risk for the species (*e.g.,* population abundance and trends, productivity, spatial structure, age structure, sex ratio, diversity, current and historical range, habitat integrity or fragmentation), and the potential contribution of identified demographic risks to extinction risk for the species. We then evaluate the potential links between these demographic risks and the causative impacts and threats identified in section 4(a)(1).

Information presented on impacts or threats should be specific to the species and should reasonably suggest that one or more of these factors may be operative threats that act or have acted on the species to the point that it may warrant protection under the ESA. Broad statements about generalized threats to the species, or identification of factors that could negatively impact a species, do not constitute substantial information indicating that listing may be warranted. We look for information indicating that not only is the particular species exposed to a factor, but that the species may be responding in a negative fashion; then we assess the potential significance of that negative response.

Many petitions identify risk classifications made by non-governmental organizations, such as the International Union on the Conservation of Nature (IUCN), the American Fisheries Society, or NatureServe, as evidence of extinction risk for a species. Risk classifications by other organizations or made under other Federal or state statutes may be informative, but the classification alone may not provide the rationale for a positive 90-day finding under the ESA. For example, as explained by NatureServe, their assessments of a species' conservation status do ''not constitute a recommendation by NatureServe for listing under the U.S. Endangered Species Act'' because NatureServe assessments ''have different criteria, evidence requirements, purposes and taxonomic coverage than government lists of endangered and threatened species, and therefore these two types of lists should not be expected to coincide'' (*http://www.natureserve.org/prodServices/statusAssessment.jsp*). Thus, when a petition cites such classifications, we will evaluate the source of information that the classification is based upon in light of the standards on extinction risk and impacts or threats discussed above.

Distribution and Life History of the Scalloped Hammerhead Shark

The scalloped hammerhead shark is a circumglobal species that lives in coastal warm temperate and tropical seas. It occurs over continental and insular shelves, as well as adjacent deep waters, but is seldom found in waters cooler than 22 °C (Compagno, 1984; Schulze-Haugen *et al.,* 2003). Scalloped hammerhead sharks are highly mobile and partly migratory and are likely the most abundant of the hammerhead species (Maguire *et al.,* 2006). However, Maguire *et al.* (2006) also notes that ''although its worldwide distribution and known high abundance gives the species some protection globally, the risk of local depletions remains a serious concern.''

In the western Atlantic Ocean, the scalloped hammerhead range extends from the Northeast coast of the United States (from New Jersey to Florida) to Brazil, including the Gulf of Mexico and Caribbean Sea. In the eastern Atlantic, it can be found from the Mediterranean Sea to Namibia. Populations in the Indian Ocean are found in the following locations: South Africa and the Red Sea to Pakistan, India, and Myanmar, and in the western Pacific the scalloped hammerhead can be found from Japan and China to New Caledonia, including throughout the Philippines, Indonesia, and off Australia. Distribution in the eastern Pacific Ocean extends from the coast of southern California (U.S.), including the Gulf of California, to Ecuador and possibly Peru (Compagno, 1984), and off waters of Hawaii (U.S.) and Tahiti.

The general life history pattern of the scalloped hammerhead shark is that of a long lived (oldest known sharks of both sexes aged at 30.5 years; Piercy *et al.,* 2007), slow growing, and late

maturing species. The scalloped hammerhead shark has a laterally expanded head that resembles a hammer, hence the common name ''hammerhead,'' and belongs to the Sphyrnidae family. The scalloped hammerhead shark is distinguished from other hammerheads by a marked central indentation on the anterior margin of the head, along with two more indentations on each side of this central indentation, giving the head a ''scalloped'' appearance. It has a broadly arched mouth and the rear margin of the head is slightly swept backward. The dentition of the hammerhead consists of small, narrow, and triangular teeth with smooth edges (often slightly serrated in larger individuals), and is similar in both jaws. The front teeth are erect while subsequent teeth have oblique cusps, and the lower teeth are more erect than the upper teeth (Florida Museum of Natural History, 2011). The body of the scalloped hammerhead is fusiform, with a large first dorsal fin and low second dorsal and pelvic fins. The first dorsal fin is moderately hooked with its origin over or slightly behind the pectoral fin insertions and the rear tip in front of the pelvic fin origins. The height of the second dorsal fin is less than the anal fin height and has a posterior margin that is approximately twice the height of the fin, with the free rear tip almost reaching the precaudal pit. The pelvic fins have relatively straight rear margins while the anal fin is deeply notched on the posterior margin (Compagno, 1984). The scalloped hammerhead generally has a uniform gray, grayish brown, bronze, or olive coloration on top of the body that shades to white on the underside with dusky or black pectoral fin tips.

The oldest aged scalloped hammerhead sharks had lengths of 241 cm (females) and 234 cm (males) (Piercy *et al.,* 2007), but the scalloped hammerhead shark can reach lengths of up to 365–420 cm (Compagno, 1984). The estimates on the exact age and length at sexual maturity for the scalloped hammerhead vary widely by region. In the Gulf of Mexico, Branstetter (1987) estimated that females mature around 270 cm, or about 15 years of age, and males mature around 180 cm, or 9–10 years of age. In Northeastern Taiwan waters, Chen *et al.* (1990) calculated age at maturity to be 4 years for females and 3.8 years for males, corresponding to lengths of 210 cm and 198 cm, respectively. Zeeberg *et al.* (2006) considered hammerheads greater than 140 cm to be mature in Northwest Africa, while off the coast of northern Australia, males are thought to reach maturity at 150 cm and females at 200 cm (Stevens and Lyle, 1989). On the east coast of South Africa, observed median length at maturity for scalloped hammerheads was 184 cm for females and 161 cm for males, with age estimated around 11 years (Dudley and Simpfendorfer, 2006). While it may appear that maturity estimates vary by region, it is unclear whether these differences are truly biological or a result of differences in band interpretations in aging methodology approaches (Piercy *et al.,* 2007).

The scalloped hammerhead shark is viviparous (*i.e.,* give birth to live young), with a gestation period of 9–12 months and likely followed by a one-year resting period (Branstetter, 1987; Stevens and Lyle, 1989; Chen *et al.,* 1990; Liu and Chen, 1999). Females move inshore to birth during the summer months, with litter sizes anywhere between 2 and 41 live pups (Branstetter, 1987; Stevens and Lyle, 1989; Hazin *et al.,* 2001; White *et al.,* 2008). Length at birth estimates for scalloped hammerheads range from 31–50 cm (Branstetter, 1987; Stevens and Lyle, 1989; Chen *et al.,* 1990; Zeeberg *et al.,* 2006). Juveniles remain close to inshore waters but will migrate to deeper waters as they grow. Both juveniles and adult scalloped hammerhead sharks have been found to occur as solitary individuals, as pairs, and in schools. The schooling behavior has been documented during summer migrations off the coast of South Africa as well as in permanent resident populations, like those in the East China Sea (Compagno, 1984). Adult aggregations are most common offshore over seamounts and near islands, especially near the Galapagos, Malpelo, Cocos and Revillagigedo Islands, and within the Gulf of California (Compagno, 1984; CITES, 2010). The schooling behavior exhibited by scalloped hammerheads makes them vulnerable to being caught in large numbers (Hayes *et al.,* 2009).

The scalloped hammerhead shark is a high trophic level predator (Cortés, 1999) and opportunistic feeder, with a diet that includes a wide variety of teleosts, cephalopods, crustaceans, and rays (Compagno, 1984).

Analysis of Petition and Information Readily Available in NMFS Files

We evaluated the information provided in the petition and readily available in our files to determine if the petition presented substantial scientific or commercial information indicating that the petitioned action may be warranted. The petition contains information on the species, including the taxonomy, species description, geographic distribution, habitat, population status and trends, and factors contributing to the species' decline. The petition states that the primary threat to the scalloped hammerhead shark is exploitation by fishing, with the ongoing practice of ''finning'' of particular concern. The petitioners also assert that the lack of adequate regulatory protection programs worldwide, as well the species' biological constraints, increase the susceptibility of the scalloped hammerhead shark to exploitation and extinction. Although data are not available to determine the actual number or size of the global population of scalloped hammerhead sharks, the information from our files and from the petitioners' references suggest that the scalloped hammerhead underwent significant range-wide declines from historical abundance levels (Feretti *et al.,* 2008; Hayes *et al.,* 2009; CITES, 2010).

According to the petition, at least three of the five causal factors in section 4(a)(1) of the ESA are adversely affecting the continued existence of the scalloped hammerhead shark, specifically: (B) Overutilization for commercial, recreational, scientific, or educational purposes; (D) inadequacy of existing regulatory mechanisms; and (E) other natural or manmade factors affecting its continued existence. In the following sections, we use the information presented in the petition and in our files to determine whether the petitioned action may be warranted. We consider the global population of scalloped hammerhead sharks and will revisit the question of DPSs during a status review, if necessary. We summarize our analysis and conclusions regarding the information presented by the petitioner and in our files on the specific ESA section 4(a)(1) factors affecting the species' risk of global extinction below.

Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Information from the petition and in our files suggests that the primary threat to the scalloped hammerhead shark is from fisheries. We refer to the U.S. and Palau CITES (2010) proposal to list *S. lewini* under Appendix II (henceforth, referred to as the CITES proposal) for much of the available abundance and catch trend data as this is a recent compilation of information on the species.

Scalloped hammerhead sharks are both targeted and taken as bycatch in many global fisheries (*e.g.,* bottom and pelagic longlines, coastal gillnet

fisheries, artisanal fisheries). Because of their large fins with high fin noodle content (a gelatinous product used to make shark fin soup), scalloped hammerheads fetch a high commercial value in the Asian shark fin trade (Abercrombie *et al.,* 2005). In Hong Kong, the world's largest fin trade market, *S. lewini* and *S. zygaena* (smooth hammerhead) are mainly traded under the ''Chun chi'' market category, which also happens to be the second most traded fin category. Together, smooth and scalloped hammerheads are estimated to comprise 4–5 percent of the total fins traded in the Hong Kong market, which suggests that 1.3 to 2.7 million individuals of these species (equivalent to a biomass of 49,000–90,000 tons) are used in the Hong Kong fin trade annually (Clarke *et al.,* 2006; Camhi *et al.,* 2009).

In the United States, scalloped hammerhead sharks are mainly caught as bycatch in longline and coastal gillnet fisheries and are known to suffer high mortality from capture. In the northwest Atlantic, on-line mortalities (for all age groups) were estimated at 91.4 percent and 93.8 percent (Mejuto *et al.,* 2002; Morgan and Burgess, 2007; Camhi *et al.,* 2009). Scalloped hammerheads have also become a popular target species of recreational fishermen in the last several decades. A recent stock assessment by Hayes *et al.* (2009) found that the northwestern Atlantic population in 1981, which ranged between 146,000 and 165,000 individuals, has since decreased to approximately 25,000–28,000 individuals in 2005, a level estimated to be at 45 percent of the biomass that would produce the maximum sustainable yield (MSY). Fishing mortality was also estimated to be 129 percent of fishing mortality associated with MSY. Given the data, Hayes *et al.* (2009) concluded that the northwestern Atlantic *S. lewini* stock is only 17 percent of the virgin stock size, or, in other words, has been depleted by approximately 83 percent since 1981. In another study, Myers *et al.* (2007) documented a 98 percent decline of *S. lewini* off the coast of North Carolina between 1972 and 2003 using standardized catch per unit effort (CPUE) data from shark targeted, fishery-independent surveys. Myers *et al.* (2007) remarks that the trends in abundance may be indicative of coastwide population changes, because the survey was situated ''where it intercepts sharks on their seasonal migrations.'' A time-series analysis conducted by Carlson *et al.* (2005) since 1995 suggests that the northwest Atlantic population may be stabilized but at a very low level (CITES, 2010).

According to the CITES proposal, overutilization of scalloped hammerheads has also been documented off the coast of Belize, leading to an observed decline in the abundance and size of hammerheads and prompting a halt in the Belize-based shark fishery. However, fishing pressure on hammerheads still continues as a result of Guatemalan fishermen entering Belizean waters (CITES, 2010). Further south, in Brazil, declines between 60 and 90 percent of adult female scalloped hammerheads have been reported from 1993 to 2001 using CPUE data, while the abundance of neonates has significantly decreased over the past 10 years (CITES, 2010). In inshore waters, neonates are heavily targeted by coastal gillnets and recreational fisheries, and are also caught as bycatch in shrimp and pair trawls (CITES, 2010). Further offshore, catches of scalloped hammerheads have been documented as incidental take in other directed fisheries, such as a tuna fishery based in Santos City, São Paulo State, Brazil, where data has revealed a decline in these incidental catch weights, from 290 t in 1990 to 59 t in 1996 (Amorim *et al.,* 1998).

In the Pacific Ocean, juvenile scalloped hammerheads are targeted mainly in directed fisheries but also taken as bycatch by shrimp trawlers and coastal teleost fisheries. Importance of scalloped hammerheads in fishery landings appears to vary by region, from 11.9 percent of the total catch from El Salvador (number of individuals (n)=412; 1991–1992) to 36 percent from the Gulf of Tehauntepec, Mexico (n=8,659; 1996–1998), and ranging from 6 percent (n=339) to 74 percent (n=800) of the total catch off different parts of Guatemala (1996–1999) (CITES, 2010). In Ecuador, landings of hammerhead sharks have decreased since 1996, with a 51 percent decline in artisanal fishery landings between 2004 and 2006 in the Port of Manta, an area where artisanal and drift-net fleets account for 80 percent of shark landings in Ecuador (CITES, 2010).

In the Indian Ocean, pelagic sharks, including the scalloped hammerhead, are targeted in various fisheries, including semi-industrial, artisanal, and recreational fisheries. Countries that fish for sharks include: Egypt, India, Iran, Oman, Saudi Arabia, Sudan, United Arab Emirates, and Yemen, where the probable or actual status of the shark populations is unknown, and Maldives, Kenya, Mauritius, Seychelles, South Africa, and United Republic of Tanzania, where the actual status of the shark population is presumed to be fully to over exploited (Young, 2006). We conclude that the information in the petition and in our files suggests that fisheries may be impacting the continued existence of the scalloped hammerhead.

Inadequacy of Existing Regulatory Mechanisms

The petition asserts that the inadequacy of existing Federal, state, or international regulatory mechanisms require that the scalloped hammerhead shark be listed under the ESA. The petition contends that the lack of specific regulations for the scalloped hammerhead has failed to prevent large population declines of the shark species. However, the latest stock assessment for the northwestern Atlantic scalloped hammerhead shark population estimated that a total allowable catch (TAC) of 2,853 scalloped hammerhead sharks per year (or 69 percent of the 2005 catch) would allow a 70 percent probability of rebuilding to MSY in 10 years (Hayes *et al.,* 2009). Based on this assessment, on April 28, 2011, NMFS determined that the northwestern Atlantic scalloped hammerhead shark stock was ''overfished'' and that ''overfishing is occurring,'' prompting NMFS to ''take action to end or prevent overfishing in the fishery and implement conservation and management measures to rebuild overfished stocks within 2 years'' (76 FR 23794; April 28, 2011). This status determination is specific to the northwestern Atlantic scalloped hammerhead shark stock and any additional regulations would be implemented to prevent large population declines of that stock.

In addition, the petition asserts that there is little international regulation of fishing or trading to protect scalloped hammerheads; however, in 2010, the International Commission for the Conservation of Atlantic Tunas (ICCAT) developed recommendations 10–07 and 10–08, which specifically prohibit the retention, transshipping, landing, sorting, or selling of hammerhead sharks, other than bonnethead sharks, caught in association with ICCAT fisheries. The ICCAT is responsible for the conservation of tuna and tuna-like species in the Atlantic Ocean and adjacent seas and its recommendations are binding to Contracting Parties (of which there are 48, including the United States), unless Parties object pursuant to the treaty. On April 29, 2011, NMFS proposed and on August 29, 2011, finalized the implementation of these recommendations, which affect the U.S. commercial HMS pelagic

longline (PLL) fishery and recreational fisheries for tunas, swordfish, and billfish in the Atlantic Ocean, including the Caribbean Sea and Gulf of Mexico (76 FR 53652; August 29, 2011).

The petition notes that finning bans are a common form of shark management regulation and have been adopted by 19 countries, including Mexico, Costa Rica, and Chile, but argues that many of these bans contain loopholes that allow for the continued removal of shark fins at sea. It is important to note that the petition does not provide information that some countries and management bodies are working to address these issues, including the United States and the European Union (EU). In fact, on January 4, 2011, the 2010 U.S. Shark Conservation Act was signed. This legislation requires that all sharks caught in U.S. waters, with an exemption for smooth dogfish, be landed with fins naturally attached, effectively ending the practice of removing fins at sea in the United States (Pub. L. 111–348). However, even with the increase and strengthening of finning bans, the lack of internationally enforced catch limits or trade regulations allows for the continued and unregulated fishing of scalloped hammerheads in international waters. In 2010, the United States and Palau proposed to list *S. lewini* under Appendix II of CITES, which would have imposed international trade regulations and provided protection for the species through the requirement of export permits or re-export certificates. However, this proposal was rejected. In 2011, the EU failed in its proposals to secure Indian Ocean Tuna Commission (IOTC) and Inter-American Tropical Tuna Commission (IATTC) protection for the scalloped hammerhead, which would have prohibited retaining onboard, transhipping, landing, storing, selling, or offering for sale any part or whole carcass of hammerhead sharks of the family Sphyrnidae taken in the IOTC and IATTC area of competence, respectively. In addition, information in our files and in the petition indicates that illegal fishing of this species may be occurring in certain regions. For example, in Cocos Island National Park, off Costa Rica, a ''no take'' zone was established in 1992, yet populations of *S. lewini* continued to decline by an estimated 71 percent from 1992 to 2004 (Myers *et al.,* 2004). In Ecuador, concern over illegal fishing around the Galapagos Islands prompted a 2004 ban on the exportation of fins; however, this only resulted in the establishment of new illegal trade routes and continued exploitation of *S. lewini* (CITES, 2010). Thus, the information in the petition and in our files suggests that while there is increasing support for domestic and international shark conservation and regulation, the existing regulatory mechanisms in some portions of the *S. lewini* range may be inadequate to address threats to the global scalloped hammerhead population.

Other Natural or Manmade Factors

The petition contends that ''biological vulnerability'' in the form of long gestation periods, late maturity, large size, and documented schooling behavior, is affecting the species' ability to recover from exploitation. However, a recent ecological risk assessment for pelagic sharks found that scalloped hammerheads ranked among the less vulnerable species in terms of its biological productivity and susceptibility to the pelagic longline fisheries in the Atlantic Ocean (Cortés *et al.,* 2010), suggesting a low risk of overexploitation. In addition, the petition states that ''high predation on pups further hampers the species' ability to recover,'' but Clarke (1971) noted that despite this mortality, the population of pups remains high in nursery grounds and suggested that birth rates may match mortality rates, hence protecting the population from significant losses. Thus, available information is insufficient to indicate that there has been any negative effect on the scalloped hammerhead shark's ability to recover due to its biological characteristics.

The petition also asserts that ''human population growth'' may pose a serious threat to the scalloped hammerhead population. However, broad statements about generalized threats to the species do not constitute substantial information indicating that listing may be warranted. Although the petition presents information that the human population may be expanding, it does not provide information indicating an increase in fishing pressure on scalloped hammerhead sharks due specifically to this human population growth, or information that scalloped hammerhead sharks are responding in a negative fashion to human population growth.

Summary of Section 4(a)(1) Factors

We conclude that the petition presents substantial scientific or commercial information indicating that a combination of two of the section 4(a)(1) factors: Overutilization for commercial, recreational, scientific, or educational purposes, and inadequate existing regulatory mechanisms, may be causing or contributing to an increased risk of extinction for the scalloped hammerhead shark.

Petition Finding

After reviewing the information contained in the petition, as well as information readily available in our files, and based on the above analysis, we conclude the petition presents substantial scientific information indicating the petitioned action of listing the scalloped hammerhead shark as threatened or endangered may be warranted. Therefore, in accordance with section 4(b)(3)(B) of the ESA and NMFS' implementing regulations (50 CFR 424.14(b)(2)), we will commence a status review of the species. During our status review, we will first determine whether the species is in danger of extinction (endangered) or likely to become so (threatened) throughout all or a significant portion of its range. If it is not, then we will consider whether the populations identified by the petitioner meet the DPS policy criteria, and if so, whether any of these are threatened or endangered. We now initiate this review, and thus, the scalloped hammerhead shark is considered to be a candidate species (69 FR 19975; April 15, 2004). Within 12 months of the receipt of the petition (August 14, 2012), we will make a finding as to whether listing the species (or any identified DPSs) as endangered or threatened is warranted as required by section 4(b)(3)(B) of the ESA. If listing the species (or any identified DPSs) is found to be warranted, we will publish a proposed rule and solicit public comments before developing and publishing a final rule.

Information Solicited

To ensure that the status review is based on the best available scientific and commercial data, we are soliciting information on whether the scalloped hammerhead shark is endangered or threatened. Specifically, we are soliciting information in the following areas: (1) Historical and current distribution and abundance of this species throughout its range; (2) historical and current population trends; (3) life history in marine environments; (4) shark fin trade data; (5) any current or planned activities that may adversely impact the species; (6) ongoing or planned efforts to protect and restore the species and their habitats; (7) population structure information, such as genetics data; and (8) management, regulatory, and enforcement information. We request that all information be accompanied by: (1) Supporting documentation such as

maps, bibliographic references, or reprints of pertinent publications; and (2) the submitter's name, address, and any association, institution, or business that the person represents.

References Cited

A complete list of references is available upon request from NMFS Protected Resources Headquarters Office (see **ADDRESSES**).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: November 21, 2011.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2011–30599 Filed 11–25–11; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 76, No. 228
Monday, November 28, 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

Submission for OMB Review; Comment Request

November 21, 2011.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (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 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: National School Lunch Program: School Food Service Account Revenue Amendments Related to the Healthy, Hunger-Free Kids Act.

OMB Control Number: 0584–NEW.

Summary of Collection: The Food and Nutrition Service (FNS) published an interim rule that amended the School Lunch Program (NSLP) regulations to conform to requirements contained in the Healthy, Hunger-Free Kids Act of 2010 (Pub. L. 111–296) regarding equity in school lunch pricing and revenue from nonprogram foods sold in schools. The rule requires school food authorities participating in the NSLP to provide the same level of financial support for lunches served to students who are not eligible for free or reduced price lunches as is provided for lunches served students eligible for free lunches.

Need and Use of the Information: FNS will collect information using FNS–828, School Food Authority Paid Lunch Price Report. The information collected will be used to monitor the school food authority and the State agency compliance on the rule, without the information collected from School Food Service Accounts Revenue.

Description of Respondents: State, Local or Tribal Govt.; Not-for-profit institutions; Federal Government.

Number of Respondents: 20,915.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 322,827.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2011–30432 Filed 11–25–11; 8:45 a.m.]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2010–0007]

Privacy Act Systems of Records; APHIS Animal Health Surveillance and Monitoring System

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of a proposed new system of records; request for comment.

SUMMARY: The Animal and Plant Health Inspection Service proposes to add a system of records to its inventory of records systems subject to the Privacy Act of 1974, as amended. The system of records being proposed is the APHIS Animal Health Surveillance and Monitoring System, USDA–APHIS–15. This notice is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of record systems maintained by the agency.

Although the Privacy Act requires only that the portion of the system which describes the ''routine uses'' of the system be published for comment, we invite comment on all portions of this notice.

DATES: *Effective Date:* This system will be adopted without further notice on January 9, 2012 unless modified to respond to comments received from the public and published in a subsequent notice.

Comment date: Comments must be received, in writing, on or before December 28, 2011.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to: *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS–2010–0007* to submit or view comments.
- *Postal Mail/Commercial Delivery:* Please send one copy of your comment to Docket No. APHIS–2010–0007, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2010–0007.

Docket: You may view any comments we receive at the Federal eRulemaking Portal (Web address above) or in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Diane Sutton, Senior Staff Veterinarian,

VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737; (301) 734–4913.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, as amended (5 U.S.C. 552a), requires agencies to publish in the **Federal Register** notice of new or revised systems of records maintained by the agency. A system of records is a group of any records under the control of any agency, from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to an individual.

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is proposing to add a new system of records, entitled APHIS Animal Health Surveillance and Monitoring System (AHSM), that will be used to maintain records of activities conducted by the agency pursuant to its mission and responsibilities authorized by the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*); Bovine Johne's Disease Control Program (7 U.S.C. 7629); and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (7 U.S.C. 8401).

APHIS' Veterinary Services (VS) program will use the AHSM to collect, manage, and evaluate animal health data for disease control and surveillance programs. The AHSM will assist APHIS in obtaining and analyzing relevant epidemiological information, identifying appropriate response tactics, and effectively responding to an animal disease event in the United States. It will also allow us to identify and notify the owners of animals that have been or may have been exposed in an animal disease event. The AHSM may also be used to document animal health program results to justify expenditures and compile statistical data about animal disease control or surveillance programs.

The AHSM contains modules for the Veterinary Services Laboratory Submissions (VSLS), the National Poultry Improvement Plan (NPIP), and the Mobile Information Management system (MIM).

The AHSM contains personally identifiable information about the individual listed as the contact person for the location where the animals subject to animal disease control or surveillance programs are maintained and the owner of animals involved with animal disease control or surveillance programs. Such information includes name; mailing and physical address, including city, county, State, postal code, and latitude/longitude coordinates; telephone number; email address; and any animal, sample, or location identification numbers associated with the person. The system also contains information about APHIS employees, cooperators, and contractors who are directly involved in animal disease control or surveillance program activities such as name, home and work address, home and work email addresses, telephone number(s), and any assigned identification numbers.

Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of Such Uses

APHIS may routinely share data in the AHSM with certain Federal and State animal health officials or Federal or State wildlife agencies for assistance in conducting, managing, and analyzing animal disease or surveillance programs, and monitoring animal diseases including those related to wildlife, feral animals, or alternative livestock. Data may also be shared with Federal or State agencies involved with public health such as the Departments of Homeland Security and Health and Human Services for the purposes of zoonotic disease surveillance or control activities. APHIS may also share data in the AHSM with the public through a Web site that lists participants in voluntary animal disease certification or quality assurance programs, and lists individuals or entities not in compliance with animal disease regulations. APHIS may also use the Web site to notify individuals who may have acquired exposed or potentially exposed animals when other means of contact are unavailable.

Other routine uses of this information include releases related to investigations pertaining to violations of law or related to litigation. A complete listing of the routine uses for this system is included in the accompanying document that is published along with this notice.

The proposed information collection requests associated with this system have been approved by or submitted for approval by the Office of Management and Budget under the Paperwork Reduction Act.

Title and Business Address of the Agency Official Responsible for the System of Record

Chief Information Officer, U.S. Department of Agriculture, 1400 Independence Ave. SW., Washington, DC 20250.

Report on New System

A report on the new system of records, required by 5 U.S.C. 552a(r), as implemented by Office of Management and Budget Circular A–130, was sent to the Chairman, Committee on Homeland Security and Governmental Affairs, United States Senate; the Chairman, Committee on Oversight and Government Reform, House of Representatives; and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget.

Signed in Washington, DC, on November 11, 2011.

Thomas J. Vilsack,

Secretary.

SYSTEM NAME:

APHIS Animal Health Surveillance and Monitoring System, USDA–APHIS–15.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

The AHSM is a Web-based system hosted at secure and geographically dispersed locations. A backup copy of the data is maintained at a secure U.S. government facility.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are listed as the contact person for the location where the animals subject to animal disease control or surveillance programs are maintained; owners of animals involved with animal disease control or surveillance programs; dealers, agents, and brokers of animals; owners or operators of animal product processing, slaughter, or rendering establishments; accredited veterinarians; contractors; cooperators; and certain APHIS employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

For the individuals listed as the contact person for the location where the animals subject to animal disease control or surveillance programs are maintained; owners of animals involved with animal disease control or surveillance programs; dealers, agents, and brokers of animals; or owners or operators of animal product processing, slaughter, or rendering establishments; the following information will be retained: Name; address, including city, county, State, postal code, and latitude/longitude coordinates; e-mail address; telephone number; operation type; species and breed of animals maintained; and data necessary for managing and analyzing animal disease control or surveillance programs and monitoring diseases related to wildlife, feral animals, or alternative livestock. The information retained for APHIS employees, cooperators, and contractors

may include name; home and work address; home and work e-mail addresses; telephone number(s); and any assigned identification numbers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Animal Health Protection Act (7 U.S.C. 8301 *et seq.*); Bovine Johne's Disease Control Program (7 U.S.C. 7629); and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (7 U.S.C. 8401).

PURPOSE(S):

APHIS Veterinary Services (VS) program uses the AHSM to collect, manage, and evaluate animal health data for disease management and surveillance programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, records maintained in the system may be disclosed outside USDA as follows:

(1) To certain Federal and State animal health officials to conduct, analyze, and report on the progress of animal disease control or surveillance programs;

(2) To Federal and State wildlife agencies for assistance in managing and analyzing animal disease control or surveillance programs and monitoring diseases related to wildlife, feral animals, or alternative livestock;

(3) To Federal or State agencies involved with public health such as the Departments of Homeland Security and Health and Human Services for the purposes of zoonotic disease surveillance or control activities;

(4) To the public through a public Web site which lists participants in voluntary animal disease certification or quality assurance programs and documents compliance with such programs; lists individuals not in compliance with animal disease regulations; and notifies individuals who may have acquired exposed or potentially exposed animals when other means of contact are unavailable;

(5) To the appropriate agency, whether Federal, State, local, or foreign, charged with responsibility of investigating or prosecuting a violation of law or of enforcing, implementing, or complying with a statute, rule, regulation, or order issued pursuant thereto, of any record within this system when information available indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and either arising by general statute or particular program statute, or by rule, regulation, or court order issued pursuant thereto;

(6) To the Department of Justice when the agency, or any component thereof, or any employee of the agency in his or her official capacity, or any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or the United States, in litigation, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected;

(7) For use in a proceeding before a court or adjudicative body before which the agency is authorized to appear, when the agency, or any component thereof, or any employee of the agency in his or her official capacity, or any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee, or the United States, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the agency determines that use of such records is relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the court is a use of the information contained in the records that is compatible with the purpose for which the records were collected;

(8) To appropriate agencies, entities, and persons when the agency suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; the agency has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, a risk of identity theft or fraud, or a risk of harm to the security or integrity of this system or other systems or programs (whether maintained by the agency or another agency or entity) that rely upon the compromised information; and the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the agency's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm;

(9) To contractors and other parties engaged to assist in administering the program. Such contractors and other parties will be bound by the nondisclosure provisions of the Privacy Act. This routine use assists the agency in carrying out the program, and thus is compatible with the purpose for which the records are created and maintained;

(10) To USDA contractors, partner agency employees or contractors, or private industry employed to identify patterns, trends or anomalies indicative of fraud, waste, or abuse; and

(11) To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

STORAGE:

Records are maintained on magnetic tape and optical disk. Backup media is taken weekly to an offsite storage facility and stored on tape.

RETRIEVABILITY:

Records are retrieved primarily by first or last name, address, or phone number of the individual listed as the contact person for the location where the animal(s) subject to animal disease control or surveillance programs are maintained or the owner of animals involved with animal disease control or surveillance programs; and by animal, flock, herd, or premises numbers. However, under this system records can be retrieved by any of the categories that have been recorded.

SAFEGUARDS:

The AHSM security plan includes management, operational, and technical controls to prevent misuse of data by system users. These controls include the use of role-based security and access rights, network firewalls, and requiring all users to obtain a government-issued login. Access to the system is monitored by USDA officials to ensure authorized and appropriate use of the data.

RETENTION AND DISPOSAL:

Individual electronic records are retained within the system for 150 years from the last date of creation, edit, or access of the records. Incremental and full system tape backups are retained for 1 month.

SYSTEM MANAGERS(S) AND ADDRESS:

Associate Deputy Administrator, National Animal Health Policy and

Programs, Veterinary Services, APHIS, USDA, 4700 River Road Unit 33, Riverdale, MD 20737.

NOTIFICATION PROCEDURE:

Any individual may request general information regarding this system of records or information as to whether the system contains records pertaining to him/her from the system manager at the address above. All inquiries pertaining to this system should be in writing, must name the system of records as set forth in the system notice, and must contain the individual's name, telephone number, address, and email address.

RECORD ACCESS PROCEDURES:

Any individual may obtain information from a record in the system that pertains to him or her. Requests for hard copies of records should be in writing, and the request must contain the requesting individual's name, address, name of the system of records, timeframe for the records in question, any other pertinent information to help identify the file, and a copy of his/her photo identification containing a current address for verification of identification. All inquiries should be addressed to the Freedom of Information and Privacy Act Staff, Legislative and Public Affairs, APHIS, 4700 River Road Unit 50, Riverdale, MD 20737–1232.

CONTESTING RECORD PROCEDURES:

Any individual may contest information contained within a record in the system that pertains to him/her by submitting a written request to the system manager at the address above. Include the reason for contesting the record and the proposed amendment to the information with supporting documentation to show how the record is inaccurate.

RECORD SOURCE CATEGORIES:

Information in this system comes primarily from the customers, including the individuals listed as the contact person for the location where the animals subject to animal disease control or surveillance programs are maintained, and the owners of animals involved with animal disease control or surveillance programs. Such information may be supplemented by information from other USDA agencies such as the Food Safety and Inspection Service, Farm Service Agency, APHIS' Wildlife Services, or from State veterinary health officials and animal testing laboratories.

Employee, cooperator, and contractor information is obtained primarily from the employee, cooperator, or contractor.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2011–30429 Filed 11–25–11; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Advisory Committee Meeting

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice of advisory committee meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, this constitutes notice of the upcoming meeting of the Grain Inspection, Packers and Stockyards Administration (GIPSA) Grain Inspection Advisory Committee (Advisory Committee). The Advisory Committee meets twice annually to advise the GIPSA Administrator on the programs and services that GIPSA delivers under the U.S. Grain Standards Act. Recommendations by the Advisory Committee help GIPSA better meet the needs of its customers who operate in a dynamic and changing marketplace.

DATES: December 6, 2011, 8 a.m. to 4:30 p.m.; and December 7, 2011, 8 a.m. to 3:30 p.m.

ADDRESSES: The Advisory Committee meeting will take place at the Embassy Suites Hotel-Portland Downtown, 319 SW Pine Street, Portland, Oregon, 97204.

Requests to orally address the Advisory Committee during the meeting or written comments may be sent to: Administrator, GIPSA, U.S. Department of Agriculture, 1400 Independence Avenue SW., STOP 3601, Washington, DC 20250–3601. Requests and comments may also be faxed to (202) 690–2173.

FOR FURTHER INFORMATION CONTACT: Terri L. Henry by phone at (202) 205–8281 or by email at *Terri.L.Henry@usda.gov*.

SUPPLEMENTARY INFORMATION: The purpose of the Advisory Committee is to provide advice to the GIPSA Administrator with respect to the implementation of the U.S. Grain Standards Act (7 U.S.C. 71–87k). Information about the Advisory Committee is available on the GIPSA Web site at *http://www.gipsa.usda.gov*. Under the section, ''I Want To * * *,'' select ''Learn about the Grain Inspection Advisory Committee.''

The agenda will include an overview of Federal Grain Inspection Service operations, updated tonnage fee projections, international programs, sorghum odor, moisture measurement, and the quality management program.

For a copy of the agenda please contact Terri L. Henry by phone at (202) 205–8281 or by email at *Terri.L.Henry@usda.gov*.

Public participation will be limited to written statements unless permission is received from the Committee Chairperson to orally address the Advisory Committee. The meeting will be open to the public.

Persons with disabilities who require alternative means of communication of program information or related accommodations should contact Terri L. Henry at the telephone number listed above.

Randall Jones,

Acting Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 2011–30499 Filed 11–25–11; 8:45 am]

BILLING CODE 3410–KD–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Connecticut Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the Connecticut Advisory Committee to the Commission will be held at the Legislative Building, Hearing Group Room 3C, 210 Capitol Avenue, Hartford, CT 06106, and will convene at 9:30 a.m. on Tuesday, December 6, 2011. The purpose of the briefing meeting is to discuss police practices and the changing demographics in Connecticut. The purpose of the planning meeting is to plan future activities.

Members of the public are entitled to submit written comments. The comments must be received in the regional office by Friday, January 6, 2012. Comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 624 9th Street NW., Suite 740, Washington, DC 20425, faxed to (202) 376–7548, or emailed to *ero@usccr.gov.*

Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records generated from this meeting may be inspected and reproduced at the

Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *http://www.usccr.gov,* or to contact the Eastern Regional Office at the above email or street address.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission and FACA.

Dated in Washington, DC, November 21, 2011.

Peter Minarik,

Acting Chief, Regional Programs Coordination Unit.

[FR Doc. 2011–30385 Filed 11–25–11; 8:45 am]

BILLING CODE 6335–01–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: Shipboard Observation Form for Floating Marine Debris.

OMB Control Number: None.

Form Number(s): None.

Type of Request: Regular submission (request for a new information collection).

Number of Respondents: 45.

Average Hours per Response: 1 hour.

Burden Hours: 45.

Needs and Uses: This request is for a new information collection. This data collection project will be coordinated by James Callahan (private citizen/recreational sailor who began this data collection on a small-scale in 2008) with assistance from the NOAA Marine Debris Program, recreational sailors (respondents), NGOs (respondents) as well as numerous experts on marine debris observations at sea. The Shipboard Observation Form for Floating Marine Debris was created based on methods used in studies of floating marine debris by established researchers, previous shipboard observational studies conducted at sea by NOAA, and the experience and input of recreational sailors. The goal of this form is to be able to calculate the density of marine debris within an area of a known size. Additionally, this form will help collect data on potential marine debris resulting from the March 2011 Japan tsunami in order to better model movement of the debris as well as prepare (as needed) for debris arrival to areas around the Pacific. This form may be used to collect data on floating marine debris in any water body. This survey will assist in carrying out activities prescribed in the Marine Debris Research, Prevention, and Reduction Act of 2006 (33 U.S.C. 1951 *et seq.*), mainly ''mapping, identification and impact assessment''.

Affected Public: Individuals or households; not-for-profit organizations.

Frequency: On occasion.

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: November 21, 2011.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–30394 Filed 11–25–11; 8:45 a.m.]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Department of Commerce.

ACTION: Notice and opportunity for public comment.

Pursuant to Section 251 of the Trade Act of 1974, as amended (19 U.S.C. 2341 *et seq.*), the Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of these firms contributed importantly to the total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[9/21/2011 through 11/18/2011]

Firm name	Address	Date accepted for investigation	Products
Acme Express, Inc.	3821 Prospect Avenue, Cleveland, OH 44115.	16-Nov-11	The firm manufactures scheduling software on recorded optical media, such as CDs and DVDs.
Aspen Graphics, Inc.	4795 Oakland Street, Denver, CO 80239.	11-Oct-11	The firm manufactures commercial printed products including brochures, leaflets, and manuals.
FELCO, LLC dba FELCO Industries.	P.O. Box 16750, Missoula, MT 59808.	16-Nov-11	The firm manufactures attachments for excavators and backfill equipment and other attachments and parts for heavy equipment.
Modular Sound System, Inc	22272 Pepper Road, Barrington, IL 60010.	15-Nov-11	The firm manufactures loud speakers and components.
Possperity, Inc. dba Shapes Supply, Inc.	320 W. Northwest Hwy., Arlington Heights, IL 60004.	17-Nov-11	The firm manufactures bathroom shower doors, walls, mountings and surrounds, and also distributes, installs and resells kitchen and bathroom cabinets, sinks, vanity tops and plumbing fixtures.
Quantum Windows & Doors, Inc	2720 34th Street, Everett, WA 98201.	17-Nov-11	The firm manufactures wood windows and doors.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE—Continued

[9/21/2011 through 11/18/2011]

Firm name	Address	Date accepted for investigation	Products
Trans-Tech, LLC	1600 Grider Avenue, El Reno, OK 73036.	07-Oct-11	The firm manufactures transfers and decals used in railroad industry.
Troscan, LLC	400 North Oakley Boulevard, Chicago, IL 60612.	14-Nov-11	The firm designs and manufactures residential and commercial furniture in wood, metal, stone and upholstery.
Verne Q. Powell Flutes, Inc	1 Clock Tower Place, Suite 300, Maynard, MA 01754.	24-Oct-11	The firm manufactures intermediate and student musical instruments such as flutes, piccolos, trumpets, trombones, flugelhorns and baritones.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance for Firms Division, Room 7106, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

November 21, 2011.

Miriam Kearse,

Eligibility Certifier.

[FR Doc. 2011–30488 Filed 11–25–11; 8:45 am]

BILLING CODE 3510–24–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials Processing Equipment Technical Advisory Committee; Notice of Partially Closed Meeting

The Materials Processing Equipment Technical Advisory Committee (MPETAC) will meet on December 12, 2011, 9 a.m., Room 3884, in the Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials processing equipment and related technology.

Agenda

Open Session

1. Opening remarks and introductions.

2. Presentation of papers and comments by the Public.

3. Discussion on proposals from last and for next Wassenaar Meeting.

4. Report on proposed and recently issued changes to the Export Administration Regulations.

5. Other business.

Closed Session

6. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov,* no later than December 5, 2011.

A limited number of seats will be available for the public session. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate the distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on November 21, 2011, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § 10(d)), that the portion of the meeting dealing with matters the premature disclosure of which would be likely to frustrate significantly implementation of a proposed agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public. For more information, call Yvette Springer at (202) 482–2813.

Dated: November 21, 2011.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2011–30438 Filed 11–25–11; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Emerging Technology and Research Advisory Committee; Notice of Partially Closed Meeting

The Emerging Technology and Research Advisory Committee (ETRAC) will meet on December 14 and 15, 2011, 8:30 a.m., Room 3884, at the Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration on emerging technology and research activities, including those related to deemed exports.

Agenda

Wednesday, December 14

Closed Session: 8:30 a.m.–5 p.m.

1. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

Thursday, December 15

Open Session: 8:30 a.m.–3:30 p.m.

1. ETRAC Member Discussion Emerging Technology Analysis; and Impact of Export Controls on the conduct of U.S. science and technology activities in the United States.

2. Public Comments.

The open sessions will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at

Yvette.Springer@bis.doc.gov no later than, December 7, 2011.

A limited number of seats will be available for the public session. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate the distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on November 21, 2011, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended, that the portion of the meeting dealing with matters which would be likely to frustrate significantly implementation of a proposed agency action as described in 5 D.S.C. 552b(c)(9) (B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)1 and 10(a) (3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482–2813.

Dated: November 21, 2011.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2011–30437 Filed 11–25–11; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–868]

Folding Metal Tables and Chairs From the People's Republic of China: Notice of Correction to the Final Results of the 2009–2010 Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* November 28, 2011.

FOR FURTHER INFORMATION CONTACT: Lilit Astvatsatrian or Trisha Tran, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; *telephone:* (202) 482–6412 or (202) 482–4852, respectively.

SUPPLEMENTARY INFORMATION:

Correction

On October 25, 2011, the Department of Commerce (''Department'') published in the **Federal Register** the final results of the 2009–2010 administrative review of the antidumping duty order on folding metal tables and chairs from the People's Republic of China (''PRC'').[1] The period of review covered June 1, 2009, through May 31, 2010. The published **Federal Register** notice contained an inadvertent error, in that it stated that ''* * * we are revoking the order with respect to subject merchandise exported by New-Tec Integration (Xiamen) Co., Ltd. (''New-Tec'').'' [2]

However, pursuant to our *Preliminary Results*,[3] the Department intended to state that ''* * * we are revoking the order with respect to subject merchandise produced and exported by New-Tec.'' The corrected language is consistent with the *Preliminary Results* where we stated that ''* * * if these preliminary findings are affirmed in our final results, we will revoke this order, in part, with respect to folding metal tables and chairs produced and exported by New-Tec.'' [4] After the *Preliminary Results,* parties had an opportunity to comment on the revocation of the order with respect to New-Tec. We received no comments regarding this partial revocation and the Department did not intend to change what was stated in the *Preliminary Results* with regard to what merchandise would be affected by the revocation. We note that New-Tec's revocation was never mentioned in the *Final Results'* section regarding ''Changes Since the Preliminary Results.'' The change in the *Final Results* was inadvertent and we are now correcting this to conform with the *Preliminary Results.* Finally, with respect to subject merchandise produced and exported by New-Tec, we will instruct U.S. Customs and Border Protection to terminate the suspension of liquidation for imports of such merchandise entered, or withdrawn from warehouse, for consumption on or after June 1, 2010, and to refund all cash deposits collected.

This correction is published in accordance with sections 751(h) and 777(i) of the Tariff Act of 1930, as amended.

Dated: November 21, 2011.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2011–30594 Filed 11–25–11; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Folding Metal Tables and Chairs From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and New Shipper Review, and Revocation of the Order in Part,* 76 FR 66036 (October 25, 2011) (''Final Results'').

[2] *See id.*

[3] *See Folding Metal Tables and Chairs from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and New Shipper Review, and Intent to Revoke Order in Par*t, 76 FR 35832, 35836 (June 20, 2011) (''*Preliminary Results*'').

[4] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–953]

Narrow Woven Ribbons With Woven Selvedge From the People's Republic of China: Rescission of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* November 28, 2011.

FOR FURTHER INFORMATION CONTACT: Joshua Morris at (202) 482–1779; AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

Background

On September 2, 2011, the Department of Commerce (''the Department'') published a notice announcing the opportunity to request an administrative review of the countervailing duty order on narrow woven ribbons with woven selvedge (''ribbons'') from the People's Republic of China (''PRC'') covering the period of September 1, 2010, through December 31, 2010. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 76 FR 54735 (September 2, 2011). On September 21, 2011, Weifang Dongfang Ribbon Weaving Co., Ltd. (''Dongfang''), a producer and exporter of ribbons, timely requested that the Department conduct an administrative review of Dongfang. In accordance with 19 CFR 351.221(c)(1)(i), the Department published a notice initiating this administrative review. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 76 FR 67133 (October 31, 2011).

Rescission of Review

Pursuant to 19 CFR 351.213(d)(l), the Secretary will rescind an administrative review, in whole or in part, if the party that requested a review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. On November 2, 2011, Dongfang withdrew its request for review within the 90-day period. Therefore, in response to Dongfang's timely withdrawal request, and as no other party requested a review, the Department is rescinding this administrative review.

Assessment

The Department will instruct U.S. Customs and Border Protection (''CBP'') to assess countervailing duties on all appropriate entries. For Dongfang, countervailing duties shall be assessed at rates equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice of rescission of administrative review.

Notification Regarding Administrative Protective Order

This notice serves as a final reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice of rescission is issued and published in accordance with sections 751(a)(l) and 777(i)(l) of the Tariff Act, as amended, and 19 CFR 351.213(d)(4).

Dated: November 18, 2011.

Gary Taverman,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–30581 Filed 11–25–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Construction Safety Team Advisory Committee Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Construction Safety Team (NCST) Advisory Committee (Committee), will hold a meeting via teleconference on Wednesday, December 21, 2011 from 3 p.m. to 5 p.m. Eastern Time. The primary purpose of this meeting is to discuss the NCST Advisory Committee's draft annual report to Congress. A copy of the draft report will be posted on the NCST Advisory Committee's web site at *http://www.nist.gov/el/disasterstudies/ncst/index.cfm.* Interested members of the public will be able to participate in the meeting from remote locations by calling into a central phone number.

DATES: The NCST Advisory Committee will hold a meeting via teleconference on Wednesday, December 21, 2011, from 3 p.m. until 5 p.m. Eastern Time.

ADDRESSES: Questions regarding the meeting should be sent to the Disaster and Failure Studies Program Director, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8611, Gaithersburg, Maryland 20899–8611. For instructions on how to participate in the meeting, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Mr. Eric Letvin, Disaster and Failure Studies Program Director, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8611, Gaithersburg, Maryland 20899–8611. Mr. Letvin's email address is *eric.letvin@nist.gov* and his phone number is (301) 975–5412.

SUPPLEMENTARY INFORMATION: The NCST Advisory Committee was established pursuant to Section 11 of the National Construction Safety Team Act (15 U.S.C. 7301 *et seq.*). The NCST Advisory Committee is comprised of ten members, appointed by the Director of NIST, who were selected for their technical expertise and experience, established records of distinguished professional service, and their knowledge of issues affecting teams established under the NCST Act. The NCST Advisory Committee will advise the Director of NIST on the functions and composition of Team established under the NCST Act and on the exercise of authorities enumerated in the NCST Act and will review the procedures developed to implement the NCST Act and reports issued under section 8 of the NCST Act. Background information on the NCST Act and information on the NCST Advisory Committee is available at *http://www.nist.gov/el/disasterstudies/ncst.*

Pursuant to the Federal Advisory Committee Act, 5 U.S.C. app., notice is hereby given that the NCST Advisory Committee will hold a meeting via teleconference on Wednesday, December 21, 2011, from 3 p.m. until 5 p.m. Eastern Time. There will be no central meeting location. Interested members of the public will be able to participate in the meeting from remote locations by calling into a central phone number. The primary purpose of this meeting is to discuss the NCST Advisory Committee's draft annual report to Congress. A copy of the draft report will be posted on the NCST Advisory Committee's web site at *http://www.nist.gov/el/disasterstudies/ncst/index.cfm.*

Individuals and representatives of organizations who would like to offer comments and suggestions related to the NCST Advisory Committee's affairs are invited to request detailed instructions by contacting Eric Letvin on how to dial in from a remote location to participate in the meeting. Eric Letvin's email address is *eric.letvin@nist.gov,* and his phone number is (301) 975–5412. Approximately fifteen minutes will be reserved from 4:45 p.m.–5 p.m. Eastern Time for public comments; speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be about 3 minutes each. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to participate are invited to submit written statements to the National Construction Safety Team Advisory Committee, National Institute of Standards and Technology, 100 Bureau Drive, MS 8611, Gaithersburg, Maryland 20899–8600, via fax at (301) 975–4032, or electronically by email to *ncstac@nist.gov.*

All participants in the meeting are required to pre-register. Anyone wishing to participate must register by 5 p.m. Eastern Time on Monday, December 19, 2011, in order to be included. Please submit your name, email address, and phone number to Eric Letvin. After registering, participants will be provided with detailed instructions on

how to dial in from a remote location in order to participate. Eric Letvin's email address is *eric.letvin@nist.gov,* and his phone number is (301) 975–5412.

Dated: November 22, 2011.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2011–30536 Filed 11–25–11; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Advisory Committee on Earthquake Hazards Reduction Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Earthquake Hazards Reduction (ACEHR or Committee), will hold a meeting via teleconference on Tuesday, December 20, 2011 from 11 a.m. to 1 p.m. Eastern Time. The primary purpose of this meeting is to develop an outline for the Committee's draft annual report to the NIST Director. Any draft meeting materials will be posted on the NEHRP Web site at *http://nehrp.gov/*. Interested members of the public will be able to participate in the meeting from remote locations by calling into a central phone number.

DATES: The ACEHR will hold a meeting via teleconference on Tuesday, December 20, 2011, from 11 a.m. until 1 p.m. Eastern Time.

ADDRESSES: Questions regarding the meeting should be sent to National Earthquake Hazards Reduction Program Director, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8604, Gaithersburg, Maryland 20899–8604. For instructions on how to participate in the meeting, please see the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Dr. Jack Hayes, National Earthquake Hazards Reduction Program Director, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8604, Gaithersburg, Maryland 20899–8604. Dr. Hayes' email address is *jack.hayes@nist.gov* and his phone number is (301) 975–5640.

SUPPLEMENTARY INFORMATION: The Committee was established in accordance with the requirements of Section 103 of the NEHRP Reauthorization Act of 2004 (Public Law 108–360). The Committee is composed of 12 members appointed by the Director of NIST, who were selected for their technical expertise and experience, established records of distinguished professional service, and their knowledge of issues affecting the National Earthquake Hazards Reduction Program. In addition, the Chairperson of the U.S. Geological Survey (USGS) Scientific Earthquake Studies Advisory Committee (SESAC) serves in an ex-officio capacity on the Committee. The Committee assesses:

- Trends and developments in the science and engineering of earthquake hazards reduction;
- The effectiveness of NEHRP in performing its statutory activities (improved design and construction methods and practices; land use controls and redevelopment; prediction techniques and early-warning systems; coordinated emergency preparedness plans; and public education and involvement programs);
- Any need to revise NEHRP; and
- The management, coordination, implementation, and activities of NEHRP.

Background information on NEHRP and the Advisory Committee is available at *http://nehrp.gov/*.

Pursuant to the Federal Advisory Committee Act, 5 U.S.C. app., notice is hereby given that the ACEHR will hold a meeting via teleconference on Tuesday, December 20, 2011, from 11 a.m. until 1 p.m. Eastern Time. There will be no central meeting location. Interested members of the public will be able to participate in the meeting from remote locations by calling into a central phone number. The primary purpose of this meeting is to develop an outline for the Committee's draft annual report to the NIST Director. Any draft meeting materials will be posted on the NEHRP Web site at *http://nehrp.gov/*.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's affairs are invited to request detailed instructions by contacting Michelle Harman on how to dial in from a remote location to participate in the meeting. Michelle Harman's email address is *michelle.harman@nist.gov,* and her phone number is (301) 975–5324. Approximately fifteen minutes will be reserved from 12:45 p.m.–1 p.m. Eastern Time for public comments; speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be about 3 minutes each. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated, and those who were unable to participate are invited to submit written statements to the ACEHR, National Institute of Standards and Technology, 100 Bureau Drive, MS 8604, Gaithersburg, Maryland 20899–8604, via fax at (301) 975–5433, or electronically by email to *info@nehrp.gov*.

All participants of the meeting are required to pre-register. Anyone wishing to participate must register by close of business Wednesday, December 14, 2011, in order to be included. Please submit your name, email address, and phone number to Michelle Harman. After registering, participants will be provided with detailed instructions on how to dial in from a remote location in order to participate. Michelle Harman's email address is *michelle.harman@nist.gov,* and her phone number is (301) 975–5324.

Dated: November 21, 2011.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2011–30601 Filed 11–25–11; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Certification Requirements for Distributors of NOAA Electronic Navigational Charts/NOAA Hydrographic Products

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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.

DATES: Written comments must be submitted on or before January 27, 2012.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the Internet at *dHynek@doc.gov).*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection

instrument and instructions should be directed to Julia Powell (301) 713–0388, ext. 169 or *Julia.Powell@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection.

NOS Office of Coast Survey manages the Certification Requirements for Distributors of NOAA Electronic Navigational Charts (NOAA ENCs®). The certification allows entities to download, redistribute, repackage, or in some cases reformat, official NOAA ENCs and retain the NOAA ENC's official status. The regulations for implementing the Certification are at 15 CFR part 995.

The recordkeeping and reporting requirements of 15 CFR part 995 form the basis for this collection of information. This information allows the Office of Coast Survey to administer the regulation, and to better understand the marketplace resulting in products that meet the needs of the customer in a timely and efficient manner.

II. Method of Collection

Responses from the Certified ENC Distributors are all electronic and sent via email. All distributors have an Excel spreadsheet which they submit for the twice-yearly report.

III. Data

OMB Control Number: 0648–0508.

Form Number: None.

Type of Review: Regular submission (extension of a currently approved collection).

Affected Public: Not-for-profit institutions; and business or other for-profit organizations.

Estimated Number of Respondents: 8.

Estimated Time per Response: 1 hour to provide a distribution report twice a year; 18 hours for reporting of errors in the ENC.

Estimated Total Annual Burden Hours: 320.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information;

(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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 21, 2011.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–30384 Filed 11–25–11; 8:45 a.m.]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA846

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) and its Mid-Atlantic Monkfish Subcommittee will hold public meetings.

DATES: The meetings will be held Tuesday, December 13 through Thursday, December 15, 2011. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meetings will be held at Kingsmill, 1010 Kingsmill Road, Williamsburg, VA 23185; telephone: (757) 253–1703.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901–3910; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Dr. Christopher Moore, Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 674–2331 ext. 255.

SUPPLEMENTARY INFORMATION:

Tuesday, December 13, 2011

9 a.m. until noon—The Monkfish Subcommittee will meet.

1 p.m.—The Council will convene.

1 p.m. until 2:30 p.m.—There will be a presentation on the CIE Review of the June 2012 Excessive Shares Workshop and Council discussion on next steps.

2:30 p.m. until 3:30 p.m.—An Atlantic Wind Connection Project presentation will occur.

3:30 p.m. until 4:30 p.m.—A presentation from the National Marine Fisheries Service (NMFS) Habitat Division will occur.

4:30 p.m. until 5:30 p.m.—A discussion on the November 14 Ecosystem and Ocean Planning Committee meeting will be held.

Wednesday, December 14, 2011

8 a.m.—The Council will convene.

8 a.m. until 4 p.m.—The Council will adopt recommendations for 2012 commercial and recreational harvest levels and commercial management measures for summer flounder and scup and finalize summer flounder, scup, and black sea bass recreational management measures for 2012 in conjunction with the Atlantic States Marine Fisheries Commission's (ASMFC) Summer Flounder, Scup, and Black Sea Bass Boards.

4 p.m. until 5:30 p.m.—There will be a review with the ASMFC Board of Amendment 17 to the Summer Flounder, Scup, and Black Sea Bass FMP alternatives.

5:30 p.m. until 6:30 p.m.—There will be a Public Listening Session.

Thursday, August 18, 2011

8:30 a.m.—The Council will convene.

8:30 a.m. until 9 a.m.—The Ricks E Savage Award will be presented.

9 a.m. until 9:30 a.m.—The Council will receive a presentation on Fishery Management Councils: Decision-making, Communication, and Social Factors Associated with Ecosystem-based Fisheries Management.

9:30 a.m. until 1:30 p.m.—The Council will conduct its regular Business Session, receive Organizational Reports, Council Liaison Reports, Executive Director's Report, Science Report, Committee Reports, and any continuing and/or new business.

Agenda items by day for the Council's Committees and the Council itself are:

On Tuesday, December 13, the Mid-Atlantic Monkfish Subcommittee will discuss issues and concerns unique to the Mid-Atlantic Monkfish fishery and potential management solutions. The Council will receive presentation on the CIE Review of the June 2012 Excessive Shares Workshop and followed by Council discussion on next steps. Kris Ohleth will provide the Council with a presentation on the Atlantic Wind Connection Project. The Council will receive a presentation from Chris Boelke and Lou Chiarella of the NMFS Habitat Division. The Council will discuss and identify the next steps related to the

November 14 Ecosystem and Ocean Planning Committee meeting.

On Wednesday, December 14, the Council in conjunction with the ASMFC's Summer Flounder, Scup, and Black Sea Bass Boards will review the Scientific and Statistical Committee's (SSC) and the associated Monitoring Committee's and Advisory Panel's specification recommendations and adopt 2012 commercial and recreational harvest levels and commercial management measures for summer flounder and scup, and finalize recreational management measures for summer flounder, scup, and black sea bass. The Council will review alternatives to address spatial and regional management of the black sea bass recreational fishery and discuss potential complimentary action by the Council and ASMFC Board related to Amendment 17 to the Summer Flounder, Scup, and Black Sea Bass FMP.

On Thursday, December 15, the Council will present the Ricks E Savage Award. The Council will receive a presentation by Ingrid Biedron of Cornell University on Fishery Management Councils: Decision-making, Communication, and Social Factors Associated with Ecosystem-based Fisheries Management. The Council will hold its regular Business Session to approve the October 2011 minutes and address any outstanding actions from the October 2011 meeting, review and approve SOPPs, review and approve 5-year research plan, receive Organizational Reports, Liaison Reports, the Executive Director's Report, the Science Report, Committee Reports, and any continuing and/or new business.

Although non-emergency issues not contained in this agenda may come before these groups for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: November 22, 2011.

Tracey L. Thompson,

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

[FR Doc. 2011–30459 Filed 11–25–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA845

International Affairs; U.S. Fishing Opportunity in the Northwest Atlantic Fisheries Organization Regulatory Area

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

ACTION: Notification of U.S. fishing opportunity.

SUMMARY: NMFS announces a U.S. fishing opportunity for 1,000 mt yellowtail flounder in Division 3LNO of the Northwest Atlantic Fisheries Organization (NAFO) Regulatory Area during 2011. This action is necessary to make available this U.S. fishing opportunity on an equitable basis.

DATES: Expressions of interest regarding NAFO Division 3LNO yellowtail flounder will be accepted through December 13, 2011. Fishing operations must take place during 2011.

ADDRESSES: Expressions of interest regarding NAFO Division 3LNO yellowtail flounder should be made in writing to Patrick E. Moran in the NMFS Office of International Affairs, at 1315 East-West Highway, Silver Spring, MD 20910 (*phone:* (301) 427–8370, *fax:* (301) 713–2313, *email: Pat.Moran@noaa.gov*).

Information relating to NAFO fish quotas, NAFO Conservation and Enforcement Measures, and the High Seas Fishing Compliance Act (HSFCA) Permit is available from Douglas Christel, at the NMFS Northeast Regional Office at 55 Great Republic Drive, Gloucester, MA 01930 (*phone:* (978) 281–9141, *fax:* (978) 281–9135, *email: douglas.christel@noaa.gov*) and from NAFO on the World Wide Web at *http://www.nafo.int.*

FOR FURTHER INFORMATION CONTACT: Patrick E. Moran, (301) 427–8370.

SUPPLEMENTARY INFORMATION:

Background

NAFO has established and maintains conservation measures in its Regulatory Area that include one effort limitation fishery as well as fisheries with total allowable catches (TACs) and member nation quota allocations. The principal species managed are cod, flounder, redfish, American plaice, halibut, hake, capelin, shrimp, skates and squid. The United States currently receives no yellowtail flounder allocation from NAFO. However, as the result of a bilateral arrangement with Canada, the United States may request a transfer of up to 1,000 mt of NAFO Division 3LNO yellowtail flounder from Canada's quota allocation for use by U.S. vessels during 2011, or any succeeding year through 2017. In January 2011, this fishing opportunity was announced in the **Federal Register** and two U.S. vessels were subsequently identified to harvest the fish during 2011. Due to changing economic and other circumstances, these vessels will now be unable to fish during 2011. New procedures for obtaining NMFS authorization to fish for NAFO Division 3LNO yellowtail are specified below.

U.S. Fishing Vessel Applicants

Expressions of interest to fish 1,000 mt of yellowtail flounder in NAFO Division 3LNO will once again be considered from U.S. vessels in possession of, or eligible for, a valid HSFCA permit, which is available from the NMFS Northeast Regional Office (see **ADDRESSES**). All expressions of interest should be directed in writing to Patrick E. Moran (see **ADDRESSES**). Letters of interest from U.S. vessel owners should include the name, registration, and home port of the applicant vessel as required by NAFO in advance of fishing operations. In addition, any available information on dates of fishing operations should be included. To ensure equitable access by U.S. vessel owners, NMFS may promulgate regulations designed to choose one or more U.S. applicants from among expressions of interest.

Note that vessels issued valid HSFCA permits under 50 CFR part 300 are exempt from multispecies permit, mesh size, effort-control, and possession limit restrictions, specified in 50 CFR 648.4, 648.80, 648.82 and 648.86, respectively, while transiting the U.S. exclusive economic zone (EEZ) with multispecies on board the vessel, or landing multispecies in U.S. ports that were caught while fishing in the NAFO Regulatory Area, provided:

1. The vessel operator has a letter of authorization issued by the Regional Administrator on board the vessel;

2. For the duration of the trip, the vessel fishes, except for transiting purposes, exclusively in the NAFO Regulatory Area and does not harvest fish in, or possess fish harvested in, or from, the U.S. EEZ;

3. When transiting the U.S. EEZ, all gear is properly stowed in accordance with one of the applicable methods specified in § 648.23(b); and

4. The vessel operator complies with the HSFCA permit and all NAFO conservation and enforcement measures while fishing in the NAFO Regulatory Area.

NAFO Conservation and Management Measures

Relevant NAFO Conservation and Enforcement Measures include, but are not limited to, maintenance of a fishing logbook with NAFO-designated entries; adherence to NAFO hail system requirements; presence of an on-board observer; deployment of a functioning, autonomous vessel monitoring system; and adherence to all relevant minimum size, gear, bycatch, and other requirements. Further details regarding these requirements are available from the NMFS Northeast Regional Office, and can also be found in the current NAFO Conservation and Enforcement Measures on the Internet (see **ADDRESSES**).

Chartering Operations Using Canadian Vessels

In the event that no adequate expressions of interest in harvesting NAFO Division 3LNO yellowtail flounder during 2011 are made on behalf of U.S. vessels, expressions of interest will be considered from U.S. processors and other fishing interests intending to make use of a Canadian vessel under a chartering arrangement. Under the bilateral arrangement with Canada, the United States may enter into a chartering (or other) arrangement with a Canadian vessel to harvest the transferred yellowtail flounder. Prior notification to the NAFO Executive Secretary is necessary in this case. Expressions of interest from U.S. processors and other fishing interests intending to make use of a Canadian vessel under chartering arrangements should provide the following information: the name and registration number of the intended vessel; a copy of the charter; a detailed fishing plan, and a written letter of consent from the Department of Fisheries and Oceans, Canada. In addition, expressions of interest using a Canadian vessel under charter should be accompanied by a detailed description of anticipated benefits to the United States. Such benefits might include, but are not limited to, the use of U.S. processing facilities/personnel; the use of U.S. fishing personnel; marketing of the product in the United States; other specific positive effects on U.S. employment; evidence that fishing by the Canadian vessel will actually take place; and any available documentation of the physical characteristics and economics of the fishery for future use by the U.S. fishing industry.

Any Canadian vessel wishing to enter into a chartering arrangement with the United States must be in full current compliance with the requirements outlined in the NAFO Convention and Conservation and Enforcement Measures including, but not limited to, submission of the following reports to the NAFO Executive Secretary: provisional monthly catches within 30 days following the calendar month in which the catches were made; observer reports within 30 days following the completion of a fishing trip; and an annual statement of actions taken in order to comply with the NAFO Convention; and notification to NMFS of the termination of the charter fishing activities. Furthermore, the United States may also consider the vessel's previous compliance with NAFO bycatch, reporting and other provisions, as outlined in the NAFO Conservation and Enforcement Measures, before entering into a chartering arrangement. More details on NAFO requirements are available from NMFS (see **ADDRESSES**).

In the event that multiple expressions of interest are made by U.S. fishing vessels, processors, or interests to fish for NAFO Division 3LNO yellowtail in 2011, the information submitted regarding benefits to the United States will be used in making a selection. After reviewing all requests for allocations submitted, NMFS may decide not to grant any allocations if it is determined that no requests meet the criteria described in this notice. Once a decision has been made regarding the disposition of the fishing opportunity, NMFS will immediately take appropriate steps to notify all applicants and will contact Canada and NAFO to take appropriate action. If the 3LNO yellowtail flounder transferred from Canada is awarded to a U.S. vessel or a specified chartering operation during 2011, it may not be transferred without the express, written consent of NMFS.

Dated: November 22, 2011.

Rebecca Lent,

Director, Office of International Affairs, National Marine Fisheries Service.

[FR Doc. 2011–30520 Filed 11–25–11; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to the Procurement List.

SUMMARY: The Committee is proposing to add products and a service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must Be Received On or Before: 12/29/2011.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Patricia Briscoe, *Telephone:* (703) 603–7740, *Fax:* (703) 603–0655, or *email CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and service to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and service proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following products and service are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Blades, Surgical Knives, Detachable, Carbon Steel, Disposable, Sterile

NSN: 6515–00–660–0009—No. 12
NSN: 6515–00–660–0010—No. 11
NSN: 6515–00–660–0011—No. 10
NPA: The Lighthouse for the Blind, St. Louis, MO.
Contracting Activity: DEFENSE LOGISTICS AGENCY TROOP SUPPORT, PHILADELPHIA, PA
COVERAGE: C-List for 100% of the requirement of the Department of Defense, as aggregated by the Defense Logistics Agency Troop Support, Philadelphia, PA

Service

Service Type/Location: Corrosion Repair Services, Marine Corps Base Hawaii (MCBH), Kaneohe Bay, HI.
NPA: Goodwill Contract Services of Hawaii, Inc., Honolulu, HI.
Contracting Activity: Regional Contracting Office, Marine Corps Base Hawaii, Kaneohe Bay, HI.

Patricia Briscoe,

Deputy Director, Business Operations, (Pricing and Information Management).

[FR Doc. 2011–30481 Filed 11–25–11; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2011–OS–0137]

Privacy Act of 1974; System of Records

AGENCY: Defense Logistics Agency, Department of Defense (DoD).

ACTION: Notice to amend a system of records.

SUMMARY: The Defense Logistics Agency is proposing to amend a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The proposed action will be effective without further notice on December 28, 2011 unless comments are received which would result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Jody Sinkler, DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221, or by phone at (703) 767–5045.

SUPPLEMENTARY INFORMATION: The Defense Logistics Agency's system of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**.

The specific changes to the record system being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendment is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of new or altered systems reports.

Dated: November 22, 2011.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

S284.89

SYSTEM NAME:

Government Telephone Use Records (August 7, 2009, 74 FR 39652).

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with ''Records are located at System Engineering and Network Services (J6FIS), Defense Logistics Agency Headquarters, 8725 John J. Kingman Road, Stop 6220, Fort Belvoir, VA 22060–6221, and at the telephone control offices of the DLA Primary Level Field Activities. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Add ''BlackBerry devices'' to entry.

* * * * *

PURPOSE(S):

Add ''and wireless devices'' to first paragraph.

* * * * *

STORAGE:

Delete entry and replace with ''Records are stored on paper.''

* * * * *

SAFEGUARDS:

Delete second sentence from entry.

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Staff Director, System Engineering and Network Services (J6FIS), Defense Logistics Agency Headquarters, 8725 John J. Kingman Road, Stop 6220, Fort Belvoir, VA 22060–6221, and the Telecommunications Control Officers of DLA Primary Level Field Activities. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Individuals need to provide their full name and the DLA facility or activity where employed at the time the records were created or processed.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system should address written inquiries to the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J.

Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Individuals need to provide their full name and the DLA facility or activity where employed at the time the records were created or processed.''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''The DLA rules for accessing records, for contesting contents, and appealing initial agency determinations are contained in 32 CFR part 323, or may be obtained from the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.''

* * * * *

S284.89

SYSTEM NAME:

Government Telephone Use Records.

SYSTEM LOCATION:

Records are located at System Engineering and Network Services (J6FIS), Defense Logistics Agency Headquarters, 8725 John J. Kingman Road, Stop 6220, Fort Belvoir, VA 22060–6221, and at the telephone control offices of the DLA Primary Level Field Activities. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

DLA employees, military members, contractors, and individuals authorized to use government telephone systems, including wireless devices such as cellular telephones, pagers, BlackBerry devices, and telecommunications devices for the deaf or speech impaired and wireless air cards. The records also cover individuals who have been issued telephone calling cards.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records include individual's name and physical location; duty telephone, cell, and pager numbers; billing account codes; government issued telephone calling card account number; equipment and calling card receipts and turn-in documents; device serial numbers; and details of telephone use to include dates and times of telephone calls made or received, numbers called or called from, city and state, duration of calls, and assessed costs.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 133, Under Secretary of Defense for Acquisition, Technology, and Logistics; 44 U.S.C. 3501 et seq., Federal Information Policy; Committee on National Security Systems Directive No. 900, Governing Procedures of the Committee on National Security Systems promulgated pursuant to 47 U.S.C. 901 *et seq.,* National Telecommunications; E.O. 12731, Principles of ethical conduct for Government officers and employees; 5 CFR part 2635, Standards of Ethical Conduct for Employees of the Executive Branch; and DoD Instruction 5335.1, Telecommunications Services In The National Capital Region (NCR).

PURPOSE(S):

Records are maintained to verify that telephones and wireless devices are used for official business or authorized purposes; to identify inappropriate calls and the persons responsible, and to collect the costs of those calls from those responsible. These records may be used as a basis for disciplinary action against offenders.

Records are also maintained to ensure proper certification and payment of bills; to safeguard telecommunications assets; for internal management control; for reporting purposes; and to forecast future telecommunications requirements and costs. Statistical data, with all personal identifiers removed, may be used by management officials for purposes of conducting studies, evaluations, and assessments.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974 these records may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Information may be released to telecommunications service providers to permit servicing the account.

The DoD ''Blanket Routine Uses'' also apply to this system of records.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on paper.

RETRIEVABILITY:

Records are retrieved by individual's name, billing account code, or telephone number.

SAFEGUARDS:

Access to the data is limited to those who require the records in the performance of their official duties. Physical entry is restricted by the use of locks, guards, and administrative procedures. Employees are periodically briefed on the consequences of improperly accessing restricted databases or records.

RETENTION AND DISPOSAL:

Records are destroyed when 3 years old. Initial telephone use reports may be destroyed earlier if the information needed to identify abuse has been captured in other records.

SYSTEM MANAGER(S) AND ADDRESS:

Staff Director, System Engineering and Network Services (J6FIS), Defense Logistics Agency Headquarters, 8725 John J. Kingman Road, Stop 6220, Fort Belvoir, VA 22060–6221, and the Telecommunications Control Officers of DLA Primary Level Field Activities. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Individuals need to provide their full name and the DLA facility or activity where employed at the time the records were created or processed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Individuals need to provide their full name and the DLA facility or activity where employed at the time the records were created or processed.

CONTESTING RECORD PROCEDURES:

The DLA rules for accessing records, for contesting contents, and appealing initial agency determinations are contained in 32 CFR part 323, or may be obtained from the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

RECORD SOURCE CATEGORIES:

Data is supplied by the telephone user, telecommunications service providers, and DLA management.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2011–30539 Filed 11–25–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

TRICARE, Formerly Known as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Fiscal Year 2012 Mental Health Rate Updates

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Notice of updated mental health rates for Fiscal Year 2012.

SUMMARY: This notice provides the updated regional per-diem rates for low-volume mental health providers; the update factor for hospital-specific per-diems; the updated cap per-diem for high-volume providers; the beneficiary per-diem cost-share amount for low-volume providers; and, the updated per-diem rates for both full-day and half-day TRICARE Partial Hospitalization Programs for Fiscal Year 2012.

DATES: *Effective Date:* The Fiscal Year 2012 rates contained in this notice are effective for services on or after October 1, 2011.

ADDRESSES: TRICARE Management Activity (TMA), Medical Benefits and Reimbursement Branch, 16401 East Centretech Parkway, Aurora, CO 80011–9066.

FOR FURTHER INFORMATION CONTACT: Elan Green, Medical Benefits and Reimbursement Branch, TMA, telephone (303) 676–3907.

SUPPLEMENTARY INFORMATION: The final rule published in the **Federal Register** (FR) on September 6, 1988, (53 FR 34285) set forth reimbursement changes that were effective for all inpatient hospital admissions in psychiatric hospitals and exempt psychiatric units occurring on or after January 1, 1989. The final rule published in the **Federal Register** on July 1, 1993, (58 FR 35400) set forth maximum per-diem rates for all partial hospitalization admissions on or after September 29, 1993. Included in these final rules were provisions for updating reimbursement rates for each federal Fiscal Year. As stated in the final rules, each per-diem shall be updated by the Medicare update factor for hospitals and units exempt from the Medicare Prospective Payment System (*i.e.,* this is the same update factor used for the inpatient prospective payment system). For Fiscal Year 2012, the market basket rate is 3.0 percent. This year, Medicare applied two reductions to its market basket amount: (1) A 1.0 percent reduction for economy-wide productivity required by section 3410(a) of the Patient Protection and Affordable Care Act (PPACA) which amended section 1886(b)(3)(B) of the Social Security Act, and (2) a 0.1 percent point adjustment as required by section 1886(b)(3)(B)(xii) of the Act as added and amended by sections 3401 and 10319(a) of the PPACA. These two reductions do not apply to TRICARE. Hospitals and units with hospital-specific rates (hospitals and units with high TRICARE volume) and regional-specific rates for psychiatric hospitals and units with low TRICARE volume will have their TRICARE rates for Fiscal Year 2012 updated by 3.0 percent

Partial hospitalization rates for full-day and half-day programs also will be updated by 3.0 percent for Fiscal Year 2012.

The cap amount for high-volume hospitals and units also will be updated by the 3.0 percent for Fiscal Year 2012.

The beneficiary cost share for low-volume hospitals and units also will be updated by the 3.0 percent for Fiscal Year 2012.

Per 32 CFR 199.14, the same area wage indexes used for the CHAMPUS Diagnosis-Related Group (DRG)-based payment system shall be applied to the wage portion of the applicable regional per-diem for each day of the admission. The wage portion shall be the same as that used for the CHAMPUS DRG-based payment system. For wage index values greater than 1.0, the wage portion of the regional rate subject to the area wage adjustment is 68.8 percent for Fiscal Year 2012. For wage index values less than or equal to 1.0, the wage portion of the regional rate subject to the area wage adjustment is 62 percent.

Additionally, 32 CFR 199.14, requires that hospital specific and regional per-diems shall be updated by the Medicare update factor for hospitals and units exempt from the Medicare prospective payment system.

The following reflect an update of 3.0 percent for Fiscal Year 2012.

REGIONAL-SPECIFIC RATES FOR PSYCHIATRIC HOSPITALS AND UNITS WITH LOW TRICARE VOLUME FOR FISCAL YEAR 2012

United States Census Region	Regional rate
Northeast:	
New England	$787
Mid-Atlantic	758
Midwest:	
East North Central	655
West North Central	618
South:	
South Atlantic	780
East South Central	834
West South Central	711
West:	
Mountain	710
Pacific	838
Puerto Rico	53

Beneficiary cost-share: Beneficiary cost-share (other than dependents of Active Duty members) for care paid on the basis of a regional per-diem rate is the lower of $208 per day or 25 percent of the hospital billed charges effective for services rendered on or after October 1, 2011.

Cap Amount: Updated cap amount for hospitals and units with high TRICARE volume is $ 989 per day for services on or after October 1, 2011.

The following reflect an update of 3.0 percent for Fiscal Year 2012 for the partial hospitalization rates.

PARTIAL HOSPITALIZATION RATES FOR FULL-DAY AND HALF-DAY PROGRAMS

[Fiscal year 2012]

United States Census Region	Full-day rate (6 hours or more)	Half-day rate (3–5 hours)
Northeast:		
New England (Maine, N.H., Vt., Mass., R.I., Conn.)	$315	$234
Mid-Atlantic:		
(N.Y., N.J., Penn.)	343	258
Midwest:		
East North Central (Ohio, Ind., Ill., Mich., Wis.)	302	225

PARTIAL HOSPITALIZATION RATES FOR FULL-DAY AND HALF-DAY PROGRAMS—Continued

[Fiscal year 2012]

United States Census Region	Full-day rate (6 hours or more)	Half-day rate (3–5 hours)
West North Central:		
(Minn., Iowa, Mo., N.D., S.D., Neb., Kan.)	302	225
South:		
South Atlantic (Del., Md., DC, Va., W.Va., N.C., S.C., Ga., Fla.)	323	244
East South Central:		
(Ky., Tenn., Ala., Miss.)	350	264
West South Central:		
(Ark., La., Texas, Okla.)	350	264
West:		
Mountain (Mon., Idaho, Wyo., Col., N.M., Ariz., Utah, Nev.)	353	267
Pacific (Wash., Ore., Calif., Alaska, Hawaii)	347	260
Puerto Rico	225	170

The above rates are effective for services rendered on or after October 1, 2011.

Dated: November 22, 2011.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer,

Department of Defense.

[FR Doc. 2011–30514 Filed 11–25–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

TRICARE; Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Fiscal Year 2012 Diagnosis-Related Group (DRG) Updates

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Notice of DRG revised rates.

SUMMARY: This notice describes the changes made to the TRICARE DRG-based payment system in order to conform to changes made to the Medicare Prospective Payment System (PPS).

It also provides the updated fixed loss cost outlier threshold, cost-to-charge ratios and the data necessary to update the FY 2012 rates.

DATES: *Effective Dates:* The rates, weights and Medicare PPS changes which affect the TRICARE DRG-based payment system contained in this notice are effective for admissions occurring on or after October 1, 2011.

ADDRESSES: TRICARE Management Activity (TMA), Medical Benefits and Reimbursement Systems, 16401 East Centretech Parkway, Aurora, CO 80011–9066.

FOR FURTHER INFORMATION CONTACT: Mark A. Jacobs, Medical Benefits and Reimbursement Systems, TMA, telephone (303) 676–3802.

Questions regarding payment of specific claims under the TRICARE DRG-based payment system should be addressed to the appropriate contractor.

SUPPLEMENTARY INFORMATION: The final rule published on September 1, 1987 (52 FR 32992) set forth the basic procedures used under the CHAMPUS DRG-based payment system. This was subsequently amended by final rules published August 31, 1988 (53 FR 33461), October 21, 1988 (53 FR 41331), December 16, 1988 (53 FR 50515), May 30, 1990 (55 FR 21863), October 22, 1990 (55 FR 42560), and September 10, 1998 (63 FR 48439).

An explicit tenet of these final rules, and one based on the statute authorizing the use of DRGs by TRICARE, is that the TRICARE DRG-based payment system is modeled on the Medicare PPS, and that, whenever practicable, the TRICARE system will follow the same rules that apply to the Medicare PPS. The Centers for Medicare and Medicaid Services (CMS) publishes these changes annually in the **Federal Register** and discusses in detail the impact of the changes.

In addition, this notice updates the rates and weights in accordance with our previous final rules. The actual changes we are making, along with a description of their relationship to the Medicare PPS, are detailed below.

I. Medicare PPS Changes Which Affect the TRICARE DRG-Based Payment System

Following is a discussion of the changes CMS has made to the Medicare PPS that affect the TRICARE DRG-based payment system.

A. DRG Classifications

Under both the Medicare PPS and the TRICARE DRG-based payment system, cases are classified into the appropriate DRG by a Grouper program. The Grouper classifies each case into a DRG on the basis of the diagnosis and procedure codes and demographic information (that is, sex, age, and discharge status). The Grouper used for the TRICARE DRG-based payment system is the same as the current Medicare Grouper with two modifications. The TRICARE system has replaced Medicare DRG 435 with two age-based DRGs (900 and 901), and has implemented thirty-four (34) neonatal DRGs in place of Medicare DRGs 385 through 390. For admissions occurring on or after October 1, 2001, DRG 435 has been replaced by DRG 523. The TRICARE system has replaced DRG 523 with the two age-based DRGs (900 and 901). For admissions occurring on or after October 1, 1995, the CHAMPUS grouper hierarchy logic was changed so the age split (age <29 days) and assignments to MDC 15 occur before assignment of the PreMDC DRGs. This resulted in all neonate tracheostomies and organ transplants to be grouped to MDC 15 and not to DRGs 480–483 or 495. For admissions occurring on or after October 1, 1998, the CHAMPUS grouper hierarchy logic was changed to move DRG 103 to the PreMDC DRGs and to assign patients to PreMDC DRGs 480, 103 and 495 before assignment to MDC 15 DRGs and the neonatal DRGs. For admissions occurring on or after October 1, 2001, DRGs 512 and 513 were added to the PreMDC DRGs, between DRGs 480 and 103 in the TRICARE grouper hierarchy logic. For admissions occurring on or after October 1, 2004, DRG 483 was deleted and replaced with DRGs 541 and 542, splitting the assignment of cases on the basis of the performance of a major operating room procedure. The description for DRG 480 was changed to ''Liver Transplant and/or Intestinal Transplant'', and the description for DRG 103 was changed to ''Heart/Heart

Lung Transplant or Implant of Heart Assist System''. For FY 2007, CMS implemented classification changes, including surgical hierarchy changes. The TRICARE Grouper incorporated all changes made to the Medicare Grouper, with the exception of the pre-surgical hierarchy changes, which will remain the same as FY 2006. For FY 2008, Medicare implemented the Medicare-Severity DRG (MS–DRG) based payment system. TRICARE, however, continued with the Centers for Medicare and Medicaid Services DRG-based (CMS–DRG) payment system for FY 2008. For FY 2009, the TRICARE/CHAMPUS DRG-based payment system was modeled on the MS–DRG system, with the following modifications.

The MS–DRG system consolidated the 43 pediatric CMS DRGs that were defined based on age less than or equal to 17 into the most clinically similar MS–DRGs. In the CMS Inpatient Prospective Payment System final rule for MS–DRGs, CMS stated for the Medicare population these pediatric CMS DRGs contained a very low volume of patients. At the same time, Medicare encouraged private insurers and other non-Medicare payers to make refinements to MS–DRGs to better suit the needs of the patients they serve. Consequently, TRICARE finds it appropriate to retain the pediatric CMS–DRGs for our population. TRICARE is also retaining the TRICARE-specific DRGs for neonates and substance use.

TRICARE retained the MS–DRG numbering system for FY09 and those TRICARE-specific DRGs were assigned available, blank DRG numbers unused in the MS–DRG system. We refer the reader to *http://www.tricare.mil/drgrates* for a complete crosswalk containing the TRICARE DRG numbers for FY09.

For FY09, TRICARE used the MS–DRG v26.0 pre-MDC hierarchy, with the exception that MDC 15 is applied after DRG 011–012 and before MDC 24.

For FY 10, there were no additional or deleted DRGs.

For FY 11, DRG 009 was deleted; DRGs 014 and 015 were added.

For FY 12, the added DRGs and deleted DRGs are the same as those included in CMS' final rule published on August 18, 2011 (76 FR 51476–51846). That is, DRG 015 is deleted; DRGs 016 and 017 are being added.

B. Wage Index and Medicare Geographic Classification Review Board Guidelines

TRICARE will continue to use the same wage index amounts used for the Medicare PPS. TRICARE will also duplicate all changes with regard to the wage index for specific hospitals that are re-designated by the Medicare Geographic Classification Review Board. In addition, TRICARE will continue to utilize the out commuting wage index adjustment.

C. Revision of the Labor-Related Share of the Wage Index

TRICARE is adopting CMS' percentage of labor related share of the standardized amount. For wage index values greater than 1.0, the labor related portion of the Adjusted Standardized Amount (ASA) shall equal 68.8 percent. For wage index values less than or equal to 1.0 the labor related portion of the ASA shall continue to equal 62 percent.

D. Hospital Market Basket

TRICARE will update the adjusted standardized amounts according to the final updated hospital market basket used for the Medicare PPS for all hospitals subject to the TRICARE DRG-based payment system according to CMS's August 18, 2011, final rule. For FY 2012, the market basket is 3.0%. Medicare applied reductions to the market basket in FY 2012, with an adjustment of 1.0 percentage point for economy-wide productivity and less 0.1 percentage point for hospitals in all areas. However, these reductions do not apply to TRICARE.

E. Outlier Payments

Since TRICARE does not include capital payments in our DRG-based payments (TRICARE reimburses hospitals for their capital costs as reported annually to the contractor on a pass through basis), we will use the fixed loss cost outlier threshold calculated by CMS for paying cost outliers in the absence of capital prospective payments. For FY 2012, the TRICARE fixed loss cost outlier threshold is based on the sum of the applicable DRG-based payment rate plus any amounts payable for Indirect Medical Education (IDME) plus a fixed dollar amount. Thus, for FY 2012, in order for a case to qualify for cost outlier payments, the costs must exceed the TRICARE DRG base payment rate (wage adjusted) for the DRG plus the IDME payment plus $21,482 (wage adjusted). The marginal cost factor for cost outliers continues to be 80 percent.

F. National Operating Standard Cost as a Share of Total Costs

The FY 2012 TRICARE National Operating Standard Cost as a Share of Total Costs (NOSCASTC) used in calculating the cost outlier threshold is 0.919. TRICARE uses the same methodology as CMS for calculating the NOSCASTC; however, the variables are different because TRICARE uses national cost to charge ratios while CMS uses hospital specific cost to charge ratios.

G. Indirect Medical Education (IDME) Adjustment

Passage of the MMA of 2003 modified the formula multipliers to be used in the calculation of the indirect medical education IDME adjustment factor. Since the IDME formula used by TRICARE does not include disproportionate share hospitals (DSHs), the variables in the formula are different than Medicare's, however; the percentage reductions that will be applied to Medicare's formula will also be applied to the TRICARE IDME formula. The multiplier for the IDME adjustment factor for TRICARE for FY 2012 is 1.02.

H. Expansion of the Post Acute Care Transfer Policy

For FY 2012 TRICARE is adopting CMS' expanded post acute care transfer policy according to CMS' final rule published August 18, 2011.

I. Cost to Charge Ratio

While CMS uses hospital-specific cost to charge ratios, TRICARE uses a national cost to charge ratio. For FY 2012, the cost-to-charge ratio used for the TRICARE DRG-based payment system for acute care hospitals and neonates will be 0.3460. This shall be used to calculate the adjusted standardized amounts and to calculate cost outlier payments, except for children's hospitals. For children's hospital cost outliers, the cost-to-charge ratio used is 0.3757.

J. Updated Rates and Weights

The updated rates and weights are accessible through the Internet at *http://www.tricare.osd.mil* under the sequential headings TRICARE Provider Information, Rates and Reimbursements, and DRG Information. Table 1 provides the ASA rates and Table 2 provides the DRG weights to be used under the TRICARE DRG-based payment system during FY 2012. The implementing regulations for the TRICARE/CHAMPUS DRG-based payment system are in 32 CFR part 199.

Dated: November 22, 2011.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2011–30511 Filed 11–25–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

Army Educational Advisory Committee

AGENCY: Department of the Army, DoD.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150, the following meeting notice is announced:

Name of Committee: U.S. Army War College Subcommittee of the Army Education Advisory Committee.

Dates of Meeting: December 14, 2011.

Place of Meeting: U.S. Army War College, 122 Forbes Avenue, Carlisle, PA, Command Conference Room, Root Hall, Carlisle Barracks, Pennsylvania 17013.

Time of Meeting: 8:30 a.m.–12:30 p.m.

Proposed Agenda: Receive various information briefings and updates and dialogue with the Commandant on issues and matters related to the continued growth and development of the United States Army War College.

For Further Information Contact: To request advance approval or obtain further information, contact COL Donald Myers, (717) 245–3907 or *Donald.myers@us.army.mil*

Supplementary Information: This meeting is open to the public. Interested persons may submit a written statement for consideration by the U.S. Army War College Subcommittee. Written statements should be no longer than two type-written pages and must address: The issue, discussion, and a recommended course of action. Supporting documentation may also be included as needed to establish the appropriate historical context and to provide any necessary background information.

Individuals submitting a written statement must submit their statement to the Designated Federal Officer at the following address: *Attn:* Designated Federal Officer, Dept. of Academic Affairs, 122 Forbes Avenue, Carlisle, PA 17013. At any point, however, if a written statement is not received at least 10 calendar days prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the U.S. Army War College Subcommittee until its next open meeting.

The Designated Federal Officer will review all timely submissions with the U.S. Army War College Subcommittee Chairperson, and ensure they are provided to members of the U.S. Army War College Subcommittee before the meeting that is the subject of this notice. After reviewing the written comments, the Chairperson and the Designated Federal Officer may choose to invite the submitter of the comments to orally present their issue during an open portion of this meeting or at a future meeting.

The Designated Federal Officer, in consultation with the U.S. Army War College Subcommittee Chairperson, may, if desired, allot a specific amount of time for members of the public to present their issues for review and discussion by the U.S. Army War College Subcommittee.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2011–30479 Filed 11–25–11; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket No. DARS 2011–0072–0002]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Government Property (OMB Control Number 0704–0246)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. DoD invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection for use through November 30, 2012. DoD proposes that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD will consider all comments received by January 27, 2012.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0246, using any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: dfars@osd.mil.* Include OMB Control Number 0704–0246 in the subject line of the message.
- *Fax:* (703) 602–0350.
- *Mail:* Defense Acquisition Regulations System, Attn: Ms. Meredith Murphy, OUSD(AT&L)DPAP(DARS), 3060 Defense Pentagon, Room 3B855, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *http://www.regulations.gov* approximately two to three days after submission to verify posting, except allow 30 days for posting of comments submitted by mail.

FOR FURTHER INFORMATION CONTACT: Ms. Meredith Murphy, telephone (703) 602–1302; facsimile (703) 602–0350. The information collection requirements addressed in this notice are available on the World Wide Web at: *http://www.acq.osd.mil/dpap/dars/dfars.html.*

Paper copies are available from Ms. Meredith Murphy, OUSD(AT&L)DPAP(DARS), 3060 Defense Pentagon, Room 3B855, Washington, DC 20301–3060.

SUPPLEMENTARY INFORMATION:

Title, Associated Forms, and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) part 245, Government Property; DD Form 1149, Requisition and Invoice/Shipping Document; DD Form 1348–1A, DoD Single Line Item Release/Receipt Document; DD Form 1637, Notice of Acceptance of Inventory Schedules; DD Form 1639, Scrap Warranty; DD Form 1640, Request for Plant Clearance; DD Form 1641, Disposal Determination/Approval; and DD Form 1822, End Use Certificate; OMB Control Number 0704–0246.

Needs and Uses: DoD needs this information to account for Government property in the possession of contractors. Property administrators, contracting officers, and contractors use this information to maintain property records and material inspection, shipping, and receiving reports.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Annual Burden Hours: 18,135.

Number of Respondents: 10,625.

Responses Per Respondent: 1.95.

Annual Responses: 20,765.

Average Burden per Response: 0.87 hours.

Frequency: On occasion.

Summary of Information Collection

This requirement provides for the collection of information related to providing Government property to contractors; contractor use and management of Government property;

and reporting, redistribution, and disposal of contractor inventory.

a. DFARS 245.302(1)(i) requires contractors to request and obtain contracting officer approval before using Government property on work for foreign governments and international organizations.

b. DFARS subpart 245.70, Plant Clearance Forms, prescribes the requirements for the use of the following forms:

(1) *DD Form 1149,* Requisition and Invoice/Shipping Document (JUL 2006): Prescribed at DFARS 245.7001–2, the form is completed by the contractor for transfer and donation of excess contractor inventory.

(2) *DD Form 1348–1A,* DoD Single Line Item Release/Receipt Document: Prescribed at DFARS 245.7001–3, the form is used when authorized by the plant clearance officer.

(3) *DD Form 1640,* Request for Plant Clearance (JUN 2003): Prescribed at DFARS 245.7001–4, the contractor completes this form to request plant clearance assistance or transfer plant clearance.

(4) *DD Form 1641,* Disposal Determination/Approval (APR 2000): Prescribed at DFARS 245.7001–5, this form is used to record rationale for the following disposal determinations:

(i) Downgrade useable property to scrap.

(ii) Abandonment or destruction.

(iii) Noncompetitive sale of surplus property.

(iv) Other disposal actions.

(5) *DD Form 1822,* End Use Certificate: Addressed at DFARS 245.7001–6, this form is prescribed by DoDI 5230.18, entitled ''The DoD Foreign Disclosure and Technical Information System,'' and is used when directed by the plant clearance officer.

c. In addition, the following DD forms are prescribed in the clause at DFARS 252.245–7004, Reporting, Reutilization, and Disposal (AUG 2011):

(1) *DD Form 1637,* Notice of Acceptance of Inventory Schedules (JUN 2003): There is no information collection burden on contractors associated with this form. Government plant clearance officers use this form to indicate acceptance of the contractor's inventory schedules.

(2) *DD Form 1639,* Scrap Warranty: When scrap is sold by the contractor, after Government approval, the purchaser of the scrap material(s) may be required to certify, by signature on the DD Form 1639, that (i) the purchased material will be used only as scrap and (ii), if sold by the purchaser, the purchaser will obtain an identical warranty from the individual buying the scrap from the initial purchaser. The warranty contained in the DD Form 1639 expires by its terms five years from the date of the sale.

Ynette R. Shelkin,

Editor, Defense Acquisition Regulations System.

[FR Doc. 2011–30484 Filed 11–25–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

[Docket No. DARS 2011–0071–0002]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; DoD Acquisition Process (Various Miscellaneous Requirements) (OMB Control Number 0704–0187)

AGENCY: Department of Defense (DoD).

ACTION: Notice and request for comments.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. DoD invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection requirement for use through April 30, 2012. DoD proposes that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD will consider all comments received by January 27, 2012.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0187, using any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''OMB Control Number 0704–0187'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''OMB Control Number 0704–0187.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''OMB Control Number 0704–0187'' on your attached document.
- *Email: dfars@osd.mil.* Include OMB Control Number 0704–0187 in the subject line of the message.
- *Fax:* 703–602–0350.
- *Mail:* Defense Acquisition Regulations System, Attn: Dr. Laura Welsh, OUSD (AT&L) DPAP/DARS, Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *http://www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Dr. Laura Welsh, Defense Acquisition Regulations System, OUSD(AT&L)DPAP/DARS, Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060. Telephone 703–602–0326; facsimile 703–602–0350. The information collection requirements addressed in this notice are available on the World Wide Web at: *http://www.acq.osd.mil/dpap/dars/dfars.html.* Paper copies are available from Ms. Meredith Murphy, OUSD (AT&L) DPAP (DARS), 3060 Defense Pentagon, Room 3B855, Washington, DC 20301–3060.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Information Collection in Support of the DoD Acquisition Process (Various Miscellaneous Requirements)(Defense Federal Acquisition Regulation Supplement (DFARS) Parts 208, 209, and 235 and Associated Clauses in Part 252)), OMB Control Number 0704–0187.

Needs and Uses: This information collection requirement pertains to information required in DFARS parts 208, 209, 235, and associated clauses in part 252 that an offeror must submit to DoD in response to a request for proposals or an invitation for bids or a contract requirement. DoD uses this information to—

- Determine whether to provide precious metals as Government-furnished material;
- Determine an entity's eligibility for award of a contract due to ownership or control by the government of a terrorist country;
- Determine an entity's eligibility for award of a contract under a national

security program due to ownership or control by a foreign government;

• Determine whether there is a compelling reason for a contractor to enter into a subcontract in excess of $30,000 with a firm, or subsidiary of a firm, that is identified in the List of Parties Excluded from Federal Procurement and Nonprocurement as being ineligible for award of Defense subcontracts because it is owned or controlled by the government of a terrorist country;

• Evaluate claims of indemnification for losses or damages occurring under a research and development contract; and

• Keep track of radio frequencies on electronic equipment under research and development contracts so that the user does not override or interfere with the use of that frequency by another user.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Annual Burden Hours: 1,628.

Number of Respondents: 573.

Responses per Respondent: Approximately 2.

Annual Responses: 1,144.

Average Burden per Response: 1.5 hours.

Frequency: On occasion.

Summary of Information Collection

This information collection pertains to information, as required in DFARS parts 208, 209, 235, and associated clauses in part 252 that an offeror must submit to DoD in response to a request for proposals or an invitation for bids or a contract requirement. In particular, the information collection covers the following DFARS requirements:

• *252.208–7000, Intent to Furnish Precious Metals as Government-Furnished Material.* Paragraph (b) of this clause requires an offeror to cite the type and quantity of precious metals required in the performance of the contract. Paragraph (c) requires the offeror to submit two prices for each deliverable item that contains precious metals: one based on the Government furnishing the precious metals, and the other based on the contractor furnishing the precious metals.

• *252.209–7001, Disclosure of Ownership or Control by the Government of a Terrorist Country.* Paragraph (c) of this provision requires an offeror to provide a disclosure with its offer if the government of a terrorist country has a significant interest in the offeror, in a subsidiary of the offeror, or in a parent company of which the offeror is a subsidiary.

• *252.209–7002, Disclosure of Ownership or Control by a Foreign Government.* Paragraph (c) requires the offeror to provide a disclosure with its offer of any interest a foreign government has in the offeror when that interest constitutes control of the offeror by a foreign government.

• *252.209–7004, Subcontracting with Firms that are Owned or Controlled by the Government of a Terrorist Country.* Paragraph (b) requires the contractor to notify the contracting officer in writing before entering into a subcontract in excess of $30,000 with a party that is identified in the List of Parties Excluded from Federal Procurement and Nonprocurement Programs as being ineligible for award of defense contracts or subcontracts because it is owned or controlled by the government of a terrorist country. The contractor must provide the name of the proposed subcontractor and the compelling reasons for doing business with the subcontractor.

• *252.235–7000, Indemnification Under 10 U.S.C. 2534—Fixed Price; and 252.235–7001, Indemnification Under 10 U.S.C. 2534—Cost-Reimbursement.* Paragraphs (f) and (e), respectively, of these clauses require contractors to notify the contracting officer of any claim and provide (1) proof or evidence of a claim and (2) copies of all pertinent papers when the contractor is to be indemnified.

• *DFARS 252.235–7003, Frequency Authorization.* Paragraph (b) requires that the contractor or subcontractor provide to the contracting officer the technical operating characteristics for any experimental, developmental, or operational equipment for which the appropriate frequency allocation has not been made.

Ynette R. Shelkin,

Editor, Defense Acquisition Regulations System.

[FR Doc. 2011–30515 Filed 11–25–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[OMB Control Number 0704–0454]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Administrative Matters

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice; request for comments.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. *DoD invites comments on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection requirement for use through January 31, 2012. DoD proposes that OMB extend its approval for three additional years.

DATES: DoD will consider all comments received by January 27, 2012.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0454, using any of the following methods:

• *Email: dfars@osd.mil.* Include OMB Control Number 0704–0454 in the subject line of the message.

• *Fax:* 703–602–0350.

• *Mail:* Defense Acquisition Regulations System, Attn: Mr. Julian Thrash, OUSD (AT&L) DPAP/DARS, Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *http://www.regulations.gov* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Julian Thrash, at (703) 602–0310. The information collection requirements addressed in this notice are available electronically on the Internet at: *http://www.acq.osd.mil/dpap/dfars/index.htm.* Paper copies are available from Mr. Julian Thrash, OUSD (AT&L) DPAP (DARS), Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 204, Administrative Matters: U.S. International Atomic Energy Agency

Additional Protocol; OMB Control Number 0704–0454.

Needs and Uses: This requirement is necessary to provide for protection of information or activities with national security significance. As such, this information collection requires contractors to comply with the notification process at DFARS clause 252.204–7010, Requirement for Contractor to Notify DoD if the Contractor's Activities are Subject to Reporting Under the U.S.-International Atomic Energy Agency Additional Protocol.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Number of Respondents: 300.

Responses per Respondent: 1.

Annual Responses: 300.

Average Burden per Response: 1 hour.

Annual Burden Hours: 300.

Frequency: On occasion.

Summary of Information Collection

Under the U.S.-International Atomic Energy Agency (IAEA) Additional Protocol, the United States is required to declare a wide range of public and private nuclear-related activities to the IAEA and potentially provide access to IAEA inspectors for verification purposes. The U.S.-IAEA Additional Protocol permits the United States unilaterally to declare exclusions from inspection requirements for activities with direct national security significance.

The clause at 252.204–7010 is included in contracts for research and development or major defense acquisition programs involving fissionable materials (e.g., uranium, plutonium, neptunium, thorium, americium); other radiological source materials; or technologies directly related to nuclear power production, including nuclear or radiological waste materials.

The clause requires a contractor to provide written notification to the applicable DoD program manager and a copy of the notification to the contracting officer, if the contractor is required to report its activities under the U.S.-IAEA Additional Protocol. Upon such notification, DoD will determine if access may be granted to IAEA inspectors, or if a national security exclusion should be applied.

Mary Overstreet,

Editor, Defense Acquisition Regulations System.

[FR Doc. 2011–30486 Filed 11–25–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education (ED).

ACTION: Notice of proposed information collection requests.

SUMMARY: 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: An emergency review has been requested in accordance with the Act (44 U.S.C. Chapter 3507 (j)), since public harm is reasonably likely to result if normal clearance procedures are followed. Approval by the Office of Management and Budget (OMB) has been requested by December 9, 2011. A regular clearance process is also beginning. Interested persons are invited to submit comments on or before January 27, 2012.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street NW., Room 10222, New Executive Office Building, Washington, DC 20503, be faxed to (202) 395–5806 or emailed to *oira_submission@omb.eop.gov* with a cc: to *ICDocketMgr@ed.gov*.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Director of OMB provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (OMB) may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. 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. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. ED invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this 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 respondents, including through the use of information technology.

Dated: November 22, 2011.

Darrin A. King,

Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

Federal Student Aid

Type of Review: New.

Title: Loan Verification Certificate for Special Direct Consolidation Loans.

OMB #: Pending.

Abstract: This Loan Verification Certificate (LVC) will serve as the means by which the U.S. Department of Education (the Department) collects certain information from commercial holders of Federal Family Education Loan (FFEL) Program loans that a borrower wishes to consolidate into the William D. Ford Federal Direct Loan (Direct Loan) Program under a special initiative announced by the White House in an October 25, 2011 fact sheet titled ''Help Americans Manage Student Loan Debt.'' Loans made under this initiative are known as Special Direct Consolidation Loans. The information collected on the LVC includes the amount needed to pay off the loans that the borrower wants to consolidate and other information required by the Department to make and service a Special Direct Consolidation Loan.

The purpose of the special consolidation initiative is to encourage borrowers who have both commercially-held FFEL Program loans and other loans that are held by the Department (either Direct Loan Program loans or FFEL Program loans previously sold to the Department by a FFEL Program lender) to consolidate their commercially-held FFEL Program loans into the Direct Loan Program. Currently, these borrowers have at least two loan servicers and are required to make at least two separate monthly payments on

their federal education loans. This makes repayment more difficult and increases the likelihood of a borrower becoming delinquent or going into default. For a borrower who has both commercially-held FFEL Program loans and Department-held loans, consolidation of the commercially-held loans into the Direct Loan Program will simplify repayment by allowing the borrower to make a single monthly loan payment to one entity (a federal loan servicer under contract to the Department), thereby reducing the likelihood of delinquency or default. As an incentive for borrowers to consolidate under the special initiative, the Department is offering reduced interest rates on Special Direct Consolidation Loans.

Additional Information

The Department is requesting emergency clearance of the Special Direct Consolidation Loan LVC because the regular clearance process would prevent the Department from making Special Direct Consolidation Loans by the announced implementation date. Further, because the statutory authority under which the Department is providing the incentives will end on June 30, 2012, the use of normal clearance procedures would significantly shorten the already limited period during which Special Direct Consolidation Loans can be offered, with the result that fewer borrowers would be able to benefit from the reduced interest rates offered as part of the special initiative.

Reporting and Recordkeeping Hour Burden

Responses: 62,633.

Burden Hours: 1,565,825.

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 4757. 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 the Internet address *ICDocketMgr@ed.gov* or faxed to (202) 401–0920. Please specify the complete title of the information collection when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–(800) 877–8339.

[FR Doc. 2011–30596 Filed 11–25–11; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2004–0015; FRL–9496–7]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Clean Water Act State Revolving Fund Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before December 28, 2011.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OW–2004–0015, to: (1) EPA online using *http://www.regulations.gov* (our preferred method), by email to: *OW–Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Office of Water Docket, Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Clifford Yee, Office of Wastewater Management, Mail Code: 4204M, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–0598; fax number: (202) 501–2403; email address: *yee.clifford@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On July 11, 2011 (76 FR 40723), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments during the comment period. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OW–2004–0015, which is available for online viewing at *http://www.regulations.gov,* or in person viewing at the Water 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 8:30 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 Water Docket is (202) 566–2426.

Use EPA's electronic docket and comment system at *http://www.regulations.gov,* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov*.

Title: Clean Water Act State Revolving Fund Program (Renewal).

ICR Numbers: EPA ICR No. 1391.10, OMB Control No. 2040–0118.

ICR Status: This ICR is scheduled to expire on December 31, 2011. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. 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, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The Clean Water Act (CWA), as amended by ''The Water Quality Act

of 1987'' (U.S.C. 1381–1387 *et seq.*), created a Title VI which authorizes grants to States for the establishment of State Water Pollution Control Revolving Funds (SRF). The American Recovery and Reinvestment Act of 2009 (ARRA) established a matching State Water Pollution Control Revolving Fund Program with funds that had to be obligated in one year. The information collection activities will occur primarily at the program level through the State ''Intended Use Plan'' (IUP) and ''Annual Report''. The information is needed annually to implement Section 606 of the CWA.

The 1987 Act declares that water pollution control revolving funds shall be administered by an instrumentality of the State subject to the requirements of the act. This means that each State has a general responsibility for administering its revolving fund and must take on certain specific responsibilities in carrying out its administrative duties. The information collection activities will occur primarily at the program level through the State IUP and Annual Report. The information is needed annually to implement section 606 of the Clean Water Act. The Act requires the information to ensure national accountability, adequate public comment and review, fiscal integrity and consistent management directed to achieve environmental benefits and results. The individual information collections are:

(1) *Capitalization Grant Application and Agreement/State IUP:* The State will prepare a Capitalization Grant application that includes a State IUP outlining in detail how it will use all of the funds available to the fund. The grant agreement contains or incorporates by reference the IUP, application materials, payment schedule, and required assurances. The bulk of the information is provided in the IUP, the legal agreement which commits the State and EPA to execute their responsibilities under the Act.

(2) *Annual Report:* The State must agree to complete and submit an Annual Report that indicates how the State has met the goals and objectives of the previous fiscal year as stated in the IUP and grant agreement. The report provides information on loan recipients, loan amounts, loan terms, project categories, environmental benefits and similar data on other forms of assistance. The report describes the extent to which the existing SRF financial operating policies, alone or in combination with other State financial assistance programs, will provide for the long term fiscal health of the Fund and carry out other provisions specified in the grant operating agreement.

(3) *Annual Audit:* Most States have agreed to conduct or have conducted a separate financial audit of the Capitalization Grant which will provide opinions on the financial statements and a report on the internal controls and compliance with program requirements. The remaining States will be covered by audits conducted under the requirements of the Single Audit Act and by EPA's Office of Inspector General.

(4) *Application for SRF Financial Assistance:* Local communities and other eligible entities have to prepare and submit applications for SRF assistance to their respective State Agency which manages the SRF program. The State reviews the completed loan application and verifies that the proposed projects will comply with applicable Federal and State requirements.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 108 hours per response for the base program and 97.5 hours per response for the ARRA program. 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.

Respondents/Affected Entities: State and Local governments; local communities and tribes.

Estimated Number of Respondents: Base Program: 8,262; ARRA Program: 4,669.

Frequency of Response: Annually.

Estimated Total Annual Hour Burden: Base Program: 441,405; ARRA Program: 364,442.

Estimated Total Annual Cost: Base Program: $12,916,260. This includes an estimated burden cost of $6,389,280 State, and $6,526,980 Local. ARRA Program: $10,902,487. This includes an estimated burden cost of $6,805,440 State, and $4,097,047 Local.

Changes in the Estimates: There is an increase of 4,437 responses and decrease of 65,376 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This increase reflects EPA's acceptance of additional loan applicants for the State SRF loan program. The decrease in burden hours is the time needed to process and report on these loans on an annual basis.

Dated: November 21, 2011.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2011–30557 Filed 11–25–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9496–9; Docket ID No. EPA–HQ–ORD–2011–0050]

Draft Integrated Science Assessment for Ozone and Related Photochemical Oxidants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of extension of public comment.

SUMMARY: EPA is announcing an extension of the public comment period for the second external review draft of a document titled, ''*Second External Review Draft Integrated Science Assessment for Ozone and Related Photochemical Oxidants''* (EPA/600/R–10/076B). The original **Federal Register** notice announcing the public comment period was published on September 30, 2011 (76 FR 60820). This assessment document was developed by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development as part of the review of the national ambient air quality standards (NAAQS) for ozone.

DATES: The public comment period began on September 30, 2011, and ends December 30, 2011. Comments must be received by EPA by December 30, 2011.

ADDRESSES: The ''*Second External Review Draft Integrated Science Assessment for Ozone and Related Photochemical Oxidants''* will be available primarily via the Web page under the Recent Additions and Publications menus at *http://www.epa.gov/ncea.* A limited number of CD–ROM or paper copies will be available. Contact Ms. Marieka Boyd by phone ((919) 541–0031) facsimile ((919) 541–5078) or email (*Boyd.Marieka@epa.gov*) to request either of these, and please provide your name, your mailing address, and the

document title, ''*Second External Review Draft Integrated Science Assessment for Ozone and Related Photochemical Oxidants''* (EPA/600/R–10/076B) to facilitate processing of your request.

FOR FURTHER INFORMATION CONTACT: For technical information, contact Dr. James Brown, NCEA; telephone: (919) 541–0765; facsimile: (919) 541–1818; or email: *Brown.James@epa.gov*.

Comments may be submitted electronically via *http://www.regulations.gov*, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions provided in the **SUPPLEMENTARY INFORMATION** section of **Federal Register** Notice (76 FR 60820).

For information on submitting comments to the docket, please contact the Office of Environmental Information Docket; telephone: (202) 566–1752; facsimile: (202) 566–1753; or email: *ORD.Docket@epa.gov*.

Dated: November 18, 2011.

Darrell A. Winner,

Acting Director, National Center for Environmental Assessment.

[FR Doc. 2011–30555 Filed 11–25–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9497–1]

Notification of a Public Teleconference of the Chartered Science Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public teleconference of the Chartered SAB on December 21, 2011 to conduct a quality review of a draft SAB report, a draft *Advisory on EPA Draft Document ''Considerations Related to Post-Closure Monitoring of Uranium In-Situ ISL/ISR Sites.''*

DATES: The public teleconference will be held on December 21, 2011 from 2:30 p.m. to 5 p.m. (Eastern Time).

ADDRESSES: The public teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain general information concerning the public teleconference may contact Dr. Angela Nugent, Designated Federal Officer (DFO). Dr. Nugent may be contacted at the EPA Science Advisory Board (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; or by telephone/voice mail at (202) 564–2218; fax at (202) 565–2098; or email at *nugent.angela@epa.gov*. General information concerning the EPA Science Advisory Board can be found on the EPA 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 EPA 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 the SAB will hold a public teleconference to conduct a quality review of a draft SAB report, a draft *Advisory on EPA Draft Document ''Considerations Related to Post-Closure Monitoring of Uranium In-Situ ISL/ISR Sites.''* The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background

EPA's Office of Air and Radiation (OAR) has requested SAB advice related to EPA's review of its regulatory standards in 40 CFR Part 192—Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings in regard to underground In-Situ Leach Recovery (ISL/ISR) facilities.

EPA is authorized to develop standards for the protection of public health, safety, and the environment from radiological and non-radiological hazards associated with residual radioactive materials. The Agency is currently undertaking a review to determine if the existing standards, last revised by EPA in 1995, should be updated. The expectation is that ISL/ISR operations will be the most common type of new uranium extraction facility in the United States. These facilities can affect groundwater. Accordingly, EPA is seeking scientific advice and relevant technical criteria to establish standards and procedures, including the relevant period of monitoring for ISL/ISR facilities, once uranium extraction operations are completed, in order to provide reasonable assurances of aquifer stability and groundwater protection. Background information about this advisory activity can be found on the SAB Web site at *http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/Monitoring%20ISL?OpenDocument*.

Availability of Meeting Materials

The agenda and other materials in support of the teleconference will be placed on the SAB Web site at *http://www.epa.gov/sab* in advance of the teleconference.

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 provides specific scientific or technical information or analysis for the SAB 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. Those interested in being placed on the public speakers list for the December 21, 2011 teleconference should contact Dr. Nugent at the contact information provided above no later than December 14, 2011.

Written Statements

Written statements should be supplied to the DFO via email at the contact information noted above by December 14, 2011 for the teleconference 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 SAB 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 Dr. Nugent (202) 564–2218 or *nugent.angela@epa.gov*. To request accommodation of a disability, please contact Dr. Nugent preferably at least ten days prior to the teleconference to give EPA as much time as possible to process your request.

Dated: November 18, 2011.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2011–30556 Filed 11–25–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9497–2]

Proposed CERCLA Administrative Bona Fide Prospective Purchaser Settlement; The City of Dowagiac Brownfield Redevelopment Authority

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with Section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement for recovery of past and projected future response costs concerning the ICG Castings, Inc., Dowagiac site in Dowagiac, Michigan with the following settling party: The City Of Dowagiac Brownfield Redevelopment Authority. The settlement requires the settling party to pay $25,000 to the Hazardous Substance Superfund and requires the performance of specified response activities for the site. The settlement includes a covenant not to sue the settling party pursuant to Sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606 and 9607(a). For 30 days following the date of publication of this notice, the United States will receive written comments relating to the settlement. The United States will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper or inadequate. The United States response to any comments received will be available for public inspection at the Dowagiac District Library, 211 Commercial Street, Dowagiac, Michigan 49047, Attn: Katherine Johnson and 77 West Jackson Boulevard, 7th floor Superfund File Room, Chicago, Illinois.

DATES: Comments must be submitted on or before December 28, 2011.

ADDRESSES: The proposed settlement is available for public inspection at 77 West Jackson Boulevard, 7th floor Superfund File Room, Chicago, Illinois. A copy of the proposed settlement may be obtained from Stuart P. Hersh, Associate Regional Counsel, C–14J, 77 West Jackson Boulevard, Chicago, Illinois 60604, telephone: (312) 886–6235. Comments should reference the ICG Castings, Inc., Dowagiac site in Dowagiac, Michigan and EPA Docket No. V–W–11–C–978 and should be addressed to Stuart P. Hersh, Associate Regional Counsel, C–14J, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Stuart P. Hersh, Associate Regional Counsel, C–14J, 77 West Jackson Boulevard, Chicago, Illinois 60604, telephone (312) 886–6235

Authority: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, 42 U.S.C. 9601, *et seq.*

Dated: November 21, 2011.

Richard C. Karl,

Director, Superfund Division, Site ID Number B5VQ.

[FR Doc. 2011–30554 Filed 11–25–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information burden for small business concerns with fewer than 25 employees.

The FCC 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 Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before January 27, 2012. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at (202) 395–5167 or via Internet at *Nicholas_A._Fraser@omb.eop.gov* and to Judith B. Herman, Federal Communications Commission, via the Internet at J*udith-b.herman@fcc.gov.* To submit your PRA comments by email send them to: *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.

Title: Section 74.405, Registration of Stationary TV Pickup Receive Sites.

Form Number: N/A.

Type of Review: New collection.

Respondents: Business or other for-profit entities, not-for-profit entities, and state, local or tribal government.

Number of Respondents: 75 respondents; 314 responses.

Estimated Time per Response: 3 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection

is contained in 47 U.S.C. Sections 303 and 308 of the Communications Act of 1934, as amended.

Total Annual Burden: 942 hours.

Total Annual Cost: $156,750.

Privacy Impact Assessment: No impact.

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: The Commission seeks Office of Management and Budget approval for this new information collection for a full three-year clearance.

Section 74.605 requires that licensees of TV pickup stations in the 6875–7125 MHz and 12700–13200 MHz bands shall register their stationary receive sites using the Commission's Universal Licensing System. TV Pickup licensees record their receive-only sites in the Universal Licensing System (ULS) database, including all fixed service locations. The TV Pickup stations, licensed under Part 74 of the Commission's rules, make it possible for television and radio stations and networks to transmit program material from the sites of breaking news stories or other live events to television studios for inclusion in broadcast programs, to transmit programming material from studios to broadcasting transmitters for delivery to consumers' televisions and radios, and to transmit programs between broadcast stations. Registering the receive sites will allow analysis to determine whether Fixed Service links will cause interference to TV Pickup stations.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2011–30423 Filed 11–25–11; 8:45 a.m.]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Federal Advisory Committee Act; Communications Security, Reliability, and Interoperability Council

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC) third Communications Security, Reliability, and Interoperability Council (CSRIC III) will hold a meeting on December 16, 2011, from 9 a.m. to 1 p.m. in the Commission Meeting Room of the Federal Communications Commission, Room TW–C305, 445 12th Street SW., Washington, DC 20554.

DATES: December 16, 2011.

ADDRESSES: Federal Communications Commission, Room TW–C305 (Commission Meeting Room), 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jeffery Goldthorp, CSRIC Designated Federal Officer, (202) 418–1096 (voice) or *jeffery.goldthorp@fcc.gov* (email); or Lauren Kravetz, CSRIC Deputy Designated Federal Officer, (202) 418–7944 (voice) or *lauren.kravetz@fcc.gov* (email).

SUPPLEMENTARY INFORMATION: The CSRIC is a Federal Advisory Committee that will provide recommendations to the FCC regarding best practices and actions the FCC can take to ensure the security, reliability, and interoperability of communications systems. On March 19, 2011, the FCC, pursuant to the Federal Advisory Committee Act, renewed the charter for the CSRIC for a period of two years through March 18, 2013.

Working Group 1 on Next Generation 9–1–1, will present a final report for vote at this meeting. Each of the remaining Working Groups from CSRIC III will present an update. Topics will include alerting systems, 9–1–1 location accuracy, and network security. The FCC will attempt to accommodate as many attendees as possible; however, admittance will be limited to seating availability. The Commission will provide audio and/or video coverage of the meeting over the Internet from the FCC's Web page at *http://www.fcc.gov/live*. The public may submit written comments before the meeting to Jeffery Goldthorp, the FCC's Designated Federal Officer for the CSRIC by email to *jeffery.goldthorp@fcc.gov* or U.S. Postal Service Mail to Jeffery Goldthorp, Associate Bureau Chief, Public Safety and Homeland Security Bureau, Federal Communications Commission, 445 12th Street SW., Room 7–A325, Washington, DC 20554. Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (tty). Such requests should include a detailed description of the accommodation needed. In addition, please include a way the FCC can contact you if it needs more information. Please allow at least five days' advance notice; last-minute requests will be accepted, but may be impossible to fill. Additional information regarding the CSRIC can be found at: *http://www.fcc.gov/pshs/advisory/csric/*.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2011–30602 Filed 11–25–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting Notice

AGENCY: Federal Election Commission.

DATE AND TIME: Thursday, December 1, 2011 at 10 a.m.

PLACE: 999 E Street NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

Items To Be Discussed

Correction and Approval of the Minutes for the Meeting of November 17, 2011.

Agency Procedure for Notice to Named Respondents in Enforcement Matters of Additional Material Facts and/or Additional Potential Violations.

Draft Advisory Opinion 2011–21: Constitutional Conservatives Fund PAC.

Draft Advisory Opinion 2011–23: American Crossroads.

Management and Administrative Matters.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the hearing date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shawn Woodhead Werth,

Secretary of the Commission.

[FR Doc. 2011–30725 Filed 11–23–11; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Savings and Loan Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and the Board's Regulation LL (12 CFR part 238) to acquire shares of a savings and loan holding company. The factors that are considered in acting on the notices are

set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 12, 2011.

A. Federal Reserve Bank of Cleveland (Nadine Wallman, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. *Timothy T. O'Dell IRA, Thad R. Perry, Susanne G. Perry, Marie-Luise Marx, and Richard M. Mershad, Trustee, for the Richard M. Mershad Revocable Trust, all of New Albany, Ohio; Robert E. Hoeweler IRA, Paula Hoeweler IRA, and Robert E. and Paula L. Hoeweler, all of Cincinnati, Ohio; Donal H. Malenick and Michael W. Lenhart, both of Naples, Florida; James H. Frauenberg, II, George K. Richards, Trustee of the George K. Richards Trust, Deborah Phillips Bower, MOCORP, LLC, Moberger LTD, and Ohio Indemnity Company of Columbus, all of Columbus, Ohio; Eric G. Leininger, Upper Arlington, Ohio; Robert C. Moberger, Dublin, Ohio; Dynalab, LLC, Reynoldsburg, Ohio; and Pozzolana Consulting, LLC, Gainesville, Florida;* to acquire voting shares of Central Federal Corporation, and thereby indirectly acquire voting share of CF Bank, both in Fairlawn, Ohio.

Board of Governors of the Federal Reserve System, November 22, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–30483 Filed 11–25–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 11–30105) published on page 72206 of the issue for Tuesday, November 22, 2011.

Under the Federal Reserve Bank of San Francisco heading, the entry for American Start-Up Financial Institutions Investments, I, L.P., and CKH Capital, Inc., both in Monterey Park, California, is revised to read as follows:

A. *Federal Reserve Bank of San Francisco* (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *America Start-Up Financial Institutions Investments, I, L.P., and CKH Capital, Inc.,* both in Monterey Park, California; to become bank holding companies by acquiring up to 62 percent of the voting shares of New Omni Bank, National Association, Alhambra, California.

In connection with this application, Applicants also have applied to retain 5.9 percent interest of the voting shares of First PacTrust Bancorp, Inc., and thereby indirectly retain Pacific Trust Bank, both in Chula Vista, California, and engage in operating as savings and loan association, pursuant to section 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, November 22, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–30482 Filed 11–25–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 101 0115]

Pool Corporation; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before December 22, 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 ''PoolCorp, File No. 101 0115'' on your comment, and file your comment online at *https://ftcpublic.commentworks.com/ftc/poolcorpconsent,* 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 D), 600 Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Linda Holleran (202) 326–2267, FTC, Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for November 21, 2011), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.* A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 22, 2011. Write ''PoolCorp, File No. 101 0115'' 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 does not include any sensitive personal information, like 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 does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not 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, do not 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 4.9(c).[1] 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/poolcorpconsent* 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 ''PoolCorp, File No. 101 0115'' 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 D), 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 December 22, 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.*

[1] 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).

Analysis of Agreement Containing Consent Order To Aid Public Comment

The Federal Trade Commission has accepted for public comment an Agreement Containing Consent Order to Cease and Desist (''Agreement'') with Pool Corporation (''PoolCorp''). PoolCorp is the world's largest distributor of products used in the construction, renovation, repair, service, and maintenance of residential and commercial swimming pools. The Agreement resolves charges that PoolCorp used exclusionary acts and practices to maintain its monopoly power in the pool product distribution market in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45.

The administrative complaint that accompanies the Agreement (''Complaint'') alleges that PoolCorp used its monopoly power in local geographic markets to prevent manufacturers from supplying pool products to new entrants since at least 2003. As a result, PoolCorp foreclosed rival distributors from obtaining pool products—a necessary input to compete—and significantly raised its rivals' costs, thereby lowering output, increasing prices, and diminishing consumer choice.

The Commission anticipates that the competitive issues described in the Complaint will be resolved by accepting the proposed Order, subject to final approval, contained in the Agreement. The Agreement has been placed on the public record for 30 days for receipt of comments from interested members of the public. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Agreement and comments received, and will decide whether it should withdraw from the Agreement or make final the Order contained in the Agreement.

The purpose of this Analysis to Aid Public Comment is to invite and facilitate public comment concerning the proposed Order. It is not intended to constitute an official interpretation of the Agreement and proposed Order or in any way to modify their terms.

The Agreement is for settlement purposes only and does not constitute an admission by PoolCorp that the law has been violated as alleged in the Complaint or that the facts alleged in the Complaint, other than jurisdictional facts, are true.

I. The Complaint

The Complaint makes the following allegations.

A. Industry Background

This case involves wholesale distribution in the swimming pool industry. There are over nine million residential pools in the United States, and over 250,000 commercial pools operated by hotels, country clubs, apartment buildings, municipalities, and others. In 2010, the distribution of pool products was an estimated $3 billion industry in the United States. Manufacturers use distributors to sell the products used to build, repair, service, and maintain residential and commercial swimming pools (''pool products''). Pool products include, among others, pumps, filters, heaters, covers, cleaners, diving boards, steps, rails, pool liners, pool walls, and the parts necessary to maintain pool equipment. Distributors purchase pool products from manufacturers, warehouse them, and then resell the products to pool retail stores, pool service companies and pool builders (collectively, ''pool dealers'' or ''dealers''). Dealers, in turn, sell the pool products to the ultimate consumer: owners of residential and commercial swimming pools. The swimming pool industry is very fragmented and wholesale distributors make it more efficient for manufacturers and dealers to sell their products. Distributors purchase most, if not all, brands of pool products that are produced by manufacturers so that they can provide convenient one-stop shopping for their dealer customers. Distributors also extend credit and provide quick delivery of pool products to thousands of dealers. The vast majority of dealers are mom-and-pop operations that are too small to buy directly from manufacturers; for these dealers, distributors are their only source of pool products. Distributors also allow manufacturers to operate their factories year-round by purchasing large quantities of pool products throughout the year, even though the pool industry is seasonal.

In general, manufacturers are willing to sell their products to any credit-worthy distributor that has a physical warehouse and personnel with knowledge of the pool industry. Manufacturers typically prefer to have two or more distributors selling their products in a local geographic market in order to ensure that the distributors compete and give competitive service and prices to their dealer customers.

To compete effectively as a distributor, a firm must be able to buy pool products directly from manufacturers. There are no cost-effective alternatives. While there are

over 100 manufacturers of pool products, there are only three full-line manufacturers that produce almost all of the products used to operate or repair swimming pools: Pentair Water Pool & Spa; Zodiac Pool Systems, Inc.; and Hayward Pool Products. Collectively, these manufacturers represent more than 50 percent of all pool product sales. To be successful, a distributor must sell the products of at least one of these manufacturers. As recognized by PoolCorp, a positive relationship with these and other manufacturers is ''critical'' to the success of a distributor.

B. PoolCorp's Monopoly Power

The relevant market is no broader than the wholesale distribution of pool products in the United States and numerous local geographic markets. With the exception of large national retail chains that purchase pool products for their retail centers located throughout the United States, competition among distributors for sales to dealers occurs locally. PoolCorp has monopoly power in numerous local markets, as evidenced by a persistently high market share of 80 percent or more for the past five years. PoolCorp's conduct of foreclosing new distributor entrants from obtaining pool products directly from manufacturers represents a significant barrier to entry.

C. PoolCorp's Conduct

Beginning in 2003 and continuing to today, PoolCorp has implemented an exclusionary policy that effectively impeded entry by new distributors by preventing them from being able to purchase pool products directly from manufacturers. Specifically, when a new distributor attempted to enter a local geographic market, PoolCorp threatened manufacturers that it would not deal with them if they also supplied the new entrant. PoolCorp threatened to terminate the purchase and sale of the manufacturer's pool products for all 200+ PoolCorp distribution centers located throughout the United States. PoolCorp's policy did not exclude existing rivals from obtaining pool products from manufacturers.

PoolCorp's threat was significant. The loss of sales to PoolCorp could be ''catastrophic'' to the financial viability of even major manufacturers. No other distributor could replace the large volume of potential lost sales to PoolCorp, particularly in markets where PoolCorp is the only distributor. New entrants could not offer any economic incentive to manufacturers that would offset the risks imposed by PoolCorp's threats.

After receiving these threats, manufacturers, including the three ''must-have'' manufacturers, refused to sell pool products to the new distributors and canceled any pre-existing orders. PoolCorp thus effectively foreclosed new distributors from obtaining pool products from manufacturers that represented more than 70 percent of all pool product sales.

In some cases, the new distributors were able to purchase pool products from other distributors. This counterstrategy, however, did not mitigate the effects of PoolCorp's conduct. As a general rule, distributors do not sell pool products to other distributors. Even when possible, this alternative is not a viable long-term strategy because it substantially increases the entrant's costs and lessens its quality of service. For example, buying pool products from a distributor forces the new distributor entrant to pay transportation costs from the distributor's location rather than receiving free shipping under manufacturer programs. The purchases are also at a marked-up price and do not qualify for key manufacturer year-end rebates.

By effectively increasing its rivals' costs, PoolCorp's exclusionary policy prevented the new distributor entrants from being able to compete aggressively on price. Additionally, without full control of their inventory, the entrants' ability to provide quality service to their dealer customers was diminished. PoolCorp specifically targeted new entrants, rather than established rivals, because the new distributors represented a significant competitive threat due to their likelihood to compete aggressively on price in order to earn new business. PoolCorp's conduct, therefore, had the purpose and effect of maintaining and enhancing PoolCorp's monopoly power in numerous local markets where its dominance would otherwise be threatened by new entrants. PoolCorp's exclusionary policy, therefore, has likely resulted in higher prices and reduced output. There are no procompetitive efficiencies that justify PoolCorp's conduct.

II. Legal Analysis

The offense of monopolization under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market; and (2) the willful acquisition, enhancement or maintenance of that power through exclusionary conduct.[2] A monopolist's refusal to deal with a firm if that firm also deals with a rival has long been recognized as exclusionary conduct. Exclusionary practices violate Section 2 of the Sherman Act when the challenged conduct significantly impairs the ability of rivals to compete effectively with the respondent and thus to constrain its exercise of monopoly power.[3]

The factual allegations in the complaint regarding market structure support a finding of monopoly power and competitive harm. PoolCorp's ''all or nothing'' threats acted as a powerful deterrent to manufacturers against dealing with new distributor entrants by jeopardizing a large and irreplaceable percentage of the manufacturer's sales. PoolCorp's conduct effectively foreclosed new entrants from manufacturers representing more than 70 percent of pool product sales. New entrants were unable to provide any economic incentive to manufacturers that could offset the risk posed by PoolCorp's threats. Raising rivals' costs by restraining their supply of inputs can be a ''particularly effective method of anticompetitive exclusion.'' [4]

Additionally, the work-around strategy employed by some new entrants of purchasing pool products from other distributors significantly raised their costs and reduced their ability to provide quality service. PoolCorp's exclusionary policy therefore prevented these firms from providing a meaningful

[2] *Verizon Commun's.* v. *Law Offices of Curtis V. Trinko LLP.,* 540 U.S. 398, 407 (2004); *United States* v. *Grinnell Corp.,* 384 U.S. 563, 570–71 (1966).

[3] *E.g., Aspen Skiing Co.* v. *Aspen Highlands Skiing Corp.,* 472 U.S. 585, 605 & n. 32 (1985) (exclusionary conduct ''tends to impair the opportunities of rivals'' but ''either does not further competition on the merits or does so in an unnecessarily restrictive way'') (citations omitted); see also *Lorain Journal Co.* v. *United States,* 342 U.S. 143, 151–54 (1951) (condemning newspaper's refusal to deal with customers that also advertised on rival radio station because it harmed the radio station's ability to compete); *United States* v. *Microsoft,* 253 F.3d 34, 68–71 (D.C. Cir. 2001) (condemning exclusive agreements that prevented rivals from ''pos[ing] a real threat to Microsoft's monopoly''); *United States* v. *Dentsply,* 399 F.3d 181, 191 (3d Cir. 2005) (condemning policy that kept competitors below ''the critical level necessary for any rival to pose a real threat to Dentsply's market share'').

[4] See Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price,* 96 Yale L.J. 209, 224 (1986) (explaining that this method of exclusion allows a dominant firm to use its vertical relationships to create additional horizontal market power); *see also Dentsply,* 399 F.3d at 195 (holding ''all or nothing'' ultimatum exclusionary when it ''created a strong economic incentive for dealers to reject competing lines in favor of Dentsply's teeth.''); *In re Transitions Optical, Inc.,* 75 FR 10799 (Mar. 2010) (proposed complaint and analysis to aid public comment).

constraint on PoolCorp's monopoly prices.

Notably, PoolCorp's conduct targeted new entry and did not exclude existing rivals. The test for exclusionary conduct, however, is not total foreclosure, but ''whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit.'' [5] New entrants may have a more disruptive impact on the market than established firms because they may have an increased incentive to compete aggressively on price in order to win business. Conduct that artificially raises entry barriers by increasing the scale, cost or time of entry harms consumers by providing a greater opportunity for monopoly pricing.[6]

A monopolist may rebut a *prima facie* showing of competitive harm by showing that the challenged conduct is reasonably necessary to achieve a procompetitive benefit. Any efficiency benefit, if proven, must be balanced against the harm caused by the challenged conduct.

There are no procompetitive efficiencies that justify PoolCorp's conduct. In some cases, for example, exclusive arrangements with suppliers could be necessary to prevent free-riding or to secure adequate supply. Here, however, PoolCorp did not offer any services upon which a new entrant could free-ride. Further, the pool industry is not subject to product shortfalls that could justify exclusive arrangements with suppliers. In short, PoolCorp's practice of foreclosing new entrants from supply did not help PoolCorp compete on the merits by improving its efficiency, quality or prices.

III. The Order

The proposed Consent Order remedies PoolCorp's anticompetitive conduct. Paragraph II of the Order addresses the core of PoolCorp's conduct. Specifically, Paragraph II of the proposed Consent Order prohibits PoolCorp from:

- Conditioning the sale or purchase of pool products, or membership in PoolCorp's preferred vendor programs, on the intended or actual sale of pool products by a manufacturer to any distributor other than PoolCorp;
- Pressuring, urging or otherwise coercing manufacturers to refrain from selling, or to limit their sales, to any distributors other than PoolCorp; and
- Discriminating or retaliating against a manufacturer for selling, or intending to sell, pool products to any distributor other than PoolCorp.

The definition of ''distributor'' includes any entity that buys pool products directly from manufacturers and resells those products to dealers or others. The Order explicitly allows PoolCorp to enter into exclusive agreements with manufacturers to purchase private-label pool products.

Paragraph III of the Proposed Order requires PoolCorp to implement an antitrust compliance program. Paragraph IV–VI impose reporting and other compliance requirements. The Order will expire in 20 years.

By direction of the Commission, Commissioner Rosch dissenting.

Donald S. Clark,

Secretary.

Statement of Commissioners Julie Brill, Jon Leibowitz and Edith Ramirez Regarding the Complaint and Proposed Consent Order in *In Re Pool Corporation*

November 21, 2011

The Commission is today issuing for public comment a Complaint and Order that would resolve allegations that Pool Corporation (''PoolCorp'') used anticompetitive acts and practices to exclude rivals from, and to maintain its monopoly power in, several local pool product distribution markets, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45.

On the basis of staff's investigation and as outlined in the Complaint, we have reason to believe that a violation of the antitrust laws has occurred—and that Commission action is in the public interest. 15 U.S.C. 45(b). Specifically, the Complaint alleges that PoolCorp, which possesses monopoly power in many local distribution markets, threatened its suppliers (*i.e.,* pool product manufacturers) that it would no longer distribute a manufacturer's products on a nationwide basis if that manufacturer sold its products to a new distributor that was attempting to enter a local market. Although these manufacturers preferred to have a broad and diverse distribution network, they declined to add distributors because they feared retribution from PoolCorp. These decisions were not made for independent business reasons.[7]

As alleged in the Complaint, PoolCorp's actions foreclosed new entrants from obtaining pool products from manufacturers representing more than 70 percent of sales. Significantly, there is no efficiency justification for PoolCorp's conduct. That is, without any legitimate justification, PoolCorp dictated whether new competitors could access the full range of merchandise needed to compete effectively in the market. *Cf. Toys ''R'' Us, Inc.* v. *FTC,* 221 F.3d 928, 930 (7th Cir. 2000) (actions by dominant toy retailer to prevent would-be entrants from obtaining access to toys judged to be anticompetitive). Some of PoolCorp's targets were able to survive by purchasing pool products from other distributors rather than directly from the manufacturers. However, we assess consumer harm relative to market conditions that would have existed but for the respondent's allegedly unlawful conduct. Here, PoolCorp's strategy significantly increased a new entrant's costs of obtaining pool products. Conduct by a monopolist that raises rivals' costs can harm competition by creating an artificial price floor or deterring investments in quality, service and innovation.[8] The higher cost structure PoolCorp imposed on new entrants prevented them from providing a competitive constraint to PoolCorp's alleged monopoly prices. And without full control of their inventory, the new distributors' ability to provide high quality service to their dealer customers was diminished. The harm to consumers that occurred as a result was substantial. In the end, consumers had fewer choices and were forced to pay higher prices for pool products.

Although we recognize that PoolCorp's alleged conduct did not target incumbent distributors, we nevertheless have reason to believe that the conduct harmed competition and consumers. Separate from PoolCorp,

[5] *LePage's, Inc.* v. *3M,* 324 F.3d 141, 159 (3d Cir. 2003); *see also Dentsply,* 399 F.3d at 190 (explaining that ''it is not necessary that all competition be removed from the market'').

[6] Herbert Hovenkamp, Antitrust Law ¶ 1802c, at 64 (2d ed. 2002) (''Consumer injury results from the delay that the dominant firm imposes on the smaller rival's growth''); *see also Microsoft,* 253 F.3d at 79 (''it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will''); *LePage's,* 324 F.3d at 159 (''When a monopolist's actions are designed to prevent one or more new or potential competitors from gaining a foothold in the market by exclusionary, *i.e.,* predatory, conduct, its success in that goal is not only injurious to the potential competitor but also to competition in general.'').

[7] We disagree with Commissioner Rosch's conclusion that manufacturers refused to deal with new entrants for independent business reasons. In our view, the evidence demonstrates a causal relationship between the manufacturers' decisions and PoolCorp's alleged conduct.

[8] *See, e.g.,* Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price,* 96 Yale L.J. 209, 224 (1986) (finding that a dominant firm's strategy of restraining rivals' access to supply can be a ''particularly effective method of anticompetitive exclusion'' because it allows the dominant firm to use its vertical relationships to create additional horizontal market power).

there are few, if any, incumbent distributors in the local markets at issue here. By targeting new distributor entrants, PoolCorp's conduct harmed the very companies that were most likely to compete aggressively on price and to introduce innovative services or ways of doing business.[9] The Commission has seen this pattern before. The targets of anticompetitive exclusion are often the new rivals that incumbents foresee as most likely to shake up the market and benefit consumers at the expense of incumbents.[10] We fail to do our job if we permit a monopolist to decide, without sufficient efficiency justification, whether or on what terms a rival will be permitted to enter the market.

Because we have reason to believe that PoolCorp's conduct had the purpose and effect of maintaining PoolCorp's monopoly power in numerous local markets where its dominance was threatened by new distributor entrants, we support the attached Complaint and Order.

Dissenting Statement of J. Thomas Rosch In the Matter of Pool Corporation, FTC File No. 101–0115

November 21, 2011

This case presents the novel situation of a company willing to enter into a consent decree notwithstanding a lack of evidence indicating that a violation has occurred. The FTC Act requires that the Commission find a ''reason to believe'' that a violation has occurred and determine that Commission action would be in the public interest any time it issues a complaint. 15 U.S.C. 45(b). In my view, the same standard applies regardless of whether the Commission is seeking a litigated decree or a consent decree for the charged violation. Accordingly, I would reject the proposed consent decree and close the investigation.

After a year and a half of investigation, we have not been able to identify any harm to consumers or competition as a result of actions by Pool Corporation, Inc. (''PoolCorp''), and further investigation appears unlikely to uncover such effects. As an initial matter, it is important to note that, even accepting the allegations in the complaint, PoolCorp did not engage in a general pattern of exclusionary conduct. Rather, the complaint alleges that PoolCorp threatened manufacturers not to supply an entering distributor in various local markets. There is no allegation that PoolCorp sought to restrict supply to (1) incumbents in any of these local markets, (2) established distributors seeking to expand into markets dominated by PoolCorp, or (3) established distributors in any of the dozens of other local markets across the country.

The limited scope of PoolCorp's alleged exclusionary conduct is, of course, no defense. PoolCorp's alleged threats to manufacturers, had they been successful, may well have violated the antitrust laws. But that is not what happened. The investigation revealed that PoolCorp's demands were not honored by manufacturers. Instead, the evidence showed that manufacturers made unilateral decisions not to supply the de novo entrants in the various local markets.

There were legitimate reasons for pool equipment manufacturers not to sell to these entrants. A manufacturer will typically accept a new distributor only if the distributor will add to the value of the distribution network by, for example, improving growth opportunities or increasing promotional activities. Manufacturers often require a de novo entrant to have adequate facilities, a history of successful operations, and a favorable credit history before supporting it. In this case, many of the allegedly excluded de novo entrants did not satisfy these requirements. The lack of evidence establishing causation between PoolCorp's requests and action by the manufacturers, combined with plausible justifications for the manufacturers' actions, should be fatal to this case.

Another problem with this case is that no entrants were actually excluded.[11] That is because the entrants were able to obtain supplies from other manufacturers or distributors. The only claim to the contrary is in Paragraph 28 of the complaint, which alleges that in Baton Rouge, ''the new entrant's business ultimately failed in 2005'' because of the lack of ''direct access to the manufacturers' pool products.'' The complaint neglects to mention that this entrant was able to secure supplies from other sources and later sold itself to an established out-of-state distributor. Since then, that distributor, which has had full access to supplies, has been a highly effective rival to PoolCorp. Thus, to the extent PoolCorp's threats had an effect in Baton Rouge, they may have led to *more,* not less, competition.

A third problem with this case is that there was no consumer injury. The investigation did not uncover price increases, service degradation, or other anticompetitive effects in any local markets.[12] Economic analysis corroborated these results and suggested that even if PoolCorp had completely foreclosed its rivals, the pricing effects would have been minimal. The lack of consumer harm should not be surprising given that PoolCorp's actions, at most, raised the costs of a single competitor in each local market, without affecting other incumbents or the entry prospects of established, out-of-market dealers.

The lack of consumer injury is also corroborated by the very low entry barriers in this industry. Opening a pool supply distributorship requires access to one or more of the major equipment suppliers, a few trucks, a medium-sized warehouse, access to credit, and no more than ten employees. There are hundreds of profitable pool supply distributors, and entry and expansion are frequent events. Thus, any effort to exclude a competitor would become a game of whack-a-mole: As soon as one competitor is driven from the market, another would pop up.

Accordingly, I cannot find that there is a ''reason to believe'' that a violation occurred or that accepting the proposed consent decree would be in the public

[9] *See id.* at 246 (explaining that potential competition by new entrants can provide a ''significant competitive check'' distinct from established firms).

[10] *See, e.g., Allied Tube & Conduit Corp.* v. *Indian Head,* Inc., 486 U.S. 492, 499–500 (1988) (condemning association action to prevent inclusion of plastic conduits in relevant standard); *Realcomp II, LTD.* v. *FTC,* 635 F.3d 815 (6th Cir. 2011) (condemning Multiple Listing Service rules that disadvantaged new brokerage model), cert. denied, 2011 U.S. Lexis 7292 (Oct. 11, 2011); *Toys ''R'' Us, Inc.* v. *FTC,* 221 F.3d 928 (7th Cir. 2000) (condemning dominant toy company's actions that limited sources of toys available to new warehouse clubs).

[11] The majority statement purports to be based on the Complaint. However, the majority statement ignores the central theory of the Complaint—exclusion of rivals through foreclosure of supply (Complaint ¶¶ 18–28)—and does not assert that any rivals were actually excluded. Instead, the majority statement focuses on an alternative theory of competitive harm—raising rivals' costs—on which the Complaint offers scant details. (Complaint ¶¶ 29–31.) As support for this theory, the majority statement relies on an article by Krattenmaker and Salop. *See* Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price,* 96 Yale L.J. 209, 224 (1986). As these authors note, however, a raising rivals' costs strategy is unlikely to be successful in a market with low entry barriers. Id. at 225 (entry must ''be difficult''), 236 n.85 (''Obviously, some barriers to entry and expansion must exist for price to rise.''). Here, neither the complaint nor the majority statement alleges that there are any significant barriers to entry in this industry.

[12] The basis for the majority statement's claim that there was ''substantial'' consumer harm resulting from the alleged conduct of Respondent is a mystery. The complaint contains no factual allegations of any harm to consumers, much less ''substantial'' harm. Likewise, there are no factual allegations in the complaint corroborating the majority's claim that consumers ''had fewer choices and were forced to pay higher prices for pool products.''

interest. 15 U.S.C. 45(b). Furthermore, I question whether this investigation represented a wise use of Commission resources, particularly given the austere climate in which we are operating. Even accepting all of the allegations in the complaint as true, the likely consumer injury would have amounted to just a few thousand dollars.

[FR Doc. 2011–30435 Filed 11–25–11; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from Vitro Manufacturing in Canonsburg, Pennsylvania, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On October 18, 2011, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All Atomic Weapons Employees who worked at Vitro Manufacturing in Canonsburg, Pennsylvania, from January 1, 1960 through September 30, 1965, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation became effective on November 17, 2011, as provided for under 42 U.S.C. 7384l(14)(C). Hence, beginning on November 17, 2011, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone (877) 222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2011–30586 Filed 11–25–11; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from W.R. Grace and Company in Curtis Bay, Maryland, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On October 18, 2011, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All Atomic Weapons Employees who worked at any building or area at the facility owned by W.R. Grace and Company in Curtis Bay, Maryland, for the operational period from May 1, 1956 through January 31, 1958, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation became effective on November 17, 2011, as provided for under 42 U.S.C. 7384l(14)(C). Hence, beginning on November 17, 2011, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone (877) 222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2011–30593 Filed 11–25–11; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from the Y–12 facility in Oak Ridge, Tennessee, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On October 18, 2011, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Y–12 facility in Oak Ridge, Tennessee, during the period from January 1, 1948 through December 31, 1957, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation became effective on November 17, 2011, as provided for under 42 U.S.C. 7384l(14)(C). Hence, beginning on November 17, 2011, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone (877) 222–7570. Information requests can also be submitted by email to DCAS@CDC.GOV.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2011–30589 Filed 11–25–11; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from the Ames Laboratory at Iowa State University, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On October 18, 2011, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All Department of Energy (DOE) employees, its predecessor agencies, and its contractors and subcontractors who worked in any area of the Ames Laboratory at Iowa State University during the period from August 13, 1942 through December 31, 1970, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more classes of employees included in the Special Exposure Cohort.

This designation became effective on November 17, 2011, as provided for under 42 U.S.C. 7384l(14)(C). Hence, beginning on November 17, 2011, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone (877) 222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2011–30587 Filed 11–25–11; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From Titanium Alloys Manufacturing in Niagara Falls, NY, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from Titanium Alloys Manufacturing in Niagara Falls, New York, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Titanium Alloys Manufacturing.

Location: Niagara Falls, New York.

Job Titles and/or Job Duties: All employees who worked in any area or building.

Period of Employment: January 1, 1950 through December 31, 1956.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone (877) 222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2011–30577 Filed 11–25–11; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Medical Office Survey on Patient Safety Culture Comparative Database.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by January 27, 2012.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Medical Office Survey on Patient Safety Culture Comparative Database.

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Medical Office Survey on Patient Safety Culture (Medical Office SOPS) Comparative Database. The Medical Office SOPS Comparative Database consists of data from the AHRQ Medical Office Survey on Patient Safety Culture. Medical offices in the U.S. are asked to voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Medical Office SOPS Database is modeled after the Hospital SOPS Database [OMB NO. 0935–0162; approved 05/04/2010] that was originally developed by AHRQ in 2006 in response to requests from hospitals interested in knowing how their patient safety culture survey results compare to those of other hospitals.

In 1999, the Institute of Medicine called for health care organizations to develop a ''culture of safety'' such that their workforce and processes focus on improving the reliability and safety of care for patients (IOM, 1999; To Err is Human: Building a Safer Health System). To respond to the need for tools to assess patient safety culture in outpatient ambulatory health care, AHRQ developed and pilot tested the Medical Office Survey on Patient Safety Culture with OMB approval (OMB NO.0935–0131; Approved July 5, 2007).

The survey is designed to enable medical offices to assess provider and staff opinions about patient safety issues, medical error, and error reporting and includes 52 items that measure 12 dimensions of patient safety culture. AHRQ released the survey to the public along with a Survey User's Guide and other toolkit materials in December 2008 on the AHRQ Web site (located at *http://www.ahrq.gov/qual/patientsafetyculture/mosurvindex.htm*). Since its release, the survey has been voluntarily used by hundreds of medical offices in the U.S.

The Medical Office SOPS and the Comparative Database are supported by AHRQ to meet its goals of promoting improvements in the quality and safety of health care in medical office settings. The survey, toolkit materials, and preliminary comparative database results are all made available to the public along with technical assistance provided by AHRQ through its contractor at no charge to medical offices, to facilitate the use of these materials for medical office patient safety and quality improvement.

The goal of this project is to create the Medical Office SOPS Comparative Database. This database will (1) Allow medical offices to compare their patient safety culture survey results with those of other medical offices; (2) provide data to medical offices to facilitate internal assessment and learning in the patient safety improvement process; and (3) provide supplemental information to help medical offices identify their strengths and areas with potential for improvement in patient safety culture. De-identified data files will also be available to researchers conducting patient safety data analysis. The database will include 52 items that measure 12 areas, or composites, of patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to: The quality, effectiveness, efficiency, appropriateness and value of healthcare services; quality measurement and improvement; and database development. 42 U.S.C. 299a(a)(1), (2), and (a)(8).

Method of Collection

To achieve the goal of this project the following activities and data collections will be implemented:

(1) Eligibility Form—The purpose of this form is to determine the eligibility status and initiate the registration process for medical offices seeking to voluntarily submit their MO SOPS data to the MO SOPS Comparative Database. The medical office point of contact (POC) will complete the form. The POC is either an office manager, nurse manager, or a survey vendor who contracts with a medical office to collect their data. The POC may submit data on behalf of multiple medical offices because many medical offices are part of a larger practice with multiple sites or part of a larger health system that includes many medical office sites.

(2) Data Use Agreement—The purpose of this form is to obtain authorization from medical offices to use their voluntarily submitted MO SOPS data for analysis and reporting according to the terms specified in the Data Use Agreement (DUA). The medical office POC will complete the form.

(3) Medical Office Information Form—The purpose of this form is to obtain basic information about the characteristics of the medical offices submitting their MO SOPS data to the MO SOPS Comparative Database (e.g., number of providers and staff, ownership, and type of specialty). The medical office POC will complete the form.

(4) Data Submission—After the medical office POC has completed the Medical Office Eligibility Form, the Data Use Agreement and the Medical Office Information Form, they will submit their data from the MO SOPS to the MO SOPS Comparative Database.

Data from the AHRQ Medical Office Survey on Patient Safety Culture are used to produce three types of products: 1) A Medical Office SOPS Comparative Database Report that is produced periodically and made available to the public on the AHRQ Web site (see *http://www.ahrq.gov/qual/mosurvey10/moresults10.htm*); 2) Medical Office Survey Feedback Reports that are confidential, customized reports produced for each medical office that submits data to the database; and 3) Research data sets of staff-level and medical office-level de-identified data that enable researchers to conduct additional analyses.

Medical offices are asked to voluntarily submit their Medical Office SOPS data to the comparative database. The data are then edited to detect and correct errors and aggregated and used to produce a Comparative Database Report that displays averages, standard deviations, and percentile scores on the survey's 52 items and 12 patient safety culture dimensions, as well as displaying these results by medical office characteristics (size of office, specialty, geographic region, etc.) and staff characteristics (staff position).

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the medical office to participate in the Medical Office SOPS Comparative Database. The POC completes a number of data submission steps and forms, beginning with completion of the online Medical Office SOPS Database Eligibility Form and Data Use Agreement, which will be completed for 150 medical offices annually. The Medical Office Information Form will be completed for each medical office; since each POC represents an average of 10 medical offices, a total of 1,500 Information Forms will be completed annually, each requiring about 5 minutes to complete. The POC will submit data for all of the medical offices they represent which will take about 4 and ½ hours, including the amount of time POCs typically spend deciding whether to participate in the database, preparing their materials and data set for submission to the database, and performing the submission. The total annual burden hours are estimated to be 816.

Medical offices administer the AHRQ Medical Office Survey on Patient Safety Culture on a periodic basis. Hospitals submitting to the Hospital SOPS Comparative Database administer the survey every 16 months on average. Similarly, the number of medical office submissions to the database is likely to vary each year because medical offices do not administer the survey and submit data every year. The 150 respondents/POCs shown in Exhibit 1 are based on an estimate.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility Form	150	1	3/60	8

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Data Use Agreement	150	1	3/60	8
Medical Office Information Form	150	10	5/60	125
Data Submission	150	1	4.5	675
Total	600	NA	NA	816

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $34,779 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents/POCs	Total burden hours	Average hourly wage rate *	Total cost burden
Eligibility Form	150	8	$42.62	$341
Data Use Agreement	150	8	42.62	341
Medical Office Information Form	150	125	42.62	5,328
Data Submission	150	675	42.62	28,769
Total	600	816	NA	34,779

* Mean hourly wage rate of $42.62 for Medical and Health Services Managers (SOC code 19111) was obtained from the May 2009 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100—Offices of Physicians located at *http://www.bls.gov/oes/2009/may/naics4_621100.htm*.

Estimated Annual Cost to the Government

The estimated annualized cost to the government for developing, maintaining, and managing the database and analyzing the data and producing reports is shown below. The cost is estimated to be $310,000 annually for 3 years. The total cost is estimated to be $930,000.

EXHIBIT 3—ESTIMATED ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$59,715	$19,905
Data Collection Activities	82,107	27,369
Data Processing and Analysis	111,963	37,321
Publication of Results	111,966	37,322
Project Management	7,464	2,488
Overhead	556,785	185,595
Total	930,000	310,000

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 7, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011–30269 Filed 11–25–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project:

''Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician and Group Survey Comparative Database.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by January 27, 2012.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov*.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician and Group Survey Comparative Database

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Consumer Assessment of Healthcare Providers and Systems (CAHPS) Database for Clinicians and Groups. The CAHPS Clinician and Group Database (CAHPS CG Database) consists of data from the AHRQ CAHPS Clinician and Group Survey (CAHPS CG Survey). Health systems administrators, medical groups and medical practitioners in the U.S. are asked to voluntarily submit data from the CAHPS CG Survey to AHRQ through its contractor.

Dating back to the first phase of the CAHPS program (1996–2000), the CAHPS Consortium recognized the need for a standardized, evidence-based instrument that would gather data on patients' experiences with physicians and staff in outpatient medical practices, enabling clinicians and administrators to assess and improve patients' experiences with medical care. In 1999, the Consortium began work on a survey that would assess patients' experiences with medical groups and clinicians. Working in collaboration with the Pacific Business Group on Health, whose Consumer Assessment Survey established a precedent for this type of instrument; the CAHPS Consortium developed a preliminary instrument known as the CAHPS Group Practices Survey (G–CAHPS).

In August 2004, AHRQ issued a notice in the **Federal Register** inviting organizations to test this instrument. These field test organizations were crucial partners in the evolution and development of the instrument, and provided critical data illuminating key aspects of survey design and administration. In July 2007 the CAHPS CG Survey was endorsed by the National Quality Forum (NQF), an organization established to standardize health care quality measurement and reporting. The endorsement represents the consensus of many health care providers, consumer groups, professional associations, purchasers, federal agencies, and research and quality organizations. The CAHPS CG Survey and related toolkit materials are available on the CAHPS Web site at *http://www.cahps.ahrq.gov/cahpskit/CG/CGChooseQX.asp*. Since its release, the survey has been used by thousands of physicians and medical practices across the U.S.

The current CAHPS Consortium includes AHRQ, the Centers for Medicare & Medicaid Services (CMS), RAND, Yale School of Public Health, and Westat.

AHRQ has developed the database for CAHPS CG Survey data following the CAHPS Health Plan Database as a model. The CAHPS Health Plan Database was developed in 1998 in response to requests from health plans, purchasers, and CMS for comparative data to support public reporting of health plan ratings, health plan accreditation and quality improvement (OMB Control Number 0935–0165, Expiration Date 7/31/2013). Demand for comparative results from the CG Survey has grown as well, and therefore AHRQ has developed a dedicated CG Database to support benchmarking, quality improvement, and research.

The CAHPS CG Database contains data from AHRQ's standardized CAHPS CG Survey, which provides comparative measures of quality to health care purchasers, consumers, regulators, and policy makers. The Database also provides data for AHRQ's annual National Healthcare Quality and National Healthcare Disparities Reports.

Health systems, medical groups and practices that administer the CAHPS CG Survey according to CAHPS specifications can participate in this project. A health system is a complex of facilities, organizations, and providers of health care in a specified geographic area. A medical group is defined as a medical group, Accountable Care Organization (ACO), state organization or some other grouping of practices. A practice is an outpatient facility in a specific location whose physicians and other providers share administrative and clinical support staff Each practice located in a building containing multiple medical offices is considered a separate practice.

The goal of this project is to continue to update the CAHPS CG Database, with the latest results of the CAHPS CG Survey. These results consist of 37 items that measure 5 areas or composites of patients' experiences with physicians and staff in outpatient medical practices. This database will 1) allow participating organizations to compare their survey results with those of other outpatient medical groups; 2) facilitate internal assessment and learning in the quality improvement process; and 3) provide information to help identify strengths and areas with potential for improvement in patient care. The five composite measures are:

Getting Timely Appointments, Care, and Information;
How Well Doctors Communicate With Patients;
Helpful, Courteous, and Respectful Office Staff;
Follow-up on Test Results;
Patients' Rating of the Doctor.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to: The quality, effectiveness, efficiency, appropriateness and value of healthcare services; quality measurement and improvement; and health surveys and database development. 42 U.S.C. 299a(a)(1), (2), and (8).

Method of Collection

To achieve the goal of this project, the following activities and data collections will be implemented:

(1) Registration Form—The purpose of this form is to determine the eligibility status and initiate the registration process for participating organizations seeking to voluntarily submit their CAHPS CG Survey data to the CAHPS CG Comparative Database. The point of contact (POC) at the participating organization (or parent organization) will complete the form. The POC is either a corporate-level health care manager or a survey vendor who contracts with a participating organization to collect the CAHPS CG Survey data.

(2) Data Use Agreement—The purpose of this form is to obtain authorization from participating organizations to use

their voluntarily submitted CAHPS CG Survey data for analysis and reporting according to the terms specified in the Data Use Agreement (DUA). The POC will complete the form.

(3) Data Submission—After the POC has completed the Registration Form and the Data Use Agreement, they will submit their patient-level data from the CAHPS CG Survey to the CAHPS CG Comparative Database. Data on the organizational characteristics such as ownership, number of patient visits per year and medical specialty, and information related to survey administration such as mode and dates of survey administration, sample size, and response rate, which are collected as part of CAHPS CG Survey operations, are also submitted. Each submission will consist of 3 data files: (1) A Group File that contains information about the group ownership and size of group, (2) a Practice File containing type of practice, the practice ownership and affiliation (*i.e.,* commercial, hospital or integrated delivery system, insurance company, university or medical school, community health center, VA or military) and number of patient visits per year, and (3) a Sample File that contains one record for each patient surveyed, the date of visit, survey disposition code and information about survey completion.

Survey data from the CAHPS CG Database is used to produce three types of products: (1) An online reporting of results available to the public on the CAHPS User Network web site; (2) comparative reports that are confidential and customized for each participating organization (*e.g.,* health system, medical group or practice) that submits data; and (3) a database available to researchers for additional analyses.

Information for the CAHPS CG Database is collected by AHRQ through its contractor Westat. Participating organizations are asked to voluntarily submit their data to the CARPS Database. The data is cleaned with standardized programs, then aggregated and used to produce comparative results. In addition, reports are produced that compare the participating organizations' results to the database in a password-protected section of the CAHPS Database online reporting system. Trend data will be available to participants when enough data is collected across consecutive years.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for participating organizations. The burden hours and costs below are based on an estimated number of participants. It is estimated that about 30 health systems, medical groups and practices will participate in the CAHPS CG Database. The number of data submissions per participating organization will vary because some participants may submit data for multiple practices, while others may only submit data for one.

The total burden for completing the registration, DUA and data submission process is estimated to be 246 hours. The 30 participating organizations that complete the registration form and submit information to the CAHPS CG Database are a combination of an estimated 20 health systems, medical groups and practices and 10 estimated vendors. Information about survey administration and the survey data files are submitted together for each participating organization.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Registration Form	30	1	6/60	3
Data Submission	30	1	7 and 6/60	213
Data Use Agreement	30	1	1	30
Total	30	NA	8 and 12/60	246

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to complete the submission process. The cost burden is estimated to be $10,485 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Registration Form	30	3	42.62	128
Data Submission	30	213	42.62	9,078
Data Use Agreement	30	30	42.62	1,279
Total	30	246	NA	10,485

* Mean hourly wage rate of $42.62 for Medical and Health Services Managers (SOC code 19111) was obtained from the May 2009 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100—Offices of Physicians located at *http://www.bls.gov/oes/2009/may/naics4_621100.htm.*

Estimated Annual Cost to the Government

Exhibit 3 shows the estimated annualized cost to the government for developing, maintaining and managing the CAHPS CG Database, analyzing the data and reporting results. The cost is estimated to be $220,000 annually. Annualized costs for collecting and processing the CAHPS CG Database are based upon 10 years of historical CAHPS Health Plan Database project costs. AHRQ wishes to continue this data collection indefinitely and requests OMB approval for 3 years.

EXHIBIT 3—ESTIMATED ANNUALIZED COST

Cost component	Total cost	Annualized cost
Database Maintenance	$120,000	$40,000
Data Submission	240,000	80,000
Data Analysis and Reporting	300,000	100,000
Total	660,000	220,000

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 15, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011–30274 Filed 11–25–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: ACF–OGM–SF–PPR–Form B—Program Indicators.

OMB No. New Collection.

Description

The Office of Grants Management (OGM), in the Administration for Children and Families (ACF) is proposing the collection of program performance data for ACF's discretionary grantees. To collect this data OGM has developed a form from the basic template of the OMB-approved reporting format of the Program Performance Report. OGM will use this data to determine if grantees are proceeding in a satisfactory manner in meeting the approved goals and objectives of the project, and if funding should be continued for another budget period.

Respondents: All ACF Discretionary Grantees. State governments, Native American Tribal governments, Native American Tribal Organizations, Local Governments, and Nonprofits with or without 501(c)(3) status with the IRS.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–OGM–SF–PPR–B	6000	1	1	6,000

Estimated Total Annual Burden Hours: 6,000.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–30518 Filed 11–25–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

State Court Improvement Program

OMB No.: 0970–0307.

Description: The Court Improvement Program (CIP) is composed of three grants, the basic, data, and training

grants, governed by two separate Program Instructions (PIs). The training and data grants are governed by the ''new grant'' PI and the basic grant is governed by the ''basic grant'' PI. Current PIs require separate applications and program assessment reports for each grant. Every State applies for at least two of the grants annually and most States apply for all three. As many of the application requirements are the same for all three grants, this results in duplicative work and high degrees of repetition for State courts applying for more than one CIP grant.

The purpose of this Program Instruction is to streamline and simplify the application and reporting processes by consolidating the PIs into one single PI and requiring one single, consolidated application (App) package and program assessment report (PAR) per State court annually. These revisions will satisfy statutory programmatic requirements and reduce both the number of required responses and associated total burden hours for State courts.

This new PI also describes programmatic and fiscal provisions and reporting requirements for the grants, specifies the application submittal and approval procedures for the grants for fiscal years 2012 through 2015, and identifies technical resources for use by State courts during the course of the grants. The agency uses the information received to ensure compliance with the statute and provide training and technical assistance to the grantees.

Respondents: Highest State Courts of Appeal

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
App	52	1	92	4784
PAR	52	1	86	4472

Estimated Total Annual Burden Hours: 9,256.

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. *Email 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) 395–7285, *Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–30553 Filed 11–25–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0264]

Amended Authorization of Emergency Use of Doxycycline Hyclate Tablet Emergency Kits for Eligible United States Postal Service Participants and Their Household Members; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the Emergency Use Authorization (EUA) (the Authorization) for doxycycline hyclate tablet emergency kits for eligible United States Postal Service (USPS) participants in the Cities Readiness Initiative (CRI) and their household members issued on October 3, 2008, as amended on February 25, 2009, and on August 23, 2010, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by the Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS). Following issuance of FDA's August 23, 2010, amended Authorization letter, on April 8, 2011, BARDA submitted a request on behalf of ASPR to further amend the Authorization to reflect certain programmatic changes, including by replacing references to the CRI with the National Postal Model (NPM). In response to BARDA's request, FDA amended the Authorization letter and reissued the Authorization in its entirety on October 14, 2011. The Authorization, as amended and reissued, includes explanations for its reissuance and is reprinted in this document.

DATES: The amended Authorization is effective as of October 14, 2011.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4121, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Luciana Borio, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4280, Silver Spring, MD 20993–0002, (301) 796–4637.

SUPPLEMENTARY INFORMATION:

I. Amendment to the October 3, 2008, Authorization for Doxycyline Hyclate Tablet Emergency Kits, as Amended

In 2004, the Secretary of the Department of Homeland Security (DHS) issued a material threat determination indicating that *Bacillus anthracis* (*B. anthracis*), the biological agent that causes anthrax disease, presents a material threat against the

population of the United States sufficient to affect national security. On September 23, 2008, under section 564(b)(1)(A) of the FD&C Act (21 U.S.C. 360bbb–3(b)(1)(A)), as amended by the Project BioShield Act of 2004 (Pub. L. 108–276), the Secretary of DHS determined that there is a significant potential for a domestic emergency involving a heightened risk of attack with a specific biological, chemical, radiological, or nuclear agent or agents—in this case, *B. anthracis.* On October 1, 2008, under section 564(b) of the FD&C Act, and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under section 564(a) of the FD&C Act, and on October 1, 2009, and on October 1, 2010, renewed the declaration. On July 20, 2011, the Secretary of HHS renewed and amended the declaration to apply to all oral formulations of doxycycline, including doxycycline hyclate tablets covered by the Authorization, accompanied by emergency use information subject to the terms of any authorization issued under section 564(a) of the FD&C Act. Notice of the declaration of the Secretary was published in the **Federal Register** of July 27, 2011 (76 FR 44926).

On October 1, 2008, BARDA requested and on October 3, 2008, FDA issued an EUA for doxycycline hyclate tablet emergency kits for eligible USPS participants in the CRI and their household members, subject to the terms and conditions of the Authorization. As required under section 564(h)(1) of the FD&C Act, in the **Federal Register** of October 21, 2008 (73 FR 62507), FDA published the Authorization for doxycycline tablet emergency kits for eligible USPS participants in the CRI and their household members, including an explanation of the reasons for its issuance. On February 19, 2009, BARDA submitted a request on behalf of ASPR to amend the Authorization to make certain changes to the written information authorized to accompany the doxycycline hyclate tablet emergency kits and to clarify the roles and responsibilities provided for in the Authorization. On February 25, 2009, in response to BARDA's request, FDA amended the Authorization letter and reissued the Authorization letter in its entirety. In the **Federal Register** of June 26, 2009 (74 FR 30577), FDA published the amended Authorization, including an explanation of the reasons for the amendment. On August 4, 2010, BARDA requested that the EUA be further amended to permit the use of a certain manufacturer and a certain repackager under the EUA. On August 23, 2010, in response to BARDA's request, FDA amended the Authorization letter and reissued the Authorization letter in its entirety. On April 8, 2011, BARDA requested that the EUA be further amended to reflect programmatic and operational changes, including by replacing references to the CRI with the NPM, clarifying roles and responsibilities, and revising or removing certain written materials provided for in the Authorization. On October 14, 2011, in response to BARDA's request, FDA amended the Authorization letter and reissued the Authorization letter in its entirety.

II. Electronic Access

An electronic version of this document and the full text of the Authorization are available on the Internet at *http://www.regulations.gov.*

III. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act were met, on October 3, 2008, FDA authorized the emergency use of doxycycline hyclate tablet emergency kits for eligible USPS participants in the CRI and their household members subject to the terms and conditions of the Authorization. The letter of Authorization in its entirety (not including the amended authorized versions of the fact sheets and other written materials), as amended on February 25, 2009, on August 23, 2010, and on October 14, 2011, follows and provides an explanation of the reasons for its amendment.

Dated: November 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

October 14, 2011

Nicole Lurie, M.D., M.S.P.H.
Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Lurie:

This letter is in response to the Biomedical Advanced Research and Development Authority's (BARDA) October 1, 2008, submission, as amended,[1] requesting that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of doxycycline hyclate tablets contained in individual or household antibacterial drug kits for the post-exposure prophylaxis[2] of inhalational anthrax during a public health emergency involving aerosolized *Bacillus anthracis* (*B. anthracis*), pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. § 360bbb-3). BARDA's request is specifically for doxycycline hyclate tablet emergency kits for eligible United States Postal Service (USPS) employee volunteers who are participating in the National Postal Model (NPM) (hereinafter USPS participants) and their household members. For the purpose of this letter, "emergency use of doxycycline hyclate tablet emergency kits" includes NPM pre-event preparedness activities for, and post-event implementation of, post-exposure prophylaxis of inhalational anthrax with authorized doxycycline hyclate tablet emergency kits for eligible USPS participants and their household members. In submitting this request, ASPR/BARDA, in coordination with USPS, will be responsible for requesting any amendments to the EUA.

In 2004, the Secretary of the Department of Homeland Security (DHS) issued a Material Threat Determination indicating that *B. anthracis*, the biological agent that causes anthrax disease, presents a material threat against the population of the United States sufficient to affect national security. On September 23, 2008, pursuant to section 564(b)(1)(A) of the FD&C Act (21 U.S.C. § 360bbb-3(b)(1)(A)), the Secretary of DHS determined that there is a significant potential for a domestic emergency involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *B. anthracis*.[3] On October 1, 2008,

[1] Following issuance of FDA's October 3, 2008, authorization letter, BARDA submitted a request on February 19, 2009, to further amend the authorization. On February 25, 2009, an amended authorization letter responding to that request was issued. On August 4, 2010, BARDA requested that the EUA be further amended, and on August 23, 2010, an amended authorization letter responding to that request was issued. On April 8, 2011, BARDA requested that the EUA be further amended to reflect programmatic and operational changes, as described in this authorization letter; to remove references to protective equipment, e.g., N95 masks; and to update or remove certain materials, including removing the unit-of-use bottle label and approved package inserts. This letter grants that request.

[2] The Act uses the terms "diagnosing, treating, or preventing" in section 564(c)(2)(A). Post-exposure prophylaxis is encompassed by these statutory terms.

[3] Memorandum from Michael Chertoff to Michael O. Leavitt, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (Sept. 23, 2008).

pursuant to section 564(b) of the FD&C Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the HHS Secretary then declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets for post-exposure prophylaxis accompanied by emergency use information subject to the terms of any authorization issued under section 564(a) of the FD&C Act (21 U.S.C. § 360bbb-3(a)), and on October 1, 2009, and on October 1, 2010, renewed that declaration.[4] On July 20, 2011, the Secretary of HHS renewed and amended that declaration so that it applies to all FDA-approved oral formulations of doxycycline products, including doxycycline hyclate tablets covered by this authorization.[5]

Following the 2004 signing of a Memorandum of Agreement by the HHS Secretary, DHS Secretary, and Postmaster General, the Cities Readiness Initiative (CRI) Postal Model (also referred to as the Postal Plan) was launched to augment the dispensing of oral antibacterial drugs through USPS participants' delivery of antibacterial drugs to residential households within pre-determined ZIP Codes where there may be an intentional release of *B.anthracis* in their geographic area. BARDA is requesting an amendment to its October 1, 2008, submission, as amended,[6] to reflect programmatic and operational changes in the Postal Model. Specifically, ASPR seeks to provide doxycycline hyclate tablet emergency kits, where not contraindicated, to eligible USPS employee volunteers who are participating in a venue-specific adaptation of the NPM and to their household members.[7] The program name "NPM" replaces references to "CRI" following Executive Order 13527, which was issued in December 2009 and directed the establishment of a national USPS model for residential delivery of antibacterial drugs following a biological attack.[8] The resulting NPM will guide local planning for venue-specific Postal Plans and is replicable in any United States metropolitan area whose jurisdictions are willing to engage in the local pre-event preparations necessary to establish such a capability. In order to sustain and expand the Postal Model, HHS/ASPR is assuming many of the programmatic and operational responsibilities for the NPM. For purposes of this authorization, ASPR is the responsible HHS entity, regardless of the office, i.e., BARDA, Office of Preparedness and Emergency Operations (OPEO), or the National Disaster Medical System (NDMS), that has been delegated the specific responsibility.

Pre-event preparation will enable USPS participants to participate in the earliest phase of the public health response to an anthrax event by delivering post-exposure prophylaxis on an emergency basis as a quick strike force directly to residences throughout an at-risk geographic area(s). The Postal carriers' role is voluntary because emergency response is neither part of the basic mission of USPS nor a provision of the contracts between USPS and the unions representing the carriers. USPS has made its participation in the Postal Model contingent on the pre-event provision of prescription antibacterial drug countermeasures to USPS participants and

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[4] Declaration of Emergency Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b) (Oct. 1, 2008); renewed October 1, 2009 (74 Fed. Reg. 51,279) (Oct. 6, 2009); renewed October 1, 2010 (75 Fed. Reg. 61,489) (Oct. 5, 2010).

[5] Authorization of Emergency Use of Oral Formulations of Doxycycline; Availability (76 Fed. Reg. 47,197) (Aug. 4, 2011).

[6] See footnote 1.

[7] In an effort to alleviate concerns for their households' safety and thus accelerate the quick preventive strike, pre-event provision of doxycycline to members of the USPS employees' households is a condition of participation specified by the unions that represent the USPS carriers (the National Association of Letter Carriers and the National Rural Letter Carriers Association) and endorsed by USPS management.

[8] Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack (75 Fed. Reg. 737) (Jan. 6, 2010).

their household members, i.e., anyone having permanent residence at the USPS participant's primary residential address.

The doxycycline hyclate tablet emergency kits for the NPM include both Household Antibiotic Kits (HAKs) and Individual Antibiotic Kits (IAKs).[9] Household Antibiotic Kits would be stored in eligible USPS participants' homes, contain unit-of-use bottles with a 10-day supply of doxycycline hyclate tablets for each eligible USPS participant and each eligible household member, and contain emergency use and home preparation instructions in a tamper-evident, transparent bag for secure storage. Each Individual Antibiotic Kit would be stored in a secure location under proper storage conditions at the eligible USPS participant's workplace in the event the USPS participant should need to deploy under the NPM immediately, contain one unit-of-use bottle with a 10-day supply of doxycycline hyclate tablets for the USPS participant, and contain emergency use instructions. For ease of reference, this letter of authorization will use the term "doxycycline hyclate tablet emergency kit(s)" to refer to both types of kits, unless otherwise specified. An EUA is needed to facilitate the NPM's pre-event planning and preparedness activities, which may include elements that would otherwise violate provisions of the FD&C Act under FDA's legal interpretations.[10]

Having consulted with the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), and having concluded that the criteria for issuance of this authorization under section 564(c) of the FD&C Act (21 U.S.C. § 360bbb-3(c)) are met, I authorized the emergency use of doxycycline hyclate tablet emergency kits, where not contraindicated, for the post-exposure prophylaxis[11] of inhalational anthrax for eligible USPS participants and their household members in the event of a public health emergency involving *B. anthracis*, subject to the terms of the authorization. By this letter, I am amending that authorization.[12] The amended EUA will apply in all circumstances in which a venue-specific Postal Plan under the NPM is in place.

The remainder of this letter is organized into five sections: (I) Criteria for Issuance of Authorization; (II) Scope of Authorization; (III) Current Good Manufacturing Practice (CGMP); (IV) Conditions of Authorization; and (V) Duration of Authorization.

I. Criteria for Issuance of Authorization

[9] Where referenced, "Individual Antibiotic Kit" (IAK) replaces "Individual Household Antibiotic Kit" (iHAK) included in the October 1, 2008, EUA, as amended.

[10] Such elements include, but are not limited to: distribution and use of emergency use information sheets, e.g., fact sheet for health care professionals, fact sheet for recipients, and fact sheet for recipients with home preparation instructions for recipients who cannot swallow pills; dispensing doxycycline without all of the required information on the prescription label per section 503(b)(2) (U.S.C. § 353(b)(2)); dispensing a partial supply of the full 60-day dosage regimen, i.e., initial start-up 10-day supply; and pre-event storage or distribution of doxycycline packaged or repackaged for emergency distribution.

[11] Prophylaxis is generally considered to apply in situations in which the person receiving the drug has not exhibited symptoms. Because, in many cases in which doxycycline may be used pursuant to this authorization, it will not be practical to distinguish between persons who have exhibited symptoms and those who have not, this authorization permits the administration of doxycycline to persons who may have been exposed to *B. anthracis* during a public health emergency whether or not they have begun to exhibit symptoms. We would expect that responsible authorities would direct any persons who have begun to exhibit symptoms to appropriate medical care as expeditiously as possible.

[12] FDA is authorizing the emergency use of FDA-approved formulations of doxycycline hyclate 100 mg oral tablets contained in doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax as described in the scope section of this letter (see Section II. Scope of Authorization).

I have concluded that the emergency use of doxycycline hyclate tablet emergency kits, where not contraindicated, for the post-exposure prophylaxis of inhalational anthrax for eligible USPS participants and their household members in the event of a public health emergency involving *B. anthracis* meets the criteria for issuance of an authorization under section 564(c) of the FD&C Act, because I have concluded that:

(1) *B. anthracis* can cause inhalational anthrax, a serious or life-threatening disease or condition;

(2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that doxycycline hyclate tablet emergency kits may be effective for the post-exposure prophylaxis of inhalational anthrax, and that the known and potential benefits of doxycycline hyclate tablet emergency kits, when used for the post-exposure prophylaxis of inhalational anthrax in the specified population, outweigh the known and potential risks of such products; and

(3) there is no adequate, approved, and available alternative to doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax.[13]

Therefore, I have concluded that the emergency use of doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax for eligible USPS participants and their household members meets the above statutory criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the FD&C Act, that the scope of this authorization is limited to the emergency use of doxycycline hyclate tablet emergency kits, where not contraindicated, by eligible USPS participants and their household members for purposes of pre-event planning and preparedness activities, and, in a post-event scenario, implementation of post-exposure prophylaxis for inhalational anthrax for eligible USPS participants and their household members who have been exposed, or who may have been exposed, to aerosolized *B. anthracis* spores. Eligible USPS participants include those employees who have agreed in writing to participate in the NPM, have been medically screened for contraindications based on completed USPS NPM Health Assessment Forms, have been given valid prescriptions, and have not otherwise been determined to be ineligible to receive doxycycline hyclate tablet emergency kits. Eligibility to receive doxycycline hyclate tablet emergency kits also must be determined for household members of eligible USPS participants. The emergency use of doxycycline hyclate tablet emergency kits under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below.

The authorized doxycycline hyclate tablets contained in the emergency kits include the following products:

[13] No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the Act.

FDA-approved formulations of doxycycline hyclate 100 mg oral tablets[14] that have been repackaged into unit-of-use bottles containing 20 oral tablets each, i.e., a 10-day supply, and relabeled[15] by HHS, and that have then been packaged into doxycycline hyclate tablet emergency kits by, or under the direction of, ASPR and, as appropriate, labeled with an expiration date based on the expiration date on the manufacturer's original container. The antibacterial drug dispensed to USPS participants will be refreshed no later than the expiration date of the repackaged product.

Doxycycline is a semisynthetic tetracycline antibacterial drug approved for prescription use by FDA for treatment and post-exposure prophylaxis of anthrax due to *B. anthracis*, including inhalational anthrax, to reduce the incidence or progression of disease following exposure to aerosolized *B. anthracis*.[16] The post-exposure prophylaxis indication generally means that drug administration is expected to start after a known or suspected exposure to aerosolized *B. anthracis* spores, but before clinical symptoms of the disease develop. The indication includes presumed exposure, since it is often difficult to know whether and when exposure has actually occurred. The indication also encompasses instances where *B. anthracis* exposure via inhalation is expected and likely imminent. In such cases, the first few doses of prophylaxis may be taken pre-exposure, but the remainder of the course would be taken post-exposure. The indication is commonly referred to as "post-exposure prophylaxis of inhalational anthrax," and this term will be used throughout this document. Generally, once symptoms develop, the approved indication for "treatment" would apply. Although it is expected that NPM emergency use plans will, to the extent possible, direct symptomatic individuals to health care professionals for appropriate treatment, FDA recognizes that circumstances may necessitate the use of doxycycline hyclate tablet emergency kits by eligible individuals who may be symptomatic.

ASPR will determine whether to initiate distribution of doxycycline hyclate tablet emergency kits under this EUA to particular NPM locations based on pre-determined NPM program requirements.

1. The above doxycycline hyclate tablet emergency kits are authorized for pre-event storage and distribution, and for post-event storage, distribution, and use, when manufactured under CGMP requirements; when repackaged and relabeled under CGMP requirements (21 C.F.R. 211),[17] despite the fact that they may not contain all of the required information on the prescription label under section 503(b)(2) of the FD&C Act (21 U.S.C. § 353(b)(2)), e.g., name and address of dispenser, serial number, date of prescription or of its filling, name of prescriber, directions for use and cautionary statements, if contained in the prescription; and when then packaged into doxycycline hyclate tablet emergency kits by, or under the direction of, ASPR health care professionals.

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[14] FDA-approved drugs can be identified at the *Drugs at FDA* website at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.

[15] The term "repackaged and relabeled" will be used to refer to the activity of putting unit-of-use bottles into tamper-evident, transparent bags with the addition of certain written information.

[16] The full course of doxycycline tablets for adults for the post-exposure prophylaxis of inhalational anthrax is 100 mg twice daily for 60 days. Children weighing 40 kg or more (89 pounds or more) should receive the adult dose. Children weighing less than 40 kg should receive 2.2 mg/kg of body weight per dose, by mouth, twice daily (maximum 100 mg per dose).

[17] It is currently planned that such repackaging and relabeling will be handled by the HHS Supply Service Center at Perry Point, Maryland. This authorization would, however, permit such repackaging and relabeling at any other HHS-selected facility that meets CGMP requirements and the terms and conditions of this EUA.

2. The doxycycline hyclate tablet emergency kits previously referenced are authorized to be accompanied by authorized emergency use information, to be made available to health care professionals involved in the NPM and to eligible USPS participants and their household members, to facilitate understanding of anthrax disease and the risks and benefits of doxycycline therapy and to improve medication compliance. This information includes:

   - USPS NPM Doxycycline EUA Fact Sheet for Health Care Professionals
   - USPS NPM Doxycycline EUA Fact Sheet for Recipients
   - In an Emergency: How to Prepare Doxycycline for Children and Adults Who Cannot Swallow Pills[18]
   - USPS NPM Information Placard[19]
   - MedWatch Form 3500[20]

   Any revisions or additional written materials to be provided by ASPR, USPS, or the PPHA are subject to FDA's prior approval, except that ASPR may provide additional materials for recruitment and program management purposes, which may be updated to reflect programmatic changes, consistent with the following authorized attachments:

   - USPS NPM Health Assessment Form[21]
   - USPS NPM Health Care Professional Quality Checklist
   - USPS NPM Questions to Determine Status of the HAKs/IAKs
   - USPS NPM Exemption Form

3. The doxycycline hyclate tablet emergency kits previously referenced are authorized to be stored, distributed, and used as a partial supply,[22] i.e., 10-day supply, of a full 60-day dosage regimen, when stored, distributed, and used as part of the NPM.

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[18] *In an Emergency: How to Prepare Doxycycline for Children and Adults Who Cannot Swallow Pills* is available in a one-page or 2-page format (or as updated by FDA) at http://www.fda.gov/doxyprepare.

[19] ASPR may use the previously-authorized version of the Information Placard, so long as the revised version authorized by this EUA is used when supplies of the previously-authorized version are exhausted.

[20] The MedWatch Form 3500 is available at http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf and can be printed double sided to generate a form that can be folded so that a business reply address is displayed for mailing.

[21] ASPR may use the previously-authorized version of the Health Assessment Form, so long as the revised version authorized by this EUA is used when supplies of the previously-authorized version are exhausted.

[22] The required and FDA-approved duration of doxycycline therapy for post-exposure prophylaxis against inhalational anthrax is 60 days. An initial, partial supply of doxycycline may be utilized to facilitate rapid initiation of antimicrobial therapy. Thus, the partial dispensing of the required quantity of doxycycline to complete therapy duration will be allowed under this EUA. Once the antimicrobial susceptibility of the associated *B. anthracis* strain involved in the exposure has been determined per its minimum inhibitory concentration, and potential exposure to *B. anthracis* has been confirmed, an additional supply of doxycycline must be dispensed to individuals to allow the full 60-day antimicrobial post-exposure prophylaxis regimen. The individual will receive further instructions on whether

ASPR is also authorized to make available additional information relating to the emergency use of authorized doxycycline hyclate tablet emergency kits that is consistent with the terms of this letter of authorization. (See Section IV. Conditions of Authorization.)

I have concluded, pursuant to section 564(d)(2) of the FD&C Act, that it is reasonable to believe that the known and potential benefits of the authorized doxycycline hyclate tablet emergency kits, when used for the post-exposure prophylaxis of inhalational anthrax, outweigh the known and potential risks of such products for USPS participants and their household members.

I have concluded, pursuant to sections 564(c)(2)(A) and 564(d)(3) of the FD&C Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized doxycycline hyclate tablet emergency kits may be effective for the post-exposure prophylaxis of inhalational anthrax. FDA has reviewed the scientific information available, including the information supporting the conclusions described in Section I above, and concludes that the authorized doxycycline hyclate tablet emergency kits, when used for the post-exposure prophylaxis of inhalational anthrax in the specified population in accordance with the conditions set out in this letter, meet the criteria set forth in section 564(c) of the FD&C Act concerning safety and potential effectiveness.

Subject to the terms of this EUA and consistent with the Secretary of DHS's determination under section 564(b)(1)(A) of the FD&C Act and the Secretary of HHS's corresponding declaration under 564(b)(1) of the FD&C Act described above, the authorized doxycycline hyclate tablet emergency kits previously described are authorized for the post-exposure prophylaxis of inhalational anthrax for eligible USPS participants and their household members who have been exposed, or who may have been exposed, to aerosolized *B. anthracis* spores.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the FD&C Act or when the EUA is revoked under section 564(g) of the FD&C Act. When this EUA ceases to be effective, the doxycycline hyclate tablet emergency kits described herein will no longer be authorized for emergency use under this EUA.[23]

III. Current Good Manufacturing Practice

This authorization only covers doxycycline hyclate tablets contained in emergency kits that have been manufactured under CGMP requirements, and that have been repackaged and relabeled under CGMP requirements (21 C.F.R. 211) by, or under the direction of, HHS.[24] Doxycycline hyclate tablets, 100 mg, subject to the Department of Defense (DOD)-FDA Shelf Life Extension Program (SLEP), will not be used for repackaging.

The doxycycline hyclate tablet emergency kits should be stored by eligible USPS participants and their household members at or close to controlled room temperature 20°C to 25°C (68°F to

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the additional 50-day supply is necessary based on the results of the antimicrobial susceptibility and also instructions on where to obtain the 50-day supply of doxycycline.

[23] Pursuant to Section 564(f)(2) of the Act, 21 U.S.C. 360bbb-3(f)(2), continued use of a product authorized by this letter may continue after the expiration of this authorization to the extent found necessary by the patient's health care professional.

[24] See footnote 17.

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77°F). All recipients will receive in writing, as part of the screening and dispensing procedures, specific recommendations about safe storage locations out of the reach of children and pets.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

ASPR

A. ASPR will provide the following written materials, as authorized under this EUA and as applicable, to health care professionals involved in the NPM, USPS participants and their eligible household members, USPS, and the principal public health authority (PPHA) for each participating municipality:

- USPS NPM Doxycycline EUA Fact Sheet for Health Care Professionals
- USPS NPM Doxycycline EUA Fact Sheet for Recipients
- In an Emergency: How to Prepare Doxycycline for Children and Adults Who Cannot Swallow Pills[25]
- USPS NPM Information Placard[26]
- USPS NPM Health Assessment Form[27]
- USPS NPM Health Care Professional Quality Checklist
- USPS NPM Questions to Determine Status of the HAKs/IAKs
- MedWatch Form 3500[28]
- USPS NPM Exemption Form

B. ASPR will be aware of and ensure that anyone storing and distributing doxycycline hyclate tablet emergency kits for preparedness and response purposes under this EUA is informed of and instructed on the actions necessary to enable them to comply with the terms and conditions of this EUA, such as data collection, recordkeeping, and records access. This includes making available to health care professionals the FDA-approved package insert[29] that covers the authorized doxycycline hyclate 100 mg oral tablets and informing its designees, USPS, and the PPHAs of their obligation to promptly report within 15 days, and to instruct recipients who have taken the medicine in their doxycycline hyclate tablet emergency kits to report, adverse events and medication errors

[25] See footnote 18.
[26] See footnote 19.
[27] See footnote 21.
[28] See footnote 20.
[29] FDA-approved package inserts for doxycycline hyclate tablets are available at www.dailymed.nlm.nih.gov.

to MedWatch directly through www.fda.gov/medwatch, by submitting the MedWatch Form 3500[30] included both inside and outside each doxycycline hyclate tablet emergency kit in hard copy, or by calling 1-800-FDA-1088. Any such report should identify the product as "doxycycline hyclate tablet emergency kit" and indicate that the product was used under the "USPS-NPM EUA" (United States Postal Service National Postal Model Emergency Use Authorization) by including a description of the event the abbreviations "USPS-NPM EUA" or "USPS-NPM Emergency Use Authorization." Recipients who have taken the medicine in their doxycycline hyclate tablet emergency kits should also be instructed to report any adverse event or medication error to their personal physician or emergency department and to the designated ASPR health care professional. ASPR will provide a supply of MedWatch Form 3500 to the PPHA for each participating municipality.

C. ASPR, with the assistance of USPS, will submit a report to FDA summarizing the information collected every 6 months for the USPS NPM Questions to Determine Status of the HAKs/IAKs items within 30 days of collecting such information.

D. ASPR will notify FDA of its decision to add a municipality or geographic area to the NPM and of its decision to initiate distribution of doxycycline hyclate tablet emergency kits under this EUA to particular locations.

E. ASPR will ensure that all NPM advertising and promotional descriptive printed matter relating to the use of doxycycline hyclate tablet emergency kits authorized under this EUA shall be consistent with the fact sheets, home preparation instructions, and placard information, as well as the terms set forth in this EUA and other requirements set forth in the FD&C Act and FDA regulations.

F. ASPR is also authorized to make available additional information, including additional recommendations and instructions, related to the emergency use of doxycycline hyclate tablet emergency kits as described in this letter of authorization, to the extent that additional recommendations and instructions are necessary to meet public health needs during a declared public health emergency involving *B. anthracis* and are reasonably consistent with, and do not exceed, the terms of this letter of authorization.

G. ASPR and its designated health care professionals will conduct medical screening of potential USPS participants and their immediate household members. ASPR, with assistance from USPS as necessary, will distribute USPS NPM Health Assessment Forms to identified USPS employee volunteers, which will include a section allowing for the volunteers to consent to direct shipment of their Individual Antibiotic Kits to USPS program staff for pre-positioning at their workplace. All household individuals must complete the screening form; caregivers will complete the form for children and other household members who are unable to complete the form. Designated ASPR health care professional(s) will review the medical history information with the USPS employee (either by telephone or in person, to establish a "therapeutic relationship"), provide two prescriptions for each employee, i.e., one for the employee's Household Antibiotic Kit and one for the employee's Individual Antibiotic Kit, and prescribe doxycycline for each member of the household for which the drug is appropriate or document that the USPS

[30] See footnote 20.

employee and/or the household member is not eligible for participation at this time, and transmit the prescription for each employee's Household Antibiotic Kit and Individual Antibiotic Kit to the designated pharmacy unit. ASPR will ensure that a designated pharmacist or other qualified person is also available to answer any questions the USPS employee may have regarding the prescription or its use.

USPS employees for whom doxycycline is contraindicated will be considered disqualified. However, if the contraindication applies only to one or more of the members of the USPS employee's household, then the USPS employee will be eligible to serve provided that he or she makes an informed choice. The employee will have the opportunity to inform ASPR in writing on the USPS NPM Exemption Form that he or she is prepared to accept an incomplete Household Antibiotic Kit and understands that, during a public health emergency involving exposure of his or her household to *B. anthracis*, the household member(s) not covered by the Household Antibiotic Kit will have the same dependency as does the rest of the community upon whatever emergency mass chemoprophylaxis the public health authority(ies) is able to provide. That is, the USPS employee will have the option to participate in the venue-specific Postal Plan and accept whatever degree of pre-event antimicrobial drug coverage is medically appropriate for the household, or decline to participate and accept for his or her entire household the same dependency upon the public health authority(ies) for emergency chemoprophylaxis as has the community, which will not have access to the Household Antibiotic Kits.

ASPR will ensure that USPS participants will be informed:

- that FDA has authorized the emergency use of doxycycline hyclate tablet emergency kits for post-exposure prophylaxis of inhalational anthrax for eligible USPS participants and their household members;
- of the significant known and potential benefits and risks of the emergency use of doxycycline hyclate tablet emergency kits for eligible USPS participants and their household members, and of the extent to which such benefits and risks are unknown; and
- of the option to accept or refuse administration of doxycycline hyclate tablet emergency kits, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available, and of their benefits and risks.

Supplying the information required to be provided with each doxycycline hyclate tablet emergency kit satisfies ASPR's obligation to inform USPS participants of this information.

H. ASPR will be responsible for procurement of doxycycline, for the receipt of prescriptions, for determining how many household members are eligible to receive doxycycline, and for the packaging of the doxycycline hyclate tablet emergency kits. The packaging for each kit requires two health care professionals who are qualified and licensed to dispense prescription products according to appropriate State pharmacy laws. ASPR will liaise directly with the designated health care professionals prescribing the kits. Packaging should be performed in a controlled environment such that there is adequate space, lighting, and freedom from debris and from other drug products to prevent mix-ups or cross-contamination.

An ASPR health care professional will initially assemble the doxycycline hyclate tablet emergency kits as outlined in the USPS NPM Health Care Professional Quality Checklist, including by recording prescription information on the USPS NPM Health Assessment Form, by recording information about the bottles dispensed on a Drug Accountability/Inventory Record, by providing in and on the outside of each kit the applicable set of written information authorized by this EUA, and by labeling each unit-of-use bottle with the name of the eligible USPS participant or household member. Before dispensing, a different designated ASPR health care professional will, as outlined in the USPS NPM Health Care Professional Quality Checklist, check each doxycycline hyclate tablet emergency kit that has been assembled. The Household Antibiotic Kit for the USPS participant and his or her household will then be sent to the employee's home address using an accountable method of shipping, and, with the employee's consent, the Individual Antibiotic Kit for the USPS participant will be sent directly to USPS program staff.

I. ASPR must maintain a Drug Accountability/Inventory Record, including lot number, quantity, receiving site, and distribution date of the unit-of-use bottles of doxycycline shipped under this EUA for the recipients. ASPR will be responsible for recording names and contact information for each person to whom the doxycycline hyclate tablet emergency kits are dispensed. This requirement does not require record-keeping related to dispensing of doxycycline products to recipients during an emergency in those circumstances in which such record-keeping would not be consistent with an efficient program for the dispensing of the drug to recipients.[31] HHS will require the reporting of any adverse reactions to doxycycline. Likewise, HHS will provide FDA access to such records when requested.

J. ASPR, with assistance from the USPS as necessary, will, every 6 months dependent on the timing for refresh of the doxycycline hyclate tablet emergency kits, disseminate USPS NPM Questions to Determine Status of the HAKs/IAKs to the participating USPS employees for their written assurance that they have stored their kits as instructed, they are able to locate their kits readily, their kits are intact, if they or any of their household members have taken any of the medication in the kit (and, if so, whether they experienced any adverse events or medication errors), and the medication in their kits has not expired. ASPR will conduct an inquiry with USPS participants who report loss of a kit or use of doxycycline from the kit in the absence of instructions to do so to ascertain the circumstances of non-compliance. Depending on the findings, the USPS participant could be subject to disqualification from the further participation in the program.

For kits that will expire prior to the next 6-month data collection, a new doxycycline hyclate tablet emergency kit(s) will be dispensed to volunteers continuing on in the program using the original enrollment procedures, provided that the EUA is still in effect. In such cases, ASPR, assisted by USPS, will be responsible for ensuring that such kits are collected, accounted for, and disposed of, as instructed by ASPR. ASPR will maintain

[31] While such record-keeping is not a requirement of this EUA, it is expected that NPM participants will, to the extent possible, keep such records for purposes of their own follow-up of recipients, including for the purpose of assuring that any individual who has been provided less than a full course of doxycycline receives, if necessary, a full course.

drug accountability records. If the 6-month kit survey coincides with the timing of the refresh and the USPS participant returns the doxycycline hyclate tablet emergency kit(s) for refresh, a USPS NPM Questions to Determine Status of the HAKs/IAKs form will not need to be completed. ASPR will work with participants to make any necessary modifications to their respective kits based on their responses to the USPS NPM Questions to Determine Status of the HAKs/IAKs. ASPR will instruct USPS participants to return the kits, when they reach their date of expiry, using instructions in the USPS NPM Doxycycline EUA Fact Sheet for Recipients.

PPHA

K. The PPHA for each participating municipality may, in collaboration with ASPR, assist in coordinating NPM activities that occur within its jurisdiction, including by providing health care professionals and other personnel to assist ASPR health care professionals in screening, prescribing, and ensuring proper storage of doxycycline hyclate tablet emergency kits; by instructing participants to use the doxycycline hyclate tablet emergency kits during an actual emergency; by periodically verifying that the quantity of medication in storage corresponds with the Drug Accountability/Inventory Record (and reconciling any differences) and that all undistributed medication in the doxycycline hyclate tablet emergency kits is within its labeled expiration date; and by maintaining a supply of MedWatch Form 3500 for the purposes of reporting adverse events and medication errors.

USPS

L. USPS management and the unions representing mail carriers will solicit applicants jointly and will conduct the initial recruitment of USPS employee volunteers[32] by conducting oral briefings and providing written materials developed by or selected in consultation with ASPR. These materials include:

- the fact sheets and information associated with this EUA;
- an explanation of the NPM and its associated safety program, of which doxycycline hyclate emergency kits are a part;
- a form whereby the employees can indicate their decision to volunteer, to be collected by USPS officials, with possible assistance from local union leadership; and
- an example of a USPS NPM Health Assessment Form to help health care professionals identify possible contraindications for doxycycline.

USPS management and the unions representing mail carriers, in accord with the process for the initial recruitment, will invite new applicants, follow up appropriately with those who respond affirmatively, and confirm the status of those already enlisted in the program.

[32] Participation by USPS staff in a venue-specific Postal Plan is voluntary. No USPS staff will be required to accept either the risks of re-aerosolization during direct residential delivery of antimicrobial drugs in response to a wide-area anthrax emergency or the risks associated with possessing a pre-event kit of antimicrobial drugs for their household strictly for emergency use as directed.

M. USPS will not knowingly deploy carriers or supporting staff for emergency duty under a venue-specific Postal Plan without proper chemoprophylaxis. USPS will maintain Individual Antibiotic Kits for each eligible USPS participant in a secure cache in each Delivery Unit that is part of the venue-specific Postal Plan. USPS will allow access to Individual Antibiotic Kits only during a public health emergency for which they are appropriate and only as necessary to help ensure eligible USPS participants' safety.

N. USPS and its designees will be responsible for promptly reporting, within 15 days, any adverse event or medication error in recipients who have taken medication from their Household Antibiotic Kits or Individual Antibiotic Kits to MedWatch through www.fda.gov/medwatch, by submitting MedWatch Form 3500 in hard copy, or by calling 1-800-FDA-1088.

O. USPS will require that USPS participants who leave the employ of the USPS, e.g., through retirement or acceptance of other employment, or who no longer wish to volunteer for participation in their venue-specific Postal Plan, return their doxycycline hyclate tablet emergency kit(s) to ASPR.

P. USPS, upon termination of the declaration of emergency under section 564(b)(2) of the FD&C Act or upon revocation of this EUA under section 564(g) of the FD&C Act, will be responsible for collecting all doxycycline hyclate tablet emergency kits and turning them over to ASPR. ASPR will dispose of doxycycline hyclate emergency kits at that time. ASPR and the PPHA for each participating municipality will ensure that drug accountability records are maintained and reconciled. Such records will be made available to FDA for inspection when requested.

The emergency use of doxycycline hyclate tablet emergency kits as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Enclosures

cc: Robin Robinson, Ph.D., Director, BARDA

[FR Doc. 2011–30450 Filed 11–25–11; 8:45 am]
BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0488]

Determination That TAXOTERE (Docetaxel) Injection, 40 Milligrams/Milliliter Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that TAXOTERE (docetaxel) Injection, 40 milligrams/milliliter (mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for docetaxel injection, 40 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nam Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6320, Silver Spring, MD 20993–0002, (301) 796–3472.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

TAXOTERE (docetaxel) Injection, 40 mg/mL is the subject of NDA 20–449, held by Sanofi-aventis U.S., and initially approved on May 14, 1996. TAXOTERE is indicated for breast cancer, non-small cell lung cancer, hormone refractory prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck cancer as described in detail on the drug product's labeling.

TAXOTERE (docetaxel) Injection, 40 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Sandoz, Inc. (Sandoz), submitted a citizen petition dated June 21, 2011 (Docket No. FDA–2011–P–0488), under 21 CFR 10.30, requesting that the Agency determine whether TAXOTERE (docetaxel) Injection, 40 mg/mL, was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that TAXOTERE (docetaxel) Injection, 40 mg/mL was not withdrawn for reasons of safety or effectiveness. The petitioner Sandoz has identified no data or other information suggesting that TAXOTERE (docetaxel) Injection, 40 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TAXOTERE (docetaxel) Injection, 40 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TAXOTERE (docetaxel) Injection, 40 mg/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to TAXOTERE (docetaxel) Injection, 40 mg/mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30472 Filed 11–25–11; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0799]

Draft Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Use of Nucleic Acid Tests (NAT) on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Recovered Plasma, Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of Hepatitis B Virus (HBV), and Requalification of Donors Who Test HBV NAT Positive,'' dated November 2011. The draft guidance document provides recommendations on the use of FDA-licensed nucleic acid tests (NAT) to screen blood donors for hepatitis B virus (HBV) deoxyribonucleic acid (DNA) and recommendations for product testing and disposition, donor management, methods for donor requalification, and product labeling. In addition, the draft guidance provides notification that FDA considers the use of an FDA-licensed HBV NAT to be necessary to reduce adequately and appropriately the risk of transmission of HBV. The guidance is intended for blood establishments that

collect Whole Blood and blood components for transfusion or for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes. The draft guidance, when finalized, is intended to supplement previous memoranda and guidance from FDA concerning the testing of donations for hepatitis B surface antigen (HBsAg) and antibody to hepatitis B core antigen (anti-HBc), and the management of donors and units mentioned in those documents.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 27, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–(800) 835–4709 or (301) 827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Levine, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, (301) 827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Use of Nucleic Acid Tests (NAT) on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Recovered Plasma, Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of Hepatitis B Virus (HBV), and Requalification of Donors Who Test HBV NAT Positive,'' dated November 2011. FDA is providing blood establishments that collect Whole Blood and blood components for transfusion or for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes; with recommendations concerning the use of FDA-licensed NAT to screen blood donors for HBV DNA. FDA is also providing these blood establishments with recommendations for product testing and disposition, donor management, methods for donor requalification, and product labeling.

In addition, FDA is notifying those blood establishments that FDA considers the use of an FDA-licensed HBV NAT to be necessary to reduce adequately and appropriately the risk of transmission of HBV. FDA-licensed HBV NAT can detect evidence of infection at an earlier stage than is possible using previously approved HBsAg and anti-HBc tests. Therefore, FDA is recommending the use of an FDA-licensed HBV NAT, in accordance with the requirements under 610.40(a) and (b) (21 CFR 610.40(a) and (b)).

The draft guidance, when finalized, is intended to supplement previous memoranda and guidance from FDA to blood establishments concerning the testing of donations for HBsAg and anti-HBc, and the management of donors and units mentioned in those documents. Note that testing Whole Blood and blood components for transfusion and Source Leukocytes for further manufacture for HBsAg and anti-HBc, and Source Plasma for HBsAg should continue when a blood establishment implements HBV NAT. FDA may consider advancements in technology for testing blood donations, as well as data obtained following the implementation of HBV NAT, to make future recommendations on adequate and appropriate testing for HBV.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 606.121, 610.40 and 640.70 have been approved under OMB Control Numbers 0910–0537, 0910–0116, and 0910–0338, respectively.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: November 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30449 Filed 11–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0386]

Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses.'' This guidance document provides industry and Agency staff with recommendations for studies to establish the performance characteristics of in vitro diagnostic devices (IVDs) intended for the

detection, or detection and differentiation, of human papillomaviruses.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to (301) 847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kate Simon, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5552, Silver Spring, MD 20993–0002, (301) 796–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this guidance to provide industry and Agency staff with recommendations for studies to establish the performance characteristics of IVDs intended for the detection, or detection and differentiation, of human papillomaviruses. These devices are used in conjunction with cervical cytology to aid in screening for cervical cancer. They include devices that detect a group of human papillomavirus (HPV) genotypes, particularly high risk human papillomaviruses, as well as devices that detect more than one genotype of HPV and further differentiate among them to indicate which genotype(s) of HPV is (are) present.

In the **Federal Register** of September 9, 2009 (74 FR 46433), FDA announced the availability of the draft guidance. Comments on the draft guidance were due by December 8, 2009. Five comments were received on the guidance document. We reviewed the comments and took their suggestions into consideration in revising this guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on establishing the performance characteristics of in vitro diagnostic devices for the detection or detection and differentiation of human papillomaviruses. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. To receive ''Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to (301) 847–8149 to receive a hard copy. Please use the document number 1740 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB control number. 0910–0231; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30552 Filed 11–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–D–0086 (formerly Docket No. 2005D–0223)]

Guidance for Industry on Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals.'' The purpose of this guidance is to provide recommendations to industry for designing nonclinical toxicity studies to determine potential late radiation effects (radiation-induced injuries occurring after a latency period of several months to years) of therapeutic radiopharmaceuticals administered systemically. The purpose of such studies is to help minimize the risk of late-occurring irreversible radiation toxicities in clinical trials of therapeutic radiopharmaceuticals. This guidance finalizes the draft guidance of the same name issued in June 2005.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY**

INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Adebayo Laniyonu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2350, Silver Spring, MD 20993–0002, (301) 796–2050; or Siham Biade, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2311, Silver Spring, MD 20993–0002, (301) 796–2050.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals.'' The objective of this guidance is to provide recommendations to industry for designing nonclinical toxicity studies to determine potential late radiation effects of therapeutic radiopharmaceutical agents. This guidance is not intended to address late radiation toxicity of radiobiologicals (e.g., radiolabeled monoclonal antibodies) or to apply to diagnostic radiopharmaceuticals whose low doses are not expected to elicit late radiation toxic effects.

This guidance focuses solely on late radiation safety concerns that are unique to therapeutic radiopharmaceuticals and provides recommendations for late radiation toxicity nonclinical study designs including issues regarding good laboratory practices, species selection, dose selection, timing of study, and study parameters.

Late radiation toxicity differs from early or acute radiation toxicity. Acute radiation toxicity (*e.g.,* bone marrow failure, nausea, vomiting, diarrhea, and oral mucositis) occurs within days to weeks of an acute dose of radiation and is often self-limiting and reversible. In contrast, late radiation toxicity (*e.g.,* renal failure, pulmonary fibrosis, and chord transection) occurs after a latency period of several months to years during which relatively normal organ function continues. Late radiation toxicity is usually progressive and irreversible.

Therapeutic radiopharmaceuticals are typically administered systemically to treat cancer. The radiation absorbed doses delivered by therapeutic radiopharmaceuticals may be comparable to those delivered with external beam radiotherapy (XRT). At therapeutic doses of radiation, the late radiation toxicities commonly associated with XRT (*e.g.,* brain necrosis, paralysis, pulmonary fibrosis, liver or kidney failure, and hemorrhagic cystitis) can also be seen with therapeutic radiopharmaceuticals. With XRT, if the total dose given to an organ is less than its tolerance dose, the probability of symptomatic late radiation toxicity to that organ (exclusive of estimated risks of secondary malignancy) will be minimal. The tolerance doses of most human organs for conventional fractionated XRT are known, and are routinely used to direct the safe administration of XRT. In FDA's experience, however, there are few clinical data from which to estimate organ tolerance doses for therapeutic radiopharmaceuticals. Furthermore, late radiation toxicity has been observed when estimates of radiation absorbed doses delivered by therapeutic radiopharmaceuticals to target organs were substantially below the published XRT organ tolerance doses.

Therefore, there is a need to gain additional knowledge in this area to support the safe administration of therapeutic radiopharmaceuticals to humans. Because studies in humans would be unethical, the best means to gain insight into this issue is by conducting nonclinical late radiation toxicity studies. These studies will aid in identifying organs at risk and establish a margin of safety for late radiation toxicity. As a result, these studies will help to minimize the risk of late-occurring radiation toxicities in clinical trials of therapeutic radiopharmaceuticals.

This guidance finalizes the draft guidance of the same name issued in June 2005 and includes edits based on public comments to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on nonclinical evaluation of late radiation toxicity of therapeutic radiopharmaceuticals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30474 Filed 11–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No: FDA–2011–N–0002]

Science Board to the Food and Drug Administration; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex and technical issues, as well as emerging issues within the scientific community in industry and academia. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of Agency sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on January 6, 2012, from 9 a.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002.

For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at *https://collaboration.fda.gov/scienceboard/.* Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm*; under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Martha Monser, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 32, rm. 4286, Silver Spring MD 20993–0002, (301) 796–4627, or FDA Advisory Committee Information Line, 1–(800) 741–8138 (301) 443–0572 in the Washington, DC area), and follow the prompt to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The Science Board will hear about and provide input regarding the two Centers for Excellence in Regulatory Science and Innovation. The Science Board will also hear updates regarding the Scientific Computing/JANUS program, and FDA's Scientific Integrity Policy. FDA's Modernizing Toxicology Working Group will present an overview to the Science Board for input and discussion. The Center for Drug Evaluation and Research (CDER) will provide their response to the May 2011 Subcommittee Report regarding the Review of the FDA/CDER Pharmacovigilance Program.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 30, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 22, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 23, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Ms. Martha Monser, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 18, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–30416 Filed 11–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Request for Nominations for Voting Members on Public Advisory Committee, Science Board to the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Science Board to the FDA (the Science Board).

FDA has special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Nominations received on or before December 28, 2011, will be given first consideration for membership on the Science Board. Nominations received after December 28, 2011, will be considered for nomination to the Science Board should nominees still be needed.

ADDRESSES: All nominations for membership should be sent electronically to *CV@FDA.HHS.GOV,* or by mail to Advisory Committee Oversight & Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is: Martha Monser, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4286, Silver Spring, MD 20993–0002, (301) 796–4627, *email: martha.monser@fda.hhs.gov.*

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link: *http://www.fda.gov/oc/advisory/default.htm.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on the Science Board.

I. General Function of the Committee

The Science Board shall provide advice primarily to the Commissioner of Food and Drugs (the Commissioner) and other appropriate officials on both general and specific scientific and technical issues as well as emerging issues within the scientific community. Additionally, the Science Board will

provide advice to the Agency on keeping pace with technical and scientific advances in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of Agency strategic science plan and its implementation as well as of related intramural and extramural scientific research and training.

II. Criteria for Voting Members

Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of food safety, nutrition, chemistry, pharmacology, toxicology, clinical research, and other scientific disciplines. Members shall represent academia and industry. The Science Board may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is either recommended by either a consortium of consumer oriented organizations or other interested persons. The Science Board may also include technically qualified federal members. FDA is currently specifically seeking persons knowledgeable in the fields of pharmacology, translational and clinical medicine, toxicology, clinical research and related biostatistics, public health and epidemiology, international public health and regulation, product safety, product manufacturing sciences and quality or other scientific areas relevant to FDA regulated products such as systems biology, advanced scientific informatics, nanotechnology, food sciences, medical devices and combination products.

III. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the Science Board. Self nominations are also accepted. Nominations shall include the name of the committee, complete curriculum vitae of each nominee, and their current business address and telephone number and email address if available. Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination, unless self nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: November 21, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–30415 Filed 11–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0828]

Wyeth Pharmaceuticals, Inc.; Withdrawal of Approval of a New Drug Application for MYLOTARG

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for MYLOTARG (gemtuzumab ozogamicin) for Injection, held by Wyeth Pharmaceuticals, Inc. (Wyeth), 500 Arcola Rd., Collegeville, PA 19426. Wyeth, now a part of Pfizer, Inc., has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

DATES: Effective November 28, 2011.

FOR FURTHER INFORMATION CONTACT: David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6254, Silver Spring, MD 20993–0002, (301) 796–3601.

SUPPLEMENTARY INFORMATION: FDA approved MYLOTARG (gemtuzumab ozogamicin) for Injection on May 17, 2000, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. MYLOTARG was indicated for the treatment of patients with CD33-positive acute myeloid leukemia in first relapse who were 60 years of age or older and who were not considered candidates for other cytotoxic chemotherapy. On May 21, 2010, FDA requested that Wyeth voluntarily withdraw MYLOTARG from the market, after results of a required postapproval clinical trial failed to verify clinical benefit to patients and raised new concerns about the drug's safety. In a letter dated October 25, 2010, Wyeth requested that FDA withdraw approval of NDA 21–174, MYLOTARG (gemtuzumab ozogamicin) for Injection, under § 314.150(d) (21 CFR 314.150(d)). In that letter, Wyeth also waived its opportunity for a hearing, provided under 21 CFR 314.150 and 314.530. In FDA's acknowledgment letter of November 2, 2010, the Agency stated that a large prospective trial that tested the addition of MYLOTARG to first-line chemotherapy for patients with newly diagnosed acute myelogenous leukemia failed to verify clinical benefit of MYLOTARG and raised safety concerns. FDA also acknowledged that Wyeth waived its opportunity for a hearing.

Therefore, under sections 505(e) and 506(b)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e) and 356(b)(3)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 21–174, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d))).

Dated: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30473 Filed 11–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: ''Ethical Dilemmas in Surgery and Utilization of Hospital Ethics Consultation Service: A Survey''

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Department of Bioethics, the Clinical Center, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Ethical Dilemmas in Surgery and Utilization of Hospital Ethics Consultation Service: A Survey. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This survey is intended to collect information about the ethical dilemmas that surgeons have faced in their practices over the past year, and assess their experiences, if any, with their hospital consultation services. Specifically, the information gathered in this study will be valuable

in understanding the ethical dilemmas that surgeons face, the utility of institution ethics consultations services for surgeons, and to identify what barriers, if any, discourage surgeons from utilizing these services. The results of this study can be used by medical professionals, hospitals, and bioethicists in several important ways. First, they will provide a better understanding the ethical dilemmas that surgeons face in their practices. Second, they will provide understanding of factors that determine the current utilization of hospital consultation services by surgeons Third, information collected on the barriers to surgeons' use of ethics consultation services will provide better insight into the perspective and culture of surgery as it relates to ethical dilemmas in their practices and how ethics consultation services could better support surgeons when faced with these dilemmas. *Frequency of Response:* One occasion. *Affected Public:* Individuals. *Type of Respondents:* Surgeons practicing in the US. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3,156; *Estimated Number of Responses per Respondent:* 29 items per questionnaire; Average Burden Hours Per Response: 0.00862; and *Estimated Total Annual Burden Hours Requested:* 789. The annualized cost to respondents is estimated at: $0. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Surgeons	3156	29	0.00862	789
Total				789

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Marion Danis at Department of Clinical Bioethics, National Institutes of Health, Building 10, Room 1C118, Bethesda, MD 20892–1156, Telephone: (301) 435–8727, Facsimile: (301) 496–0760, or email your request, including your address to: *mdanis@cc.nih.gov*.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: November 6, 2011.

Laura M. Lee,

Special Assistant to the DDCC—Patient Safety and Clinical Quality Project Clearance Liaison, CC, National Institutes of Health.

[FR Doc. 2011–30548 Filed 11–25–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Cancer Risk in U.S. Radiologic Technologists: Fourth Survey (NCI)

Summary: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 21, 2011 (76 FR 58520) and allowed 60 days for public comment. One public comment was received in which the individual suggested asking the respondents to report the number of procedures performed per month rather than per week because of the infrequency of some procedures. The program staff will assess this during the pre-test. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Cancer Risk in U.S. Radiologic Technologists: Fourth Survey (NCI). *Type of Information Collection Request:* Reinstatement with change of a previously approved collection (OMB No. 0925–0405, expiration 02/28/2011). *Need and Use of Information Collection:* By conducting a fourth cohort follow-up survey in an ongoing cohort study of U.S. Radiologic Technologists (USRT), updated information will be collected on cancer and other medical outcomes, personal medical radiation procedures, and other risk factors from all participants, plus detailed employment data from subgroups of participants who performed or assisted with fluoroscopically-guided or radioisotope procedures. Researchers at the National Cancer Institute and The University of Minnesota have followed a nationwide cohort of 146,000 radiologic technologists since 1982, of whom 110,000 completed at least one of three prior questionnaire surveys and 23,454 are deceased. This cohort is unique because estimates of cumulative radiation dose to specific organs (e.g. breast) are available and the cohort is largely female, offering a rare opportunity to study effects of low-dose radiation exposure on breast and thyroid cancers, the two most sensitive organ sites for radiation carcinogenesis in women. The fourth survey will be administered by mail to approximately 93,000 living and located cohort members who completed at least one of the three previous surveys to collect information on new cancers and other disease outcomes, detailed work

patterns and practices from technologists who worked with radioisotopes and interventional radiography procedures, and new or updated risk factors that may influence health risks. New occupational and medical radiation exposure information will be used to improve radiation dose estimates. The annual reporting burden is reported in Table 1. There are no capital costs, operating costs and/or maintenance costs to report.

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondent	Instrument	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Cohort members (overall target group).	Fourth Survey CORE Module (Attachment 1A).	21,700	1	30/60 (0.5)	10,850
Cohort members (subgroup 1 of overall target group).	Fourth Survey NM Module (Attachment 1B).	7,000	1	20/60 (0.33)	2,333
Cohort members (subgroup 2 of overall target group).	Fourth Survey FG Module (Attachment 1C).	6,300	1	10/60 (0.17)	1,050
Medical office clerks	Medical Validation (Attachment 3)	2,053	1	15/60 (0.25)	513
Total		37,053			14,746

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functioning of the National Cancer Institute, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to (202) 395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Michele M. Doody, Radiation Epidemiology Branch, National Cancer Institute, Executive Plaza South, Room 7051, Bethesda, MD 20892–7238, or call non-toll-free at (301) 594–7203 or email your request, including your address to: *doodym@mail.nih.gov*.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: November 21, 2011.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2011–30534 Filed 11–25–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, ZHD1 DSR–H 40 1.

Date: December 7, 2011.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marita R. Hopmann, Ph.D., Scientific Review Officer, Division Of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health And Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 435–6911, *hopmannm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 17, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–30281 Filed 11–25–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

4th Annual Trauma Spectrum Conference: Bridging the Gap Between Research and Clinical Practice of Psychological Health and Traumatic Brain Injury: Prevention, Diagnosis, Treatment and Recovery for the Iraq and Afghanistan Cohort

Notice is hereby given of the ''4th Annual Trauma Spectrum Conference: Bridging the Gap Between Research and Clinical Practice of Psychological Health and Traumatic Brain Injury: Prevention, Diagnosis, Treatment and Recovery for the Iraq and Afghanistan Cohort'' to be held December 8–9, 2011, at the National Institutes of Health (NIH), Bethesda, Maryland.

This year's event focuses on bridging the gap between research and clinical practices for psychological health and traumatic brain injury (TBI) health concerns for returning service members

and veterans of the conflicts in Iraq and Afghanistan.

Presented annually by three Federal partners—the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (part of the Department of Defense), the National Institutes of Health, and the Department of Veterans Affairs—the conference highlights research findings, resources, and best practices for Post-Traumatic Stress Disorder and TBI recovery. Additional topics include cognitive rehabilitation, sleep disorders, pain management, depression, implementation science, comparative effectiveness research, co-occurring disorders, and integrative telehealth/mobile technologies. Attendees are expected to include a wide array of researchers, clinicians, advocates, military service members, veterans, and their families.

The conference will be held on Thursday, December 8, and Friday, December 9, in the Natcher Conference Center on the NIH main campus, from 8:30 a.m. to 4:30 p.m. each day. The conference is free, but pre-registration is required. Registration is now open.

To view the agenda, information about continuing education units, and general conference information, visit the Trauma Spectrum Conference Web site at *http://www.dcoe.health.mil/Training/TraumaSpectrumConference.aspx.*

Information on traveling to NIH and a visitor's map can be found at *http://parking.nih.gov/visitor_access_map.htm.*

For attendees who take Metrorail, the nearest station is Medical Center (on the Red Line). Pay parking is available at the NIH Gateway parking garage. Sign language interpreters will be available.

Dated: November 18, 2011.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2011–30523 Filed 11–25–11; 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; Member Conflict: Language and Cognition.

Date: December 13, 2011.

Time: 2:30 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: Jane A Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445 *doussarj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Tissue Engineering and Signaling.

Date: December 13, 2011.

Time: 3 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: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, (301) 408–9694, *petersonjt@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: November 21, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–30526 Filed 11–25–11; 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; Exercise and Cardiovascular System.

Date: December 6, 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: Maqsood A Wani, DVM, Ph.D., 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.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR09–162: Basic Development of Cancer Therapeutics.

Date: December 8, 2011.

Time: 1 p.m. to 2 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: Cathleen L Cooper, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4208, MSC 7812, Bethesda, MD 20892, (301) 443–4512, *cooperc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cognition and Perception.

Date: December 15, 2011.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Weijia Ni, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 237–9918, *niw@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: November 21, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–30528 Filed 11–25–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed 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 Copmmittee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings.

Date: December 13–15, 2011.

Time: 7:45 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Virtual Meeting).

Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 594–3243, *haririmf@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation and Planning (U01, R34).

Date: December 16, 2011.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817.

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities/NIAID, National Institutes of Health, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 451–2634, *james.snyder@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 21, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–30524 Filed 11–25–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2011–0869]

Collection of Information Under Review by Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding Information Collection Requests (ICRs), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of revisions to the following collections of information: 1625–0067, Claims under the Oil Pollution Act of 1990; and 1625–0068, State Access to the Oil Spill Liability Trust Fund for Removal costs under the Oil Pollution Act of 1990. Our ICRs describe the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before December 28, 2011.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2011–0869] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* (a) To Coast Guard docket at *http://www.regulations.gov.* (b) To OIRA by email via: *OIRA-submission@omb.eop.gov.*

(2) *Mail:* (a) DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. (b) To OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Hand Delivery:* To DMF address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

(4) *Fax:* (a) To DMF, (202) 493–2251. (b) To OIRA at (202) 395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov.*

Copies of the ICRs are available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–611), ATTN: Paperwork Reduction Act Manager, U.S. Coast Guard, 2100 2nd St. SW., Stop 7101, Washington, DC 20593–7101.

FOR FURTHER INFORMATION CONTACT: Ms. Kenlinishia Tyler, Office of Information Management, telephone (202) 475–3652 or fax (202) 475–3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, (202) 366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collections. There is one ICR for each Collection.

The Coast Guard invites comments on whether these ICRs should be granted based on the Collections being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collections; (2) the accuracy of the estimated burden of the Collections; (3) ways to enhance the quality, utility, and clarity of information subject to the Collections; and (4) ways to minimize the burden of the Collections on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICRs referred to in this Notice.

We encourage you to respond to this request by submitting comments and

related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG 2011–0869], and must be received by December 28, 2011. We will post all comments received, without change, to *http://www.regulations.gov.* They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number [USCG–2011–0869], indicate the specific section of the document to which each comment applies, providing a reason for each comment. If you submit a comment online via *www.regulations.gov*, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an email address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**, but please submit them by only one means. To submit your comment online, go to *http://www.regulations.gov,* and type ''USCG–2011–0869'' in the ''Keyword'' 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 will address them accordingly.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this Notice 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 ''Keyword'' box insert ''USCG–2011–0869'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the DMF in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Numbers: 1625–0067 and 1625–0068.

Privacy Act

Anyone can search the electronic form of comments received in 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 statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (76 FR 58529, September 21, 2011) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments.

Information Collection Request

1. *Title:* Claims under the Oil Pollution Act of 1990.

OMB Control Number: 1625–0067.

Type of Request: Revision of a currently approved collection.

Respondents: Individuals, Businesses, Federal government, state government, local government, Indian tribes, responsible parties, guarantors.

Abstract: This information collection provides the means to develop and submit a claim to the National Pollution Funds Center to seek compensation for removal costs and damages incurred resulting from an oil discharge or substantial threat of discharge. This collection also provides the requirements for a responsible party to advertise where claims may be sent after an incident occurs.

Forms: None.

Burden Estimate: The estimated burden remains 8,267 hours a year.

2. *Title:* State Access to the Oil Spill Liability Trust Fund for Removal costs under the Oil Pollution Act of 1990.

OMB Control Number: 1625–0068.

Type of Request: Revision of a currently approved collection.

Respondents: Governor of a state or their designated representative.

Abstract: This information collection is the mechanism for a Governor, or their designated representative, of a state to make a request for payment from the Oil Spill Liability Trust Fund (OSLTF) in an amount not to exceed $250,000 for removal cost consistent with the National Contingency Plan required for the immediate removal of a discharge, or the mitigation or prevention of a substantial threat of discharge, of oil.

Forms: None.

Burden Estimate: The estimated burden will remain at 3 hours per year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: November 18, 2011.

R.E. Day,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. 2011–30485 Filed 11–25–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3344–EM; Docket ID FEMA–2011–0001]

New Hampshire; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of New Hampshire (FEMA–3344–EM), dated November 1, 2011, and related determinations.

DATES: *Effective Date:* November 1, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated November 1, 2011, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of New Hampshire resulting from a severe storm during the period of October 29–30, 2011, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of New Hampshire.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program. This assistance excludes regular time costs for subgrantees' regular employees.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Albert Lewis, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of New Hampshire have been designated as adversely affected by this declared emergency:

All 10 counties in the State of New Hampshire for emergency practice measures (Category B) limited to direct Federal assistance, under the Public Assistance program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–30460 Filed 11–25–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3343–EM; Docket ID FEMA–2011–0001]

Massachusetts; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the Commonwealth of Massachusetts (FEMA–3343–EM), dated November 1, 2011, and related determinations.

DATES: *Effective Date:* November 1, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated November 1, 2011, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the Commonwealth of Massachusetts resulting from a severe storm during the period of October 29–30, 2011, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the Commonwealth of Massachusetts.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program. This assistance excludes regular time costs for subgrantees' regular employees.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Mark H. Landry, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the Commonwealth of Massachusetts have been designated as adversely affected by this declared emergency:

The counties of Berkshire, Essex, Franklin, Hampden, Hampshire, Middlesex, Norfolk, and Worcester for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–30458 Filed 11–25–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2011–0030]

Flood Hazard Determinations (Including Flood Elevation Determinations)—Change in Notification and Appeal Procedures

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Pursuant to the Flood Disaster Protection Act of 1973, the Federal Emergency Management Agency (FEMA), via the Federal Insurance Administrator, must publish flood

elevation determinations for comment in the **Federal Register**. Currently, FEMA publishes base flood elevation (BFE) determinations for Flood Insurance Studies (FISs, also referred to as flood studies) as proposed and final rules, and Letters of Map Revision (LOMRs) that include changes to the technical content of a Flood Insurance Rate Map (FIRM) or FIS as interim and final rules. FEMA now plans to publish these determinations as notices rather than as rules. This new procedure will not affect the notice or appeals process for these determinations. FEMA also plans to publish other types of flood hazard determinations in the **Federal Register** with the opportunity for comment and appeal. These other types of flood hazard determinations include new and modified Special Flood Hazard Areas (SFHAs) and new or modified regulatory floodways.

DATES: The changes in procedure announced in this notice are effective December 1, 2011. The new procedure applies to all proposed flood hazard determinations including proposed flood elevation determinations published in the **Federal Register** on or after December 1, 2011.

ADDRESSES: The docket for this notice is available at *http://www.regulations.gov* under Docket ID FEMA–2011–0030. You may also view a hard copy of the docket at the Office of Chief Counsel, Federal Emergency Management Agency, Room 835, 500 C Street SW., Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Lora Eskandary, Program Specialist, FEMA, 1800 South Bell Street, Mail Stop 3030, Arlington, VA 20598, at *lora.eskandary@dhs.gov* or (202) 646–2717. You may also contact the FEMA Map Information exchange (FMIX) toll free at 1 (877) 336–2627 (877–FEMA MAP) for information.

SUPPLEMENTARY INFORMATION:

Change in Procedure for Base Flood Elevation (BFE) Determinations and Letters of Map Revision (LOMRs)

The Federal Insurance Administrator must propose flood elevation determinations by publication of the proposed flood elevation determination for comment in the **Federal Register**, as well as via notification by certified mail to the Chief Executive Officer (CEO) of the community, and publication in a prominent local newspaper at least twice during the ten-day period immediately following the notification of the CEO. *See* 44 CFR 67.4(a). The proposed determination is appealable pursuant to 44 CFR 67.8. The Federal Insurance Administrator must provide final notice of the flood elevation determination as follows: ''The Federal Insurance Administrator's notice of the final flood elevation determination for a community shall be in written form and published in the **Federal Register**, and copies shall be sent to the CEO, all individual appellants and the State Coordinating Agency.'' *See* 44 CFR 67.11. A ''flood elevation determination'' is ''a determination by the Federal Insurance Administrator of the water surface elevations of the base flood, that is, the flood level that has a one percent or greater chance of occurrence in any given year.'' *See* 44 CFR 59.1. These elevations are used to determine floodplain management ordinances, set flood insurance rates, and to determine whether mandatory purchase of flood insurance is required in order to obtain a federally-backed mortgage on a home.

Currently FEMA publishes base flood elevation (BFE) determinations for Flood Insurance Studies pursuant to 44 CFR 67.4 and 67.11 as proposed and final rules. However, there is no legal requirement to publish them as rules, and FEMA now plans to publish them as notices, which are administratively less burdensome. The background and legal authority for this change in procedure is explained below.

Sections 67.4 and 67.11 of Title 44 of the Code of Regulations (CFR) were initially promulgated in 1974, pursuant to section 110 of the Flood Disaster Protection Act of 1973, Public Law 93–234, which amended the National Flood Insurance Act of 1968. Section 110 states ''In establishing projected flood elevations * * * [the agency] shall first propose such determinations by publication for comment in the **Federal Register**, by direct notification to the chief executive officer of the community, and by publication in a prominent local newspaper.'' *See* 42 U.S.C. 4104. The rule implementing section 110 was promulgated by the Department of Housing and Urban Development (HUD), as HUD was the agency responsible for the National Flood Insurance Program (NFIP) before the NFIP was transferred to FEMA in 1979. The original rules appeared in HUD's regulations at 24 CFR 1917.4 and 1917.11. The preambles to the proposed and final rules which added sections 1917.4 and 1971.11 to Title 24 CFR did not indicate whether the proposed and final flood elevation determinations would be published as notices or rules. The preamble to the proposed rule simply stated ''[t]he proposed new Part 1917 would establish an administrative procedure for reviewing appeals of flood elevation determinations made in the National Flood Insurance Program.'' *See* 39 FR 12031 (Apr. 2, 1974). No further explanation was given.

Sections 1917.4 and 1971.11 were finalized as proposed on July 24, 1974. The preamble to the final rule noted that one commenter had requested that the notification by newspaper could be more effective by increasing the number of days of publication. HUD did not alter the proposed regulatory text, however, because the publication standard had been set by the Flood Disaster Protection Act and could not be altered by regulation. Other commenters requested that communities who entered the flood insurance program prior to the passage of the Flood Disaster Protection Act of 1973 be allowed to appeal past flood elevation determinations. Again HUD declined to alter the proposed regulatory text because the Act did not apply retroactively. Further, HUD noted ''an attempt to include such regular flood insurance program communities in this [sic] new appeals procedures could curtail the right of judicial review available to them under the National Flood Insurance Act of 1968 and Title 5 of the United States Code.'' *See* 39 FR 26904 (July 24, 1974). There were no other comments addressing part 1917, and the preamble did not mention whether the flood elevation determinations would be published as notices or as rules in the **Federal Register**.

The text of sections 1917.4 and 1917.11 has not changed since they were finalized in 1974.[1] In 1979 these sections were transferred to 44 CFR 67.4 and 67.11, respectively, when the NFIP was transferred to FEMA. In 1981, an editorial note was added at the end of 44 CFR 67.11, stating ''Note: For the list of communities issued under this section, and not carried in the CFR, see the List of CFR Sections Affected and appearing in the Finding Aids section of

[1] The text reads as follows:

§ 67.4 Proposed flood elevation determination.

The Federal Insurance Administrator shall propose flood elevation determinations in the following manner:

(a) Publication of the proposed flood elevation determination for comment in the **Federal Register**;

(b) Notification by certified mail, return receipt requested, of the proposed flood elevation determination to the CEO; and

(c) Publication of the proposed flood elevation determination in a prominent local newspaper at least twice during the ten day period immediately following the notification of the CEO.

§ 67.11 Notice of final determination.

The Federal Insurance Administrator's notice of the final flood elevation determination for a community shall be in written form and published in the **Federal Register**, and copies shall be sent to the CEO, all individual appellants and the State Coordinating Agency.

this volume.'' A similar note was added to section 67.4 in 1989, stating ''Note: For references to FR pages showing lists of flood elevation determinations, see the List of CFR Sections Affected appearing in the Finding Aids section of this volume.'' The notes have since been revised to direct the reader to the Finding Aids section ''of the printed volume and on GPO Access.''

Since the applicable regulations were promulgated in 1974, base flood elevation determinations listed in feet or meters for specific localities have been published in the **Federal Register** as proposed and final rules. Neither the statute nor the regulations indicate that these elevations must be published as rules, however. Both the statute (42 U.S.C. 4104) and the regulations (44 CFR 67.4, 67.11) state only that the agency must publish a ''notice.'' Section 67.3 also refers to a notice, not a rule. It states that the official docket must include ''[a] copy of the notice of the proposed flood elevation determination published in the **Federal Register**.'' *See* 44 CFR 67.3(d).

Nowhere is it mentioned that the flood elevation determinations were to be published as rules. The extensive Congressional hearings from October 1973 regarding the proposed legislation focus on *notice* of the elevation determinations, and do not mention anything about issuing them as regulations. *See* Flood Disaster Protection Act of 1973 hearings, Ninety-third Congress, first session, on S. 1495 and H.R. 8449, October 31, 1973. A major issue at the hearings focused on the desire for communities to have *notice* of the flood elevation determinations and an opportunity to contest them—to be part of the administrative process, to ensure that communities have the opportunity to present their own evidence of flood elevations that may contradict the Federal government's findings. There was a concern that if the Federal government acted independently, without input from the impacted communities, there would be a violation of due process because the government would be forcing residents to buy flood insurance without any access to the decision process. These concerns were remedied by the final legislation, which allowed for notice and appeal, allowing for communities to present scientific and technical data regarding the proposed flood elevations. But whether the proposed flood elevations needed to be issued as regulations was never mentioned in the extensive hearings.

The evidence indicates that publication in the **Federal Register,** which is just one means of the required notice (the other two being letter to the CEO and publication in the local newspaper), was being used to ensure all stakeholders had notice, since publication of a document in the **Federal Register** is considered constructive notice to anyone subject to or affected by the document so published. *See* 44 U.S.C. 1507. Viewing this issue in context of the hearings, and within the context of the statute (42 U.S.C. 4104) and the regulatory text of section 67.4 (both of which list 3 types of notice), the main reason for publication in the **Federal Register** was clearly for notification purposes only. Further, the flood elevation determinations are very specific to a certain locality; regulations usually apply more broadly.

FEMA concludes that the statute does not require that the determinations must take the form of a regulation; rather, the requirement of publication in the **Federal Register** is for notice purposes only. The statute and regulations give FEMA the authority to issue flood elevation determinations that are legally binding on the affected communities, as long as there is notice and comment afforded to those communities. It is not necessary to include specific flood elevations for affected flooding sources in feet/meters in the Code of Federal Regulations. The flood elevations themselves do not need to be codified as regulations for them to have legal effect. Absent a legal requirement to publish flood elevations as rules, FEMA now plans to publish proposed and final flood elevation determinations as notices rather than as rules, which is administratively less burdensome.

The information provided in the BFE notices will be less detailed than the information FEMA currently provides in the BFE rules. FEMA will no longer list in the **Federal Register** specific location descriptions (*e.g.,* Sawmill Creek approximately 400 feet upstream of Laurel Fort Meade Road) or specific flood elevations of the base flood (*e.g.,* + 613 feet) for each flooding source. Instead, the **Federal Register** notice will indicate which geographical areas are affected (county, town, etc.) and provide both a physical address and an internet address where the specific flood elevations (as depicted in a Flood Insurance Rate Map (FIRM) and/or a Flood Insurance Study (FIS) report) can be viewed for that geographical location.

This new procedure will *not* apply to any proposed BFE rules that are outstanding as of the effective date of this notice (December 1, 2011). FEMA will close those proposed rules out with final rules, as required by the Administrative Procedure Act, 5 U.S.C. 553.

This new procedure will also apply to certain Letters of Map Revision (LOMRs). A LOMR is a type of determination that FEMA issues under the authority of 44 CFR part 65. It may include changes to the technical content (*e.g.,* additions or modifications to BFEs) or changes to the administrative content (*e.g.,* corrections to typographical errors) of a published FIRM or FIS report. The flood elevation determinations associated with LOMRs that affect the technical content of the FIRM or FIS report are published in the **Federal Register** pursuant to 44 CFR part 67. As explained above, the notice required by part 67 does not require that the notice take the form of a rule. Notice of changes in flood elevation determinations may be published as notices rather than rules. Therefore, as with BFE determinations for Flood Insurance Studies, FEMA will issue flood elevation determinations associated with LOMRs as notices rather than rules as of December 1, 2011.

Change in Procedure for Other Types of Flood Elevation Determinations (Special Flood Hazard Areas and Regulatory Floodways)

In addition to BFE determinations, FEMA also issues other types of flood hazard determinations including new and modified Special Flood Hazard Areas (SFHAs) and new and modified regulatory floodways. SFHAs are areas subject to inundation by the base flood and include the following flood insurance risk zone designations: A, AO, AH, A1–30, AE, A99, AR, AR/A1–30, AR/AE, AR/AO, AR/AH, AR/A, VO, V1–30, VE, and V. The various flood insurance risk zones represent different levels of risk and the type of flood hazard (*e.g.,* coastal, riverine, ponding areas, etc.). The regulatory floodway is the channel of a river or other watercourse and the adjacent land areas that must be reserved in order to discharge the base flood without cumulatively increasing the water-surface elevation more than a designated height.

Under current practice, new or modified SFHAs or regulatory floodways not specifically related to changes in BFE determinations are not appealable under 44 CFR 67.8. For that reason, FEMA has not published notification of new and modified SFHAs and regulatory floodways in the **Federal Register** pursuant to 44 CFR 67.4 and 67.11.

As of the effective date of this notice (December 1, 2011), FEMA will publish notification of new or modified SFHAs

or regulatory floodways in the **Federal Register** pursuant to 44 CFR 67.4 and 67.11, and will allow appeals of those notices pursuant to 44 CFR 67.8. As with the BFE notices, the **Federal Register** notices for new or modified SFHAs or regulatory floodways will indicate which geographical areas are affected (county, town, etc.) and provide both a physical address and an internet address where the specific flood hazards (as shown in a Flood Insurance Rate Map (FIRM) and/or a Flood Insurance Study report) can be viewed for that geographical location.

As with appeals of BFE determinations, appeals of SFHA and regulatory floodway determinations must include supporting scientific and technical data certified by a registered professional engineer or licensed land surveyor pursuant to 44 CFR 67.6.

Authority: 42 U.S.C. 4104; 44 CFR parts 65 and 67.

Sandra K. Knight,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2011–30545 Filed 11–25–11; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4043–DR; Docket ID FEMA–2011–0001]

Vermont; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Vermont (FEMA–4043–DR), dated November 8, 2011, and related determinations.

DATES: *Effective Date:* November 8, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated November 8, 2011, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Vermont resulting from severe storms and flooding on May 20, 2011, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Vermont.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James N. Russo, of FEMA, is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Vermont have been designated as adversely affected by this major disaster:

Franklin, Washington, and Windham Counties for Public Assistance.

All counties within the State of Vermont are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–30465 Filed 11–25–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4042–DR; Docket ID FEMA–2011–0001]

Virginia; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Commonwealth of Virginia (FEMA–4042–DR), dated November 4, 2011, and related determinations.

DATES: *Effective Date:* November 4, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated November 4, 2011, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the Commonwealth of Virginia resulting from an earthquake during the period of August 23 to October 25, 2011, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the Commonwealth of Virginia.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas and Hazard Mitigation throughout the Commonwealth. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for

a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Donald L. Keldsen, of FEMA, is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the Commonwealth of Virginia have been designated as adversely affected by this major disaster:

Louisa County for Individual Assistance.

All counties and independent cities in the Commonwealth of Virginia are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–30464 Filed 11–25–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4044–DR; Docket ID FEMA–2011–0001]

District of Columbia; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the District of Columbia (FEMA–4044–DR), dated November 8, 2011, and related determinations.

DATES: *Effective Date:* November 8, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated November 8, 2011, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the District of Columbia resulting from an earthquake during the period of August 23–28, 2011, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the District of Columbia.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation in the District of Columbia. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Kim R. Kadesch, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the District of Columbia have been designated as adversely affected by this major disaster:

The District of Columbia for Public Assistance.

The District of Columbia is eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–30453 Filed 11–25–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4030–DR; Docket ID FEMA–2011–0001]

Pennsylvania; Amendment No. 6 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Pennsylvania (FEMA–4030–DR), dated September 12, 2011, and related determinations.

DATES: *Effective Date:* November 17, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Pennsylvania is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of September 12, 2011.

Adams, Chester, and Northampton Counties for Public Assistance (already designated for Individual Assistance).

Lackawanna and Mifflin Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–30468 Filed 11–25–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4042–DR; Docket ID FEMA–2011–0001]

Virginia; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Virginia (FEMA–4042–DR), dated November 4, 2011, and related determinations.

DATES: *Effective Date:* November 10, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Virginia is hereby amended to include the Public Assistance program for the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of November 4, 2011.

Louisa County for Public Assistance (already designated for Individual Assistance).

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–30467 Filed 11–25–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4012–DR; Docket ID FEMA–2011–0001]

Missouri; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of Missouri (FEMA–4012–DR), dated August 12, 2011, and related determinations.

DATES: *Effective Date:* November 10, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Stephen R. Thompson, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Michael L. Karl as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–30466 Filed 11–25–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1980–DR; Docket ID FEMA–2011–0001]

Missouri; Amendment No. 10 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of Missouri (FEMA–1980–DR), dated May 9, 2011, and related determinations.

DATES: *Effective Date:* November 10, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Stephen R. Thompson, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Michael L. Karl as Federal Coordinating Officer for this disaster.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–30452 Filed 11–25–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Aviation Security Advisory Committee (ASAC) Meeting

AGENCY: Transportation Security Administration, DHS.

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Transportation Security Administration (TSA) will hold a meeting of the Aviation Security Advisory Committee (ASAC) via telephone conference on December 15, 2011, to establish working groups and set the agenda for future activity. This meeting will be open to the public.

DATES: The Committee will meet on Thursday, December 15, 2011, from 1–3:30 p.m. Eastern Standard Time (EST). This meeting may end early if all business is completed.

ADDRESSES: The Committee will meet via telephone conference, on December 15, 2011. There will be 100 teleconference lines to accommodate committee members, staff and public participation. To participate via telephone conference, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Dean Walter, ASAC Designated Federal Officer, Transportation Security Administration (TSA–28), 601 12th St. South, Arlington, VA 20598–4028, *Dean.Walter@dhs.gov,* (571) 227–2645.

SUPPLEMENTARY INFORMATION:

Summary

Notice of this meeting is given under section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463). ASAC operates under the authority of 46 U.S.C. 70112 and provides advice, consults with, and makes recommendations to the Secretary of Homeland Security, via the Administrator of TSA on matters affecting civil aviation security.

This meeting is open to the public, but participation is limited to 100 telephone lines to accommodate all participants. Members of the public must make advance arrangements to present oral statements at the meeting. The public comment period will be held during the meeting on December 15, 2011, from approximately 3 to 3:30 p.m. EST, depending on the meeting progress. Speakers are requested to limit their comments to two minutes. Please note that the public comment period will end following the last call for comments. Written statements may also be presented to the Committee. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to register as a speaker or submit written statements no later than December 8, 2011. Anyone in need of assistance or a reasonable accommodation for the meeting should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Agenda

The agenda for the meeting is as follows:

(1) Welcome and introductions
(2) Charter and By Laws
(3) Overview of aviation security
(4) Presentations:
  a. Risk-based screening
  b. General Aviation airport security guidelines
  c. Air Cargo security update
(5) Working group formation; areas for consideration
(6) Public comments
(7) Discussion of topics for future meetings and next steps
(8) Closing statements

Issued in Arlington, Virginia, on November 22, 2011.

John P. Sammon,

Assistant Administrator, Transportation Sector Network Management.

[FR Doc. 2011–30558 Filed 11–25–11; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–602; Extension of an Existing Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review; Form I–602, Application by Refugee for Waiver of Grounds of Excludability; OMB Control No. 1615–0069.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal Register** on August 19, 2011, at 76 FR 51997, allowing for a 60-day public comment period. USCIS received comments from one commenter in response to the 60-day notice. A discussion of the comments and USCIS' responses are addressed in item 8 of the supporting statement that can be viewed at: *http://www.regulations.gov.*

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until December 28, 2011. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), USCIS Desk Officer. Comments may be submitted to: Sunday Aigbe, Chief, Regulatory Products Division, Office of the Executive Secretariat, USCIS, 20 Massachusetts Avenue NW., Washington, DC 20529–2020. Comments may also be submitted to DHS via facsimile to (202) 272–8352 or via email at *USCISFRComment@dhs.gov,* and OMB USCIS Desk Officer via facsimile at (202) 395–5806 or via *oira_submission@omb.eop.gov.* When submitting comments by email please make sure to add OMB Control Number 1615–0069 in the subject box.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the 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:* Application by Refugee for Waiver of Grounds of Excludability.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–602; 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. The Application by Refugee for Waiver of Grounds of Excludability, Form I–602, is necessary to establish eligibility for waiver of excludability based on humanitarian, family unity, or public interest.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 2,500 responses at 15 minutes (.25) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 625 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: *http://www.regulations.gov*.

If additional information is required contact: USCIS, Regulatory Products Division, Office of the Executive Secretariat, 20 Massachusetts Avenue NW., Washington, DC 20529–2020, telephone (202) 272–8377.

Dated: November 22, 2011.

Sunday Aigbe,

Chief, Regulatory Products Division, Office of the Executive Secretariat, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2011–30516 Filed 11–25–11; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Statement of Findings: Soboba Band of Luiseño Indians Settlement Act of 2008

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: The Secretary of the Interior is publishing this notice as required by section 10(a) of the Soboba Band of Luiseño Indians Settlement Act of 2008, Public Law 110–297, 122 Stat. 2975, 2983 (Settlement Act). The publication of this notice causes certain waivers and releases of claims to become effective as required by the Settlement Act.

DATES: *Effective Date:* In accordance with section 10(a) of the Settlement Act, the waivers and releases of claims described in section 8(a) of the Settlement Act, as well as those described in article 5 of the Settlement Agreement ratified by the Settlement Act, are effective on November 28, 2011.

FOR FURTHER INFORMATION CONTACT: Address all comments and requests for additional information to Robert Laidlaw, Senior Policy Analyst, United States Department of the Interior, 1849 C Street NW., Room 3517, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: The Settlement Act approves, ratifies, and confirms the Settlement Agreement entered into by the settlement parties, including the United States on behalf of the Tribe, the Tribe, the Metropolitan Water District of Southern California, Eastern Municipal Water District, and Lake Hemet Municipal Water District. The Settlement Act, which Congress enacted on July 31, 2008, determines the Tribe's water rights; resolves the Tribe's claims for interference with the water resources of, and damages to, the Tribe's Reservation; provides for construction of certain water projects to facilitate exercise of the Tribe's water rights secured by the Settlement Act; and resolves outstanding litigation.

Section 10(b) of the Settlement Act and article 3.3 of the Settlement Agreement provide that the Settlement Act and the Settlement Agreement shall be null and void if certain conditions are not fulfilled on or before March 1, 2012. The publication of this notice and the Statement of Findings below confirm that the conditions required by section 10(a) of the Settlement Act and article 3 of the Settlement Agreement have been fulfilled. Accordingly, the waivers and releases executed pursuant to section 8(a) of the Settlement Act and article 5 of the Settlement Agreement are effective as of November 28, 2011.

Statement of Findings

In accordance with section 10(a) of the Settlement Act and article 3.1 of the Settlement Agreement, I find as follows:

1. The Settlement Act was enacted on July 31, 2008.

2. To the extent that the Settlement Agreement conflicted with the Act, the Settlement Agreement has been revised to conform to the Act.

3. The Settlement Agreement, revised as necessary, and the waivers and releases described in article 5 of the Settlement Agreement and section 8(a) of the Settlement Act have been executed by the parties and by the Secretary.

4. Warranty deeds for the property to be conveyed to the Tribe described in article 4.6 of the Settlement Agreement have been placed in escrow and, in accordance with the Settlement Agreement, shall be delivered to the Tribe on the first business day following the Effective Date (*i.e.,* publication of this notice).

5. The Tribe and the Secretary have approved the Water Management Plan developed pursuant to article 4.8.A of the Settlement Agreement.

6. A judgment and decree substantially the same as Exhibit H to the Settlement Agreement has been approved by the United States District Court, Eastern Division of the Central District of California, and that judgment and decree has become final and non-appealable.

Dated: October 27, 2011.

Ken Salazar,

Secretary of the Interior.

[FR Doc. 2011–30440 Filed 11–25–11; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R9–IA–2011–N249; 96300–1671–0000–P5]

Endangered Species; Marine Mammals; Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have issued the following permits to conduct certain activities with endangered species, marine mammals, or both. We issue these permits under the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA).

ADDRESSES: Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358–2280; or Email *DMAFR@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2280 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION: On the dates below, as authorized by the provisions of the ESA (16 U.S.C. 1531 *et seq.*), as amended, and/or the MMPA,

as amended (16 U.S.C. 1361 *et seq.*), we issued requested permits subject to certain conditions set forth therein. For each permit for an endangered species, we found that (1) The application was filed in good faith, (2) The granted permit would not operate to the disadvantage of the endangered species, and (3) The granted permit would be consistent with the purposes and policy set forth in section 2 of the ESA.

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
46259A	Jefferey Spivery	76 FR 54480; September 1, 2011	November 2, 2011.
52683A	Carlos Ramirez	76 FR 60862; September 30, 2011	November 3, 2011.
50923A	Woolsey Caye	76 FR 60862; September 30, 2011	November 3, 2011.
49805A	Graham Banes	76 FR 57757; September 16, 2011	November 10, 2011.
Marine Mammals			
100361	Mote Marine Laboratory	76 FR 18239; April 1, 2011	November 9, 2011.

Availability of Documents

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2011–30249 Filed 11–25–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Proclaiming Certain Lands as Reservation for the Fort Sill Apache Indian Tribe

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Reservation Proclamation.

SUMMARY: This notice informs the public that the Assistant Secretary—Indian Affairs proclaimed approximately 30.00 acres, more or less, as the Fort Sill Apache Indian Reservation for the Fort Sill Apache Tribe of Indians.

FOR FURTHER INFORMATION CONTACT: Ben Burshia, Bureau of Indian Affairs, Division of Real Estate Services, Mail Stop-4639–MIB, 1849 C Street NW., Washington, DC 20240, telephone (202) 208–7737.

SUPPLEMENTARY INFORMATION: This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by part 209 of the Departmental Manual.

A proclamation was issued according to the Act of June 18, 1934 (48 Stat. 986; 25 U.S.C. 467), for the land described below. The land was proclaimed to be an addition to and part of the reservation of the Fort Sill Apache Indian Reservation for the exclusive use of Indians entitled by enrollment or by tribal membership to residence at such reservation.

New Mexico Principal Meridian

Luna County, New Mexico

That part of the North half (N1/2) of Section Eleven (11), lying north of the Interstate 10 right-of-way, Township Twenty-four (24) south, Range Six (6) west, N.M.P.M., Luna County, New Mexico, being described as follows:

BEGINNING at a spike in the center of an abandoned asphalt roadway at the Northeast corner of said Section 11 and Northeast corner of this tract:

Thence S. 0°21′53″ W., along the east line of Section 11, a distance of 500.76 feet to a No. 5 steel rod at the Southeast corner of this tract and on the North boundary of the Interstate 10 right-of-way;

Thence adjoining the North boundary of said I–10 right-of-way through the following courses and distances; along a curve to the left from a tangent which bears N. 89°56′18″ W., having a radius of 789.30 feet, a delta angle of 32°47′40″, a chord which bears S. 73°39′52″ W., 445.63 feet through an arc length of 451.77 feet to I–10 P.C. marker 10+30.62;

Thence S. 57°12′44″ W., a distance of 231.01 feet to I–10 P.T. marker 8+00;

Thence along a curve to the right from a tangent which bears S. 57°16′8″ W., having a radius of 1096.00 feet, a delta angle of 39°58′50″, a chord which bears S. 77°15′43″ W., 749.36 feet, through an arc length of 764.78 feet to I–10 P.C. marker 45+11.53;

Thence N. 82°45′27″ W., a distance of 340.58 feet to a No. 5 steel rod at the Southwest corner of this tract;

Thence N. 0°21′53″ E., along a line parallel with the east line of Section 11, a distance of 871.49 feet to a No. 5 steel rod at the Northwest corner of this tract;

Thence N. 89°55′55″ E., along the North line of Section 11, a distance of 1688.27 feet to the point of beginning.

The above-described lands contain a total of 30.00 acres, more or less, which is subject to all valid rights, reservations, rights-of-way, and easements of record.

This proclamation does not affect title to the land described above, nor does it affect any valid existing easements for public roads and highways, public utilities and for railroads and pipelines and any other rights-of-way or reservations of record.

Dated: November 16, 2011.

Larry Echo Hawk,

Assistant Secretary—Indian Affairs.

[FR Doc. 2011–30576 Filed 11–25–11; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLUT980300–L12100000–PH0000–24–1A]

Call for Nominations for the Utah Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The purpose of this notice is to request public nominations to fill one position on the Utah Resource Advisory Council (RAC) in category three (representatives of state, county, or local elected office; employees of a state agency responsible for management of natural resources; representatives of Indian tribes within or adjacent to the area for which the council is organized; representatives of academia who are employed in natural sciences; or the public-at-large).

DATES: All nominations must be received no later than December 28, 2011.

ADDRESSES: Nominations should be sent to Sherry Foot, Special Programs Coordinator, Utah State Office, Bureau of Land Management, 440 West 200 South, Suite 500, Salt Lake City, UT 84101.

FOR FURTHER INFORMATION CONTACT: Sherry Foot, Special Programs Coordinator, Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, UT 84101; phone (801) 539–4195; or email *sfoot@blm.gov*.

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, seven 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 Federal Land Policy and Management Act (FLPMA) directs the Secretary of the Interior to involve the public in planning and issues related to management of lands administered by the Bureau of Land Management (BLM). Section 309 of FLPMA directs the Secretary to establish 10- to 15-member citizen-based advisory councils that conform to the requirements of the Federal Advisory Committee Act (FACA). RAC membership must be balanced and representative of the various interests concerned with the land use planning and/or management of the public lands.

The BLM's Utah RAC is hosting a call for nominations for a position in category three (description addressed in the **SUMMARY** above, (43 CFR 1784.6–1(c)(3)). Upon appointment, the individual selected will fill the position until January 12, 2015. Nominees must be residents of Utah. BLM will evaluate nominees based on their education, training, experience, and their knowledge of the geographical area. Nominees should demonstrate a commitment to collaborative resource decision making. The Obama Administration prohibits individuals who are currently Federal-registered lobbyists to serve on all FACA and non-FACA boards, committees, or councils. The following must accompany all nominations:

—Letters of reference from represented interest or organizations,

—A completed background information nomination form; and,

—Any other information that addresses the nominee's qualifications.

Simultaneous with this notice, the BLM Utah State Office will issue a press release providing additional information for submitting nominations.

Shelley J. Smith,

Acting State Director.

[FR Doc. 2011–30493 Filed 11–25–11; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCA 942000 L57000000 BX0000]

Filing of Plats of Survey: California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey and supplemental plats of lands described below are scheduled to be officially filed in the Bureau of Land Management California State Office, Sacramento, California, thirty (30) calendar days from the date of this publication.

ADDRESSES: A copy of the plats may be obtained from the California State Office, Bureau of Land Management, 2800 Cottage Way, Sacramento, California 95825, upon required payment.

Protest: A person or party who wishes to protest a survey must file a notice that they wish to protest with the California State Director, Bureau of Land Management, 2800 Cottage Way, Sacramento, California, 95825.

FOR FURTHER INFORMATION CONTACT: Chief, Branch of Geographic Services, Bureau of Land Management, California State Office, 2800 Cottage Way, Room W–1623, Sacramento, California 95825, (916) 978–4310.

SUPPLEMENTARY INFORMATION: These surveys and supplemental plats were executed to meet the administrative needs of various federal agencies; the Bureau of Land Management, Bureau of Indian Affairs, General Services Administration or U.S. Forest Service. The lands surveyed are:

Humboldt Meridian, California

T. 10 N., R. 3 E., dependent resurvey and subdivision of sections 7 and 8 accepted October 14, 2011.

Mount Diablo Meridian, California

T. 15 S., R. 36 E., dependent resurvey and subdivision of section 32 accepted October 12, 2011.

T. 14 N., R. 4 W., dependent resurvey and metes-and bounds survey accepted October 17, 2011.

T. 6 S., R. 2 W., supplemental plat accepted November 3, 2011.

Authority: 43 U.S.C., Chapter 3.

Dated: November 7, 2011.

Lance J. Bishop,

Chief Cadastral Surveyor, California.

[FR Doc. 2011–30579 Filed 11–25–11; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L98200000–BJ0000–LXCSMT010000]

Notice of Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on December 28, 2011.

DATES: Protests of the survey must be filed before December 28, 2011 to be considered.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Marvin Montoya, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5124 or (406) 896–5009, *Marvin_Montoya@blm.gov*. 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: This survey was executed at the request of the Forest Supervisor, U.S. Forest Service, Flathead National Forest, Kalispell, Montana, and was necessary to determine federal interest lands.

The lands we surveyed are:

Principal Meridian, Montana

T. 36 N., R. 22 W.

The plat, in one sheet, representing the corrective dependent resurvey of a portion of the section line between sections 2 and 11 and a portion of the subdivision of section 11, the dependent resurvey of a portion of the subdivision of section 11, and the survey of a portion of a warranty deed in Township 36

North, Range 22 West, Principal Meridian, Montana, was accepted November 17, 2011.

We will place a copy of the plat, in one sheet, and related field notes we described in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in one sheet, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in one sheet, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Authority: 43 U.S.C. Chap. 3.

James D. Claflin,

Chief Cadastral Surveyor, Division of Resources.

[FR Doc. 2011–30588 Filed 11–25–11; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF INTERIOR

Bureau of Land Management

[LLCOF03003L12200000.FU0000]

Notice of Intent to Collect Fees on Public Land in Alamosa County, CO

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Intent.

SUMMARY: Pursuant to applicable provisions of the Federal Lands Recreation Enhancement Act (REA), the Bureau of Land Management (BLM) La Jara Field Office is proposing to collect fees at the Zapata Falls Campground in Alamosa County, Colorado (Township 28S, Range 73W, Section 17). Under Section 2(2) of the REA, Zapata Falls Campground qualifies as a site wherein visitors can be charged an ''Expanded Amenity Recreation Fee'' authorized under section 3(g). In accordance with the REA, and the BLM's implementing regulations, the La Jara Field Office is proposing to charge $11 per night for individual sites and $20 per night for group-site fees for overnight camping within the developed campground.

DATES: This notice initiates the public comment period. Comments on issues may be submitted in writing by December 28, 2011. New fee implementation is contingent on a recommendation of the Colorado Front Range Resource Advisory Council (RAC) review. Per the REA, effective 6 months after the publication of this notice, and dependent on review and an affirmative recommendation by the Colorado Front Range RAC and modification approval from the BLM Colorado State Director. To meet the terms of a RAC recommendation, the La Jara Field Office will provide final public notice under REA and initiate fee collection at the Zapata Falls Campground.

ADDRESSES: You may submit comments related to the proposed fee collection at Zapata Falls Campground by any of the following methods:

- *Web site: http://www.blm.gov/co/st/en/fo/slvplc.html.*
- *Email: snoonan@blm.gov.*
- *Fax:* (719) 655–2502.
- *Mail:* BLM, Saguache Field Office, 46525 State Hwy. 114, Saguache, CO 81149.

FOR FURTHER INFORMATION CONTACT: Sean Noonan, Outdoor Recreation Planner; telephone (719) 655–6136; see address above; email snoonan@blm.gov.

SUPPLEMENTARY INFORMATION: The Zapata Falls Campground was built in 2010 with American Recovery and Reinvestment Act funding. The campground has one camp host site, one group site, and 23 individual sites divided between a tent camping loop and an RV camping loop. The site includes water, restrooms, trails and signs. Pursuant to the REA and implementing regulations at 43 CFR subpart 2933, fees may be charged for overnight camping. Specific visitor fees will be identified and posted at the site and the La Jara Field Office. Fees must be paid at the self-service pay station located at the site. People holding the America The Beautiful—The National Parks and Federal Recreational Lands—Senior Pass (i.e., Interagency Senior Pass), a Golden Age Passport, the America the Beautiful—The National Parks and Federal Recreational Lands—Access Pass (i.e, Interagency Access Pass), or a Golden Access Passport will be entitled to a 50 percent reduction on all overnight camping fees. The BLM is committed to providing and receiving fair value for the use of developed recreation facilities and services in a manner that meets public-use demands, provides for quality experiences, and protects important resources. The BLM's policy is to collect fees at all specialized recreation sites, or where the BLM provides facilities, equipment or services, at Federal expense, in connection with outdoor use as authorized by the REA. Implementing a fee program for the campground will help ensure that funding is available to accomplish deferred maintenance, make future enhancements, maintain facilities and recreational opportunities, provide for law enforcement presence, develop additional services, and protect resources. Campground development is consistent with the 1991 San Luis Resource Area Resource Management Plan, the 2009 Zapata Falls Recreation Area Management Plan, and was analyzed in the Zapata Falls Campground Construction Project Environmental Assessment, CO–140–2009–017–EA. Proposed fees at the Zapata Falls Campground are consistent with other established fee sites in the area, including other BLM-administered sites and those managed by the United States Department of Agriculture Forest Service, United States Department of the Interior National Park Service, and Colorado Parks and Wildlife. The REA was signed into law in December 2004. The REA provides authority for the Secretaries of the Interior and Agriculture to establish, modify, charge and collect recreation fees for use of some Federal recreation lands and waters for 10 years, and contains specific provisions addressing public involvement in the establishment of recreation fees, including a requirement that Recreation Resource Advisory Committees or BLM RACs have the opportunity to make recommendations regarding establishment of such fees. The REA also directed the secretaries of the Interior and Agriculture to publish advance notice in the **Federal Register** before new recreation fee areas are established under their respective jurisdictions. In accordance with the BLM recreation fee program policy, the La Jara Field Office's Zapata Falls Campground recreation fee business plan is available at the La Jara Field Office and the BLM Colorado State Office. The business plan explains both the fee collection process and how the fees will be used at the campground. The BLM notified and involved the public at each stage of the planning process, including the proposal to collect fees. The BLM Colorado Front Range RAC has previously reviewed the fee proposal and unanimously recommended approval of the proposal at its January 12, 2011, meeting. This review did not meet the terms of the REA Review because, at the time, the REA review requirements were being fulfilled by the United States Forest Service Recreation RAC, which did not convene in time to review or recommend the proposal. The BLM welcomes public comments on this proposal. Please send comments to Sean Noonan by email at: *snoonan@blm.gov.*

Before including your address, phone number, email address, or other personal identifying information in your comment, you should 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.

Authority: 16 U.S.C. 6803(b).

Helen M. Hankins,

State Director.

[FR Doc. 2011–30470 Filed 11–25–11; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAC09000.L58790000.EU0000. LXSS008B0000; CACA 50168]

Notice of Realty Action: Competitive Sale of Public Land in Santa Clara County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action.

SUMMARY: The Bureau of Land Management (BLM), Hollister Field Office, proposes to sell a parcel of public land totaling approximately 23.42 acres, more or less, in Santa Clara County, California. The public land would be sold for appraised fair market value. The appraised value of the public land is $135,000.

DATES: Comments regarding the proposed sale must be received by the BLM on or before January 12, 2012.

ADDRESSES: Written comments concerning the proposed sale should be sent to the Field Manager, BLM, Hollister Field Office, 20 Hamilton Court, Hollister, California 95023.

FOR FURTHER INFORMATION CONTACT: Christine Sloand, Realty Specialist, BLM, Hollister Field Office, 20 Hamilton Court, Hollister, California 95023, or phone (831) 630–5022.

SUPPLEMENTARY INFORMATION: The following public land is proposed for competitive sale in accordance with Sections 203 and 209 of the Federal Land Policy and Management Act of 1976 (FLPMA), as amended (43 U.S.C. 1713 and 1719).

Mount Diablo Meridian

T. 10 S., R. 2 E.,
Sec. 5, lot 2.

The area described contains 23.42 acres, more or less, in Santa Clara County, California.

Appraised fair market value: $135,000.

The public land was first identified as suitable for disposal in the 1984 BLM Hollister Resource Management Plan (RMP) and remains available for sale under the 2007 Hollister RMP revision. The land is not needed for any other Federal purpose, and its disposal would be in the public interest. The land is difficult and uneconomic to manage as part of the public lands because it lacks legal access and is isolated from other public lands. The BLM has concluded the public interest would be best served by a competitive sale. The BLM has completed a mineral potential report which concluded there are no known mineral values in the land proposed for sale. The BLM proposes that conveyance of the Federal mineral interests would occur simultaneously with the sale of the land. The purchaser would be required to pay a $50 nonrefundable filing fee for the conveyance of the mineral interests.

On November 28, 2011, the above described land will be segregated from appropriation under the public land laws, including the mining laws, except for the sale provisions of FLPMA. Until completion of the sale, the BLM will no longer accept land use applications affecting the identified public land, except applications for the amendment of previously filed right-of-way applications or existing authorizations to increase the term of the grants in accordance with 43 CFR 2802.15 and 2886.15. The segregation will terminate upon issuance of a patent, publication in the **Federal Register** of a termination of the segregation, or on November 28, 2013, unless extended by the BLM State Director in accordance with 43 CFR 2711.1–2(d) prior to the termination date. The land would not be sold until at least January 27, 2012. Any patent issued would contain the following terms, conditions, and reservations:

1. A reservation of a right-of-way to the United States for ditches and canals constructed by authority of the United States under the Act of August 30, 1890 (43 U.S.C 945);

2. A condition that the conveyance be subject to all valid existing rights of record;

3. An appropriate indemnification clause protecting the United States from claims arising out of the patentee's use, occupancy, or operations on the patented lands;

4. Additional terms and conditions that the authorized officer deems appropriate.

Detailed information concerning the proposed sale including the appraisal, planning and environmental documents, and mineral report are available for review at the location identified in **ADDRESSES** above.

Public Comments regarding the proposed sale may be submitted in writing to the attention of the BLM Hollister Field Manager (see **ADDRESSES** above) on or before January 12, 2012. Comments received in electronic form, such as email will not be considered. Any adverse comments regarding the proposed sale will be reviewed by the BLM State Director or other authorized official of the Department of the Interior, who may sustain, vacate, or modify this realty action in whole or in part. In the absence of timely filed objections, this realty action will become the final determination of the Department of the Interior. Before including your address, phone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

Authority: 43 CFR 2711.1–2(a) and (c)

Tom Pogacnik,

Deputy State Director for Natural Resources.

[FR Doc. 2011–30491 Filed 11–25–11; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection for 1029–0035

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request renewed approval for the collection of information for surface and underground mining permit applications—minimum requirements for information on environmental resources.

DATES: Comments on the proposed information collection must be received by January 27, 2012, to be assured of consideration.

ADDRESSES: Comments may be mailed to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203—SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease, at (202) 208–2783, or by email at *jtrelease@osmre.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8 (d)]. This notice identifies an information collection that OSM will be submitting to OMB for renewed approval. This collection is contained in 30 CFR parts 779 and 783—Surface and Underground Mining Permit Applications—Minimum Requirements for Information on Environmental Resources. OSM will request a 3-year term of approval for this information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control number for parts 779 and 783 is 1029–0035. Responses are required to obtain a benefit for this collection.

OSM has revised burden estimates, where appropriate, to reflect current reporting levels or adjustments based on Creestimates of burden on respondents and costs.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice provides the public with 60 days in which to comment on the following information collection activity:

Title: 30 CFR Parts 779 and 783—Surface and Underground Mining Permit Applications—Minimum Requirements for Environmental Resources.

OMB Control Number: 1029–0035.

Summary: Applicants for surface and underground coal mining permits are required to provide adequate descriptions of the environmental resources that may be affected by proposed mining activities. The information will be used by the regulatory authority to determine if the applicant can comply with environmental protection performance standards.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: 219 coal mining operators and 24 state regulatory authorities.

Total Annual Responses: 2,175.

Total Annual Burden Hours: 188,816.

Total Annual Non-Wage Burden Cost: $0.

Dated: November 18, 2011.

Stephen M. Sheffield,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2011–30345 Filed 11–25–11; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Clean Water Act and Safe Drinking Water Act

Notice is hereby given that on November 21, 2011, a proposed Consent Decree (''proposed Decree'') in *United States, et al.* v. *Town of Fort Gay,* Civil Action No. 3:09–0855 was lodged with the United States District Court for the Southern District of West Virginia.

On September 21, 2009, the United States and the West Virginia Department of Environmental Protection and West Virginia Department of Health and Human Resources (collectively, ''Plaintiffs'') filed a complaint against the Town of Fort Gay, West Virginia (''Defendant'' or ''Fort Gay'') for permanent injunctive relief and civil penalties under the Clean Water Act, 33 U.S.C. 1251–387; the Safe Drinking Water Act, 42 U.S.C. 300f–300j–26; the West Virginia Water Pollution Control Act, W.Va Code § 22–11–22; and Chapter 16, Article I, Section 9a of the West Virginia Code.

The proposed Decree requires Defendant to comply with certain permit requirements, to prepare and submit certain reports, to make capital improvements to the Fort Gay waste water collection and treatment system and drinking water treatment system (collectively, the ''Facilities''), and to improve staffing at the Facilities. The proposed Decree appoints the County Commission of Wayne County, West Virginia as Receiver of the Facilities.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either emailed 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, et al.* v. *Town of Fort Gay,* D.J. Ref. 90–5–1–1–09447.

During the public comment period, the proposed Decree may be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed 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 emailing 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 in the amount of $20.75 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by email or fax, please forward a check in that amount to the Consent Decree Library at the stated address.

Robert Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–30422 Filed 11–25–11; 8:45 am]

BILLING CODE 4410–15–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 18, 2011, Aldrich Chemical Company Inc., DBA Isotec, 3858 Benner Road, Miamisburg, Ohio 45342–4304, 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
Methaqualone (2565)	I
Ibogaine (7260)	I
Tetrahydrocannabinols (7370)	I
2,5-Dimethoxyamphetamine (7396).	I
Psilocyn (7438)	I
Normorphine (9313)	I
Acetylmethadol (9601)	I
Alphacetylmethadol except levo–alphacetylmethadol (9603).	I
Normethadone (9635)	I
Norpipanone (9636)	I
3-Methylfentanyl (9813)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
1-Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II
Phenylacetone (8501)	II
1-Piperidinocyclohexanecarbonitrile (8603).	II
Cocaine (9041)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Benzoylecgonine (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Isomethadone (9226)	II
Meperidine (9230)	II
Meperidine intermediate-A (9232)	II
Meperidine intermediate-B (9233)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Dextropropoxyphene, bulk, (non-dosage forms) (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II

The company plans to manufacture small quantities of the listed controlled substances to produce isotope labeled standards for drug testing and analysis.

In reference to drug code 7370 the company plans to bulk manufacture a synthetic Tetrahydrocannabinol. 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 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 January 27, 2012.

Dated: November 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–30542 Filed 11–25–11; 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 September 9, 2011, Johnson Matthey Inc., Custom Pharmaceuticals Department, 2003 Nolte Drive, West Deptford, New Jersey 08066–1742, 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
Tetrahydrocannabinols (7370)	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Propiram (9649)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Nabilone (7379)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers.

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 January 27, 2012.

Dated: November 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–30551 Filed 11–25–11; 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 September 15, 2011, Johnson Matthey Pharmaceutical Materials Inc., Pharmaceutical Service, 25 Patton Road, Devens, Massachusetts 01434, 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
Nabilone (7379)	II
Hydrocodone (9193)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	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.

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 January 27, 2012.

Dated: November 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–30547 Filed 11–25–11; 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 March 30, 2010, Mallinckrodt Inc., 675 McDonnell Blvd., Hazelwood, Missouri 63042, made application 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
4-Anilino-N-phenethyl-4-piperidine (8333).	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	II

The company plans to manufacture the listed controlled substances as bulk controlled substances intermediates for distribution to its customers.

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 January 27, 2012.

Dated: November 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–30544 Filed 11–25–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances Notice of Registration

By Notice dated June 1, 2011 and published in the **Federal Register** on June 9, 2011, 76 FR 33785, Alltech Associates Inc., 2051 Waukegan Road, Deerfield, Illinois 60015, 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
Methcathinone (1237)	I
N-Ethylamphetamine (1475)	I
N,N-Dimethylamphetamine (1480)	I
4-Methylaminorex (cis isomer) (1590)	I
Alpha-ethyltryptamine (7249)	I
Lysergic acid diethylamide (7315)	I
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (7348)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
4-Bromo-2,5-dimethoxyamphetamine (7391)	I
4-Bromo-2,5-dimethoxyphenethylamine (7392)	I
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5-Dimethoxyamphetamine (7396)	I
2,5-Dimethoxy-4-ethylamphetamine (7399)	I
3,4-Methylenedioxyamphetamine (7400)	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402)	I
3,4-Methylenedioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxymethamphetamine (7405)	I
4-Methoxyamphetamine (7411)	I
Alpha-methyltryptamine (7432)	I
Bufotenine (7433)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
5-Methoxy-N,N-diisopropyltryptamine (7439)	I
N-Ethyl-1-phenylcyclohexylamine (7455)	I
1-(1-Phenylcyclohexyl)pyrrolidine (7458)	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (7470)	I
Dihydromorphine (9145)	I
Normorphine (9313)	I
Methamphetamine (1105)	II
1-Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II
Phenylacetone (8501)	II
1-Piperidinocyclohexanecarbonitrile (8603)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Ecgonine (9180)	II
Meperidine intermediate-B (9233)	II

Drug	Schedule
Noroxymorphone (9668)	II

The company plans to manufacture high purity drug standards used for analytical applications only in clinical, toxicological, and forensic laboratories.

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 Alltech Associates, Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Alltech Associates 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: November 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–30543 Filed 11–25–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances Notice of Registration

By Notice dated June 14, 2011, and published in the **Federal Register** on June 22, 2011, 76 FR 36577, Chattem Chemicals Inc., 3801 St. Elmo Avenue, Chattanooga, Tennessee 37409, made application by letter 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
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Tapentadol (9780)	II

The company plans to manufacture the listed controlled substances in bulk for distribution and sale to its customers. Regarding (9640) the company plans to manufacture another controlled substance for sale 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 Chattem Chemicals Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Chattem Chemicals 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, 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: November 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–30546 Filed 11–25–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated June 13, 2011, and published in the **Federal Register** on June 22, 2011, 76 FR 36577, Boehringer Ingelheim Chemicals, Inc., 2820 N. Normandy Drive, Petersburg, Virginia 23805–9372, 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
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Methadone (9250)	II
Methadone intermediate (9254)	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers for formulation into finished pharmaceuticals.

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 Boehringer Ingelheim Chemicals, Inc., to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Boehringer Ingelheim Chemicals, 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: November 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–30549 Filed 11–25–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances Notice of Registration

By Notice dated June 22, 2011, and published in the **Federal Register** on June 29, 2011, 76 FR 38209, Pharmagra Labs Inc., 158 McLean Road, Brevard, North Carolina 28712, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Pentobarbital (2270), a basic class of controlled substance in schedule II.

The company plans to manufacture the listed controlled substance for analytical research and clinical trials.

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 Pharmagra Labs, Inc. to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Pharmagra Labs, 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 class of controlled substance listed.

Dated: November 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–30550 Filed 11–25–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[OMB Number 1110–0004]

Agency Information Collection Activities: Proposed Collection, Comments Requested; Extension of a Currently Approved Collection, Number of Full-time Law Enforcement Employees as of October 31

ACTION: 60-day notice of information collection under review.

The Department of Justice, Federal Bureau of Investigation, Criminal Justice Information Services Division (CJIS), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with established review procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted until January 27, 2012. This process is conducted in accordance with 5 CFR 1320.10.

All comments, suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Mr. Gregory E. Scarbro, Unit Chief, Federal Bureau of Investigation, CJIS Division, Module E–3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306, or facsimile to (304) 625–3566.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques of other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of information collection:* Extension of a currently approved collection.

(2) *The title of the form/collection:* Number of Full-time Law Enforcement Employees as of October 31

(3) *The agency form number, if any, and the applicable component of the department sponsoring the collection:* Form Number 1–711, 1–711a, 1–711b; *Sponsor:* Criminal Justice Information Services Division, Federal Bureau of Investigation, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* City, county, state, Federal, and tribal law enforcement agencies. *Brief Abstract:* This collection is needed to collect information on the number of full-time law enforcement employees, both civilians and officers, throughout the United States.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are approximately 18,108 law enforcement agency respondents that submit once a year for a total of 18,108 responses with an estimated response time of 8 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with this collection:* There are approximately 2,414 hours, annual burden, associated with this information collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE., Room 2E–508, Washington, DC 20530.

Jerri Murray,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. 2011–30404 Filed 11–25–11; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF LABOR

Advisory Committee on Veterans' Employment, Training and Employer Outreach (ACVETEO): Meeting

AGENCY: Veterans' Employment and Training Service, Labor.

ACTION: Notice of open meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Advisory Committee on Veterans' Employment, Training and Employer Outreach (ACVETEO). The ACVETEO will discuss Department of Labor's Veterans' Employment and Training Services' (VETS) core programs and new initiatives regarding efforts that assist veterans seeking employment and raise employer awareness as to the advantages of hiring veterans. There will be an opportunity for persons or organizations to address the committee. Any individual or organization that wishes to do so should contact Mr. Gregory Green (202) 693–4734. Time constraints may limit the number of outside participants/presentations. Individuals who will need accommodations for a disability in order to attend the meeting (i.e., interpreting services, assistive listening devices, and/or materials in alternative format) should notify the Advisory Committee no later than Wednesday, December 7, 2011 by contacting Mr. Gregory Green (202) 693–4734. Requests made after this date will be reviewed, but availability of the requested accommodations cannot be guaranteed. The meeting site is accessible to individuals with disabilities. This notice also describes the functions of the Advisory Committee. Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public.

Date and Time: Wednesday, December 14, 2011, beginning at 10 a.m. and ending at approximately 4 p.m. (E.S.T.).

ADDRESSES: Veterans of Foreign Wars of the United States, 200 Maryland Avenue NE., Washington, DC 20002. ID is required to enter the building.

FOR FURTHER INFORMATION CONTACT: Ms. Nancy L. Hogan, Designated Federal Official, Advisory Committee on Veterans' Employment, Training and Employer Outreach, (202) 693–4700, or Mr. Gregory Green (202) 693–4734.

SUPPLEMENTARY INFORMATION: ACVETEO is a Congressionally mandated advisory committee authorized under Title 38, U.S. Code, Section 4110 and subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, as amended. The ACVETEO is responsible for: Assessing employment and training needs of veterans; determining the extent to which the programs and activities of the U.S. Department of Labor meet these needs; assisting to conduct outreach to employers seeking to hire veterans; making recommendations to the Secretary, through the Assistant Secretary of Labor for Veterans' Employment and Training (VETS), with respect to outreach activities and employment and training needs of veterans; and carrying out such other activities necessary to make required reports and recommendations. The ACVETEO meets at least quarterly.

Signed in Washington, DC, this day of November, 2011.

Joseph C. Juarez,

Acting, Deputy Assistant Secretary, Veterans' Employment and Training Service.

[FR Doc. 2011–30592 Filed 11–25–11; 8:45 am]

BILLING CODE 4510–79–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–74,593]

Whirlpool Corporation Including On-Site Leased Workers From Career Solutions TEC Staffing, Andrews International, IBM Corporation, TEK Systems, Penske Logistics, Eurest, and Canteen, Fort Smith, AR; 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 6, 2010, applicable to workers of Whirlpool Corporation, including on-site leased workers from Career Solutions TEC Staffing, Fort Smith, Arkansas. The workers are engaged in the production of refrigerators and trash compactors. The notice was published in the **Federal Register** on October 25, 2010 (75 FR 65520). The notice was amended on December 6, 2010 to include on-site leased workers from Andrews International. The notice was published in the **Federal Register** on December 13, 2010 (75 FR 77665).

At the request of a company official, the Department reviewed the certification for workers of the subject firm. The company reports that workers leased from IBM Corporation, TEK Systems, Penske Logistics, Eurest, and Canteen were employed on-site at the Fort Smith, Arkansas location of Whirlpool Corporation. The Department has determined that these workers were sufficiently under the control of Whirlpool Corporation to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from IBM Corporation, TEK Systems, Penske Logistics, Eurest, and Canteen working on-site at the Fort Smith, Arkansas location of Whirlpool Corporation.

The amended notice applicable to TA–W–74,593 is hereby issued as follows:

All workers of Whirlpool Corporation, including on-site leased workers from Career Solutions TEC Staffing, Andrews International, IBM Corporation, TEK Systems, Penske Logistics, Eurest, and Canteen, Fort Smith, Arkansas, who became totally or partially separated from employment on or after October 2, 2010, through October 6, 2012, 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 at Washington, DC, this 7th day of November 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–30380 Filed 11–25–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–73,681]

Premier Trim, LLC, Spectrum Trim, LLC and Grant Products International, Inc. D/B/A Spectrum Grant De Mexico Including Workers Whose Unemployment Insurance (UI) Wages Are Paid Through Grant Products International, Inc. Manufacturing Division Including On-Site Leased Workers From Expess Employment Professionals and Select Staff Brownsville, TX; 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 June 25, 2010, applicable to workers of Premier Trim, LLC and Spectrum Trim, LLC, d/b/a Spectrum Grant De Mexico, Manufacturing Division, including on-site leased workers from Express Employment Professionals and Select Staff, Brownsville, Texas. The workers are engaged in activities related to the production of wood steering wheels. The notice was published in the **Federal Register** on July 7, 2010 (75 FR 39047).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm.

Information shows that as of January 29, 2010, Premier Trim, LLC, Spectrum Trim, LLC and Grant Products International, Inc. have merged and are officially one company under the name of Spectrum Grant de Mexico. Some workers separated from employment at the Brownsville, Texas location of Premier Trim, LLC and Spectrum Trim, LLC and Grant Products International, Inc. d/b/a Spectrum Grant de Mexico had their wages reported under a separate unemployment insurance (UI) tax account under the name Grant Products International, Inc.

Accordingly, the Department is amending this certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by a shift in the production of wood steering wheels to Mexico.

The amended notice applicable to TA–W–73,681 is hereby issued as follows:

All workers of Premier Trim, LLC, Spectrum Trim, LLC and Grant Products

International, Inc., d/b/a Spectrum Grant de Mexico, including workers whose unemployment insurance (UI) wages are paid through Grant Products International, Inc., Manufacturing Division, including on-site leased workers from Express Employment Professionals and Select Staff, Brownsville, Texas, who became totally or partially separated from employment on or after March 10, 2009, through June 25, 2012, and all workers in the group threatened with total or partial separation from employment on 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 at Washington, DC, this 1st day of November 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–30382 Filed 11–25–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 8, 2011.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 8, 2011.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC, this 10th day of November 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[31 TAA petitions instituted between 10/24/11 and 10/28/11]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
81001	Freeman Metal Products, Inc. (Company)	Ahoskie, NC	10/24/11	10/20/11
81002	GFSI, Inc. dba GEAR For Sports (Company)	Chillicothe, MO	10/24/11	10/21/11
81003	BNY Mellon (Workers)	Pawtucket, RI	10/24/11	10/20/11
81004	Pace American Enterprises, Inc. (State/One-Stop)	McGregor, TX	10/24/11	10/20/11
81005	Terex USA LLC (Company)	Wilmington, NC	10/24/11	10/21/11
81006	Georgia-Pacific Corp-Plywood Mill (State/One-Stop)	Crossett, AR	10/25/11	10/24/11
81007	A. Schulman (Union)	Nashville, TN	10/25/11	10/19/11
81008	Lintelle Engineering, Inc. (Company)	Scotts Valley, CA	10/25/11	10/19/11
81009	Birdseye Foods (Union)	Fulton, NY	10/25/11	10/24/11
81010	Velsicol Chemical Corporation (Union)	Memphis, TN	10/25/11	10/24/11
81011	Cyberdyne Inc. (Workers)	Monongahela, PA	10/25/11	10/24/11
81012	Maersk Line, A Subsidiary of A.P. Moller Maersk (Company).	The Woodlands, TX	10/25/11	10/24/11
81013	Maersk Line (Company)	Miami, FL	10/25/11	10/24/11
81014	Maersk Line (Company)	Charlotte, NC	10/25/11	10/24/11
81015	Pageland Screen Printers, Inc. (Company)	Pageland, SC	10/25/11	10/24/11
81016	Smart Paper Holdings LLC (State/One-Stop)	Hamilton, OH	10/26/11	10/25/11
81017	Integrity Building Systems Inc. (Company)	Milton, PA	10/26/11	10/21/11
81018	Kandy Kiss (State/One-Stop)	Sylmar, CA	10/26/11	10/25/11
81019	Wells Fargo (Workers)	Chester, PA	10/26/11	10/25/11
81020	Turner & Seymour Manufacturing Company (State/One-Stop).	Torrington, CT	10/27/11	10/26/11
81021	Bayer Crop Science (Union)	Institute, WV	10/27/11	10/26/11
81022	Apex Tool Group (Workers)	York, PA	10/27/11	10/25/11
81023	Hanet Plastics USA (Workers)	Plattsburgh, NY	10/27/11	10/24/11
81024	Atmel Corporation (Company)	Colorado Springs, CO	10/27/11	10/25/11
81025	Dendreon Corporation (State/One-Stop)	Seattle, WA	10/28/11	10/25/11
81026	Cone Denim White Oak Plant (Company)	Greensboro, NC	10/28/11	10/27/11
81027	The Wise Company, Inc. (State/One-Stop)	Rector, AR	10/28/11	10/27/11
81028	Thomasville Furniture (Workers)	Lenoir, NC	10/28/11	10/27/11
81029	Hostess Brands (Company)	Various Locations	10/28/11	10/27/11
81030	Calisolar Inc. (Company)	Sunnyvale, CA	10/28/11	10/07/11
81031	Ultra Blend LLC. (Company)	Charlotte, NC	10/28/11	09/15/11

[FR Doc. 2011–30381 Filed 11–25–11; 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: Jekyll Island Ocean Front Hotel

Principal Product/Purpose: The loan, guarantee, or grant application is to construct a new full service hotel, which will be located in Jekyll Island, Georgia. The NAICS industry code for this enterprise is: 721110 (hotels and motels).

DATES: All interested parties may submit comments in writing no later than December 12, 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 email *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 21st day of November, 2011.

Jane Oates,

Assistant Secretary for Employment and Training.

[FR Doc. 2011–30379 Filed 11–25–11; 8:45 am]
BILLING CODE P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0197]

Occupational Safety and Health State Plans; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

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

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its request for an extension of the Office of Management and Budget's (OMB) approval of the information collection requirements associated with its regulations and program regarding State Plans for the development and enforcement of state occupational safety and health standards (29 CFR Parts 1902, 1952, 1953, 1954, 1955, 1956).

DATES: Comments must be submitted (postmarked, sent, or received) by January 27, 2012.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2011–0197, U.S. Department of Labor, Occupational Safety and Health Administration, Room N–2625, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and OSHA docket number for the Information Collection Request (ICR) (OSHA–2011–0197). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *http://www.regulations.gov.* For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (e.g., copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Laura Seeman at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Laura Seeman, Directorate of Cooperative and State Programs, Office of State Programs, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3700, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–2244; email, *seeman.laura@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (i.e., the 27 States with OSHA-approved State Plans) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in

the desired format, reporting burden (time and cost) is minimized, collection instruments are understandable, and OSHA's estimate of the information collection burden is accurate. Currently, OSHA is soliciting comments concerning the extension of the information collection requirements contained in the series of regulations establishing requirements for the submission, initial approval, continuing approval, final approval, monitoring and evaluation of OSHA-approved State Plans:

- 29 CFR part 1902, State Plans for the Development and Enforcement of State Standards;
- 29 CFR part 1952, Approved State Plans for Enforcement of State Standards;
- 29 CFR part 1953, Changes to State Plans for the Development and Enforcement of State Standards;
- 29 CFR part 1954, Procedures for the Evaluation and Monitoring of Approved State Plans;
- 29 CFR part 1955, Procedures for Withdrawal of Approval of State Plans; and
- 29 CFR part 1956, State Plans for the Development and Enforcement of State Standards Applicable to State and Local Government Employees in States without Approved Private Employee Plans.

Section 18 of the Occupational Safety and Health Act (29 U.S.C. 667) offers an opportunity to the states to assume responsibility for the development and enforcement of state standards through the mechanism of an OSHA-approved State Plan. Absent an approved plan, states are precluded from enforcing occupational safety and health standards in the private sector with respect to any issue for which Federal OSHA has promulgated a standard. Once approved and operational, the state adopts standards and provides most occupational safety and health enforcement and compliance assistance in the state, under the authority of its plan, instead of Federal OSHA. States also must extend their jurisdiction to cover state and local government employees and may obtain approval of State Plans limited in scope to these workers. To obtain and maintain State Plan approval, a state must submit various documents to OSHA describing its program structure and operation, including any modifications thereto as they occur, in accordance with the identified regulations. OSHA funds 50 percent of the costs required to be incurred by an approved State Plan with the state at least matching and providing additional funding at its discretion.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on participating states who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend its approval of the collection of information requirements associated with its State Plan regulations. In doing so, the Agency is proposing to increase the burden hours from 10,652 to 11,196 hours. The increase is a result of the approval of the Illinois Public Employee Only State Plan, increasing the number of approved State Plan respondents from 26 to 27, and an increase in the projected number of required State Plan responses and modifications as a result of changes in federal procedures. The total number of respondents increased to 28, including the 27 approved State Plans and one state developing a plan to seek State Plan approval. The Agency will summarize the comments submitted in response to this notice and will include this summary in its request to OMB.

Type of Review: Extension of a currently approved collection.

Title: Occupational Safety and Health State Plans.

OMB Number: 1218–0247.

Affected Public: Designated state government agencies that are seeking or have submitted and obtained approval for State Plans for the development and enforcement of occupational safety and health standards.

Number of Respondents: 28.

Frequency: On occasion; quarterly; annually.

Total Responses: 1,264.

Average Time per Response: Varies from 30 minutes (.5 hour) to respond to an information inquiry to 80 hours to document state annual performance goals.

Estimated Total Burden Hours: 11,196.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA–2011–0197). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the OSHA docket number, so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information, such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (e.g., copyrighted material) is not publicly available to read or download through this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available at the Web site's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available through the Web site and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of

Labor's Order No. 5–2010 (75 FR 55355).

Signed at Washington, DC, on November 22, 2011.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2011–30478 Filed 11–25–11; 8:45 am]

BILLING CODE 4510–26–P

LIBRARY OF CONGRESS

Copyright Office

[Docket No. 2011–1]

Cable Statutory License: Specialty Station List; Correction

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of objections and specialty station filings; correction.

SUMMARY: Periodically, the Copyright Office (''Office'') seeks to update its list of specialty stations related to the use of the cable compulsory license. In response to the publication of an initial list of specialty stations for this purpose in April of this year, the Office received objections filed by the Motion Picture Association of America to the identification of certain stations as being entitled to specialty station status in accordance with the Federal Communications Commission's (''FCC'') definition of specialty station in effect on June 24, 1981. Corrections are being made to the specialty station list published on November 8, 2011.

FOR FURTHER INFORMATION CONTACT: Ben Golant, Assistant General Counsel, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, DC 20024. *Telephone:* (202) 707–8380. *Telefax:* (202) 707–8366.

Correction

The Office corrects the following errors in the Notice of Objections published in the **Federal Register** on November 8, 2011 at 76 FR 69288:

- On page 69289, WNYA–CA, Albany, NY was misidentified as WYNA–CA.
- On page 69289, W34DI, Port Jervis, NY was misidentified as W34d1.
- On page 69289, W46DQ, Port Jervis, NY was misidentified as W42DQ.
- On page 69289, W42CX, Port Jervis, NY was missing from the list as a station to which MPAA filed an objection (no evidence of construction or the type of programming broadcast should not be identified as specialty stations)

Dated: November 21, 2011.

Maria A. Pallante,

Register of Copyrights.

[FR Doc. 2011–30522 Filed 11–25–11; 8:45 am]

BILLING CODE 1410–30–P

NATIONAL SCIENCE FOUNDATION

Advisory Panel for Integrative Activities, #1373; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Ad Hoc Advisory Committee on the Merit Review Process (MRPAC).

Date/Time: December 20, 2011; 12 p.m.–4 p.m., EST.

Place: National Science Foundation, 4201 Wilson Boulevard, Rm 920, Arlington, VA.

Type of Meeting: Open.

Contact Person: Ms. Victoria Fung, National Science Foundation 4201 Wilson Boulevard, Room 935, Arlington, VA 22230. Email: *vfung@nsf.gov*.

If you plan to attend the meeting, please send an email with your name and affiliation to the individual listed above, by the day before the meeting, so that a visitor badge can be prepared.

Purpose of Meeting: To provide advice concerning issues related to NSF's merit review process.

Agenda

- Welcome
- Update on outreach activities
- Discussion of potential enhancements to the merit review process

Dated: November 22, 2011.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 2011–30477 Filed 11–25–11; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2011–0271]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR Part 20, ''Standards for Protection Against Radiation.''

2. *Current OMB approval number:* 3150–0014.

3. *How often the collection is required:* Most reports are collected annually, but decommissioning reports are collected at license termination.

4. *Who is required or asked to report:* NRC licensees, including those requesting license terminations. Types of licensees include civilian commercial, industrial, academic, and medical users of nuclear materials. Licenses are issued for, among other things, the possession, use, processing, handling, and importing and exporting of nuclear materials, and for the operation of nuclear reactors.

5. *The number of annual respondents:* 3,000.

6. *The number of hours needed annually to complete the requirement or request:* 91,503 hours (5,476 hours reporting + 342 hours third-party disclosure + 85,685 hours recordkeeping).

7. *Abstract:* 10 CFR part 20 establishes standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the NRC. These standards require the establishment of radiation protection programs, maintenance of radiation protection programs, maintenance of radiation records recording of radiation received by workers, reporting of incidents which could cause exposure to radiation, submittal of an annual report to NRC of the results of individual monitoring, and submittal of license termination information. These mandatory requirements are needed to protect occupationally exposed individuals from undue risks of excessive exposure to ionizing radiation and to protect the health and safety of the public.

Submit, by January 27, 2012, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized,

including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. OMB clearance requests are available at the NRC Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2011–0271.

Public comments and supporting materials related to this document can be found at *http://www.regulations.gov* by searching on Docket No. NRC–2011–0271. Mail comments to NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at (301) 415–6258, or by email to *INFOCOLLECTS.Resource@NRC.GOV*.

Dated at Rockville, Maryland, this 21st day of November, 2011.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2011–30455 Filed 11–25–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2011–0263]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR Part 31, General Domestic Licenses for Byproduct Material.

2. *Current OMB approval number:* 3150–0016.

3. *How often the collection is required:* Reports are submitted as events occur. General license registration requests may be submitted at any time. Changes to the information on the registration may be submitted as they occur.

4. *Who is required or asked to report:* Persons receiving, possessing, using, or transferring devices containing byproduct material.

5. *The number of annual respondents:* 23,300 (Approximately 2,400 NRC general licensees and 20,900 Agreement State general licensees).

6. *The number of hours needed annually to complete the requirement or request:* 10,998.5 hours (1,061 hours for NRC licensees [461 hours reporting + 600 hours recordkeeping] + 9,937.5 hours for Agreement State licensees [4,712.5 hours reporting + 5,225 hours recordkeeping]).

7. *Abstract:* 10 CFR Part 31 establishes general licenses for the possession and use of byproduct material in certain devices. General licensees are required to keep testing records and submit event reports identified in Part 31, which assist NRC in determining with reasonable assurance that devices are operated safely and without radiological hazard to users or the public.

Submit, by January 27, 2012, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. OMB clearance requests are available at the NRC Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.*

The document will be available on the NRC home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2011–0263.

Public comments and supporting materials related to this document can be found at *http://www.regulations.gov* by searching on Docket No. NRC–2011–0263. Mail comments to NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at (301) 415–6258, or by email to *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 21st day of November, 2011.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2011–30456 Filed 11–25–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2011–0250]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is

summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* NRC Form 396, ''Certification of Medical Examination by Facility Licensee.''

2. *Current OMB approval number:* 3150–0024.

3. *How often the collection is required:* Upon application for an initial or upgrade operator license or, every six years for the renewal of operator or senior operator license, and upon notices of disability.

4. *Who is required or asked to report:* Facility licensees who are tasked with certifying the medical fitness of an applicant or licensee.

5. *The number of annual respondents:* 136 Facilities submitting initial and upgrade applications, renewals and disability forms.

6. *The number of hours needed annually to complete the requirement or request:* 1,224 hours (1,020 hours for reporting, and 204 hours for recordkeeping).

7. *Abstract:* NRC Form 396 is used to transmit information to the NRC regarding the medical condition of applicants for initial operator licenses or renewal of operator licenses and for the maintenance of medical records for all licensed operators. The information is used to determine whether the physical condition and general health of applicants for operator licensees is such that the applicant would not be expected to cause operational errors and endanger public health and safety.

Submit, by January 27, 2012, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. OMB clearance requests are available at the NRC Web site: *http://www.nrc.gov/public-involve/doc-omment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2011–0250.

Public comments and supporting materials related to this document can be found at *http://www.regulations.gov* by searching on Docket No. NRC–2011–0250. Mail comments to NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at (301) 415–6258, or by e-mail to *INFOCOLLECTS.Resource@NRC.GOV.*

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 21st day of November, 2011.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2011–30457 Filed 11–25–11; 8:45 a.m.]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Revised Application for a License To Export High-Enriched Uranium

The application for a license to export high-enriched Uranium has been revised as noted below. Notice of this application was previously published in the **Federal Register** on Tuesday, March 30, 2010 (75 FR 15743–15744).

Pursuant to 10 CFR 110.70 (b) ''Public Notice of Receipt of an Application,'' please take notice that the Nuclear Regulatory Commission (NRC) has received the following request for an export license. Copies of the request are available electronically through ADAMS and can be accessed through the Public Electronic Reading Room (PERR) link *http://www.nrc.gov/reading-rm.html* at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within thirty (30) days after publication of this notice in the **Federal Register**. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

A request for a hearing or petition for leave to intervene may be filed with the NRC electronically in accordance with NRC's E-Filing rule promulgated in August 2007, 72 FR 49139 (Aug. 28, 2007). Information about filing electronically is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* To ensure timely electronic filing, at least 5 (five) days prior to the filing deadline, the petitioner/requestor should contact the Office of the Secretary by email at *HEARINGDOCKET@NRC.GOV,* or by calling (301) 415–1677, to request a digital ID certificate and allow for the creation of an electronic docket.

In addition to a request for hearing or petition for leave to intervene, written comments, in accordance with 10 CFR 110.81, should be submitted within thirty (30) days after publication of this notice in the **Federal Register** to Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemaking and Adjudications.

The information concerning this application for an export license follows.

NRC EXPORT LICENSE APPLICATION

[Revised Description of Material]

Name of applicant; Date of application; Date received; Application No.; Docket No.	Material type	Total quantity	End use	Country from
DOE/NNSA—Y–12 National Security Complex; October 18, 2011; October 21, 2011; XSNM3633; 11005854.	High-Enriched Uranium (93.35%).	186.4 kilograms uranium (174.0 kilograms U–235).	To fabricate fuel elements in France for use as fuel in the Institut Laue—Langevin (ILL) High Flux Reactor (HFR) in France.	France.

Dated this 17th day of November 2011 at Rockville, Maryland.

For the Nuclear Regulatory Commission.

Janice E. Owens,

Acting Deputy Director, Office of International Programs.

[FR Doc. 2011–30387 Filed 11–25–11; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–53; Order No. 984]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Witten, South Dakota 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: November 21, 2011: Administrative record due (from Postal Service); December 13, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *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), the Commission received two petitions for review of the Postal Service's determination to close the Witten post office in Witten, South Dakota. The first petition for review received November 4, 2011, was filed by Mr. & Mrs. Calvin W. Adel. The second petition for review received November 10, 2011, was filed by Cary Long. The earliest postmark date is October 26, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–53 to consider Petitioners' appeal. If Petitioners would like to further explain their position with supplemental information or facts, Petitioners may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than December 9, 2011.

Categories of issues apparently raised. Petitioners contend that (1) 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)); 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 November 21, 2011. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service is November 21, 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 participant's submissions also will be posted on the 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, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

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 the Petitioners and respondents, 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 December 13, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the

Commission's Web site, *http://www.prc.gov,* 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 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 November 21, 2011.

2. Any responsive pleading by the Postal Service to this notice is due no later than November 21, 2011.

3. The procedural schedule listed below is hereby adopted.

4. Pursuant to 39 U.S.C. 505, Tracy Ferguson 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 and Procedural Schedule in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

PROCEDURAL SCHEDULE

November 4, 2011	Filinig of Appeal.
November 21, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 21, 2011	Deadline for the Postal Service to file any responsive pleading.
December 13, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
December 9, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
December 29, 2011	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
January 13, 2012	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 20, 2012	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).
February 23, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–30421 Filed 11–25–11; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65795; File No. SR–OPRA–2011–04]

Options Price Reporting Authority; Notice of Filing and Immediate Effectiveness of Proposed Amendment to the Plan To Implement the Datafeed Policy

November 21, 2011.

Pursuant to Section 11A of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 608 thereunder,[2] notice is hereby given that on November 7, 2011, the Options Price Reporting Authority (''OPRA'') submitted to the Securities and Exchange Commission (''Commission'') an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (''OPRA Plan'').[3] The proposed amendment implements a revised datafeed policy (the ''Policy'' or ''Datafeed Policy''). The Commission is publishing this notice to solicit comments from interested persons on the proposed OPRA Plan amendment.

I. Description and Purpose of the Plan Amendment

The purpose of OPRA's Datafeed Policy is to summarize, in one document, OPRA's definition of the term ''datafeed'' and a summary of information of interest to any prospective Vendor or Professional Subscriber that will receive a datafeed. OPRA requires that Professional Subscribers that receive OPRA datafeeds pay one of two fees, and requires that certain Vendors that receive OPRA datafeeds also pay a fee. OPRA is not proposing to change the amount of these fees in this filing, but rather to clarify the terms that describe when each of them is payable.

As stated in the Policy, OPRA defines a ''datafeed'' or ''bulk datafeed''[4] as any uncontrolled retransmission of OPRA market data—that is, as a transmission of OPRA data in respect of which the recipient has the ability to control the entitlement of devices and/or User IDs. OPRA considers a retransmission to be ''uncontrolled'' if the retransmission sender does not control the entitlements of the devices and/or User IDs to which the retransmission is being sent and, instead, the recipient controls the entitlement process.

OPRA classifies a datafeed recipient as either a ''Vendor'' or a ''Professional Subscriber.'' In either case, the datafeed recipient must enter into a contract directly with OPRA. OPRA classifies a datafeed recipient as a ''Vendor'' if the datafeed recipient intends to further retransmit the datafeed on an ''external'' basis, that is, to persons not employed by the datafeed recipient. In this case, the datafeed recipient must sign a ''Vendor Agreement'' with OPRA. A Vendor that receives an uncontrolled retransmission from another OPRA Vendor is sometimes referred to as a ''downstream Vendor,'' since it is ''downstream'' in the dissemination of the OPRA market data from the ''upstream'' Vendor that is sending the data to it. A Vendor that receives a datafeed directly from OPRA's data processor Securities Industry Automation Corporation (''SIAC'') must pay a monthly ''Direct Access Fee'' to OPRA.[5]

OPRA classifies a datafeed recipient as a ''Professional Subscriber'' if the

[1] 15 U.S.C. 78k–1.

[2] 17 CFR 242.608.

[3] The OPRA Plan is a national market system plan approved by the Commission pursuant to Section 11A of the Act and Rule 608 thereunder (formerly Rule 11Aa3–2). *See* Securities Exchange Act Release No. 17638 (March 18, 1981), 22 S.E.C. Docket 484 (March 31, 1981). The full text of the OPRA Plan is available at *http://www.opradata.com.*

The OPRA Plan provides for the collection and dissemination of last sale and quotation information on options that are traded on the participant exchanges. The nine participants to the OPRA Plan are BATS Exchange, Inc., Chicago Board Options Exchange, Incorporated, C2 Options Exchange, Incorporated, International Securities Exchange, LLC, NASDAQ OMX BX Inc., NASDAQ OMX PHLX, Inc., NASDAQ Stock Market LLC, NYSE Amex, Inc., and NYSE Arca, Inc.

[4] The Policy, as revised, makes clear that the terms ''datafeed'' and ''bulk datafeed'' as used by OPRA are synonyms.

[5] The amount of the Direct Access Fee is stated on OPRA's Fee Schedule, which is available on OPRA's Web site (www.opradata.com). The base fee is currently, and has been for many years, $1000/month.

datafeed recipient intends to further retransmit the datafeed only on an ''internal'' basis, that is, only to persons employed by the datafeed recipient. In this case, the datafeed recipient must sign a ''Professional Subscriber Agreement'' and either an ''Indirect (Vendor Pass-Through) Circuit Connection Rider'' (if the Professional Subscriber is receiving the datafeed from a Vendor) or a ''Direct Circuit Connection Rider'' (if the Professional Subscriber is receiving the datafeed from SIAC). The word ''direct'' connotes that the Professional Subscriber is receiving the datafeed directly from SIAC; the word ''indirect'' connotes that the Professional Subscriber is receiving the datafeed from a Vendor, i.e., ''indirectly,'' rather than directly from SIAC.[6] If a Professional Subscriber receives a datafeed directly from SIAC it must pay the same monthly Direct Access Fee that is payable by Vendors that receive datafeeds directly from SIAC. If a Professional Subscriber receives a datafeed from a Vendor, it must pay a monthly ''Subscriber Indirect Access Fee'' to OPRA.[7]

The Policy describes the steps in the process by which OPRA approves a datafeed and the documentation that OPRA requires for each type of datafeed. For a prospective Vendor, the documentation consists of the Vendor Agreement and OPRA's form ''Exhibit A'' to the Vendor Agreement that has been completed by the entity. For a prospective Professional Subscriber, the documentation consists of the Professional Subscriber Agreement, one of the Riders described above, and OPRA's form ''Exhibit A'' to the applicable Rider that has been completed by the entity.[8] The Policy states that OPRA will review the documentation after it has been sent to OPRA and, if necessary, contact the prospective datafeed recipient directly for additional information. The Policy states that OPRA's review of the application will include, among other things, a review of how the data will be displayed, the entitlement control process, and the reporting mechanism, and that the review and approval process will take approximately two weeks.

The Policy also describes OPRA' s reporting requirements for datafeed distributors and datafeed recipients. Datafeed distributors are required to report any changes in the datafeeds that they distribute on a monthly basis, and datafeed recipients are required to report with respect to their further distribution and use of OPRA data on a monthly basis.[9]

The text of the proposed amendment to the OPRA Plan is available at OPRA, the Commission's Public Reference Room, on OPRA's Web site at *http://opradata.com*, and on the Commission's Web site at *http://www.sec.gov.*

II. Implementation of the OPRA Plan Amendment

OPRA designated this amendment as qualified to be put into effect upon filing with the Commission in accordance with clause (i) of paragraph (b)(3) of Rule 608 under the Act.[10] The Policies describe and refine longstanding OPRA technical policies with respect to the applicability of its Direct Access Fee and Subscriber Indirect Access Fee. Accordingly, OPRA will implement the amended Policy upon filing with the Commission.

The Commission may summarily abrogate the amendment within sixty days of its filing and require refiling and approval of the amendment by Commission order pursuant to Rule 608(b)(2) under the Act [11] if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Act.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed OPRA Plan amendment is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–OPRA–2011–04 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–OPRA–2011–04. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed plan amendment that are filed with the Commission, and all written communications relating to the proposed plan amendment 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 OPRA. 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–OPRA–2011–04 and should be submitted on or before December 19, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30426 Filed 11–25–11; 8:45 am]

BILLING CODE 8011–01–P

[6] The current form of the Policy expressly refers only to indirect datafeeds. The revised form expands the discussion so that it also describes direct datafeeds.

[7] The amount of the Subscriber Indirect Access Fee is stated on OPRA's Fee Schedule. This fee is currently, and has been for many years, $600/month.

[8] These documentation requirements have not changed, but they are more clearly described in the revised form of the Policy.

[9] The revised form of the Policy corrects an inaccurate statement in the current form of the Policy that Professional Subscriber datafeed recipients ''generally report on a quarterly basis.''

[10] 17 CFR 242.608(b)(3)(i).

[11] 17 CFR 242.608(b)(2).

[12] 17 CFR 200.30–3(a)(29).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65797; File No. SR–NYSEArca–2011–83]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Regarding Fees and Rebates Relating to Executed Qualified Contingent Cross Orders

November 21, 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 November 15, 2011, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Options Fee Schedule (''Fee Schedule'') to more clearly describe the fees and rebates relating to executed Qualified Contingent Cross (''QCC'') orders. 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to more clearly describe the fees and rebates relating to executed QCC orders. Specifically, the Exchange proposes to memorialize the intent set forth in its rule filing adopting the fee for executed QCC orders, which states that the fees relating to executed QCC orders ''will apply to each side of the transaction.''[3] As such, the Exchange intends to amend the Fee Schedule to reflect that the fee of $.10 for executed QCC orders is charged per contract side. To parallel this language, the Exchange also proposes to amend the Fee Schedule to reflect a rebate to the Floor Broker of $.05 per contract side instead of $.10 per contract for executed QCC orders. There is no change to the amount rebated to the Floor Broker for executed QCC orders. As stated in the rule filing implementing the Floor Broker rebate,[4] the QCC rebate is credited to the executing Floor Broker, who handles both contract sides with respect to such orders. Thus, the Floor Broker receives a total rebate of $.10 for both contract sides together. The proposed change to the text of the Fee Schedule will take effect on November 15, 2011.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[5] in general, and Section 6(b)(4) of the Act,[6] in particular, because it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities. Specifically, the Exchange believes that the proposed change is equitable, because it will reduce confusion for all market participants relating to the way fees are charged and rebated for executed QCC orders. The Fee Schedule will state that the fee of $.10 for executed QCC orders applies per contract side, as stated in the rule filing adopting the fee for QCC orders.[7] In addition, the Fee Schedule will state that the rebate credited to the executing Floor Broker on a QCC order is $.05 per contract side, for a total of $.10 for both contract sides handled by the Floor Broker.

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

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[8] of the Act and subparagraph (f)(2) of Rule 19b–4[9] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange. At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2011–83 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-2011–83. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] *See* Securities Exchange Act Release No. 64596 (June 3, 2011), 76 FR 33797 (June 9, 2011) (SR–NYSEArca–2011–36).

[4] *See* Securities Exchange Act Release No. 65730 (November 10, 2011) (SR–NYSEArca–2011–79).

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

[7] *See* note 3, *supra.*

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(2).

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 the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca-2011–83 and should be submitted on or before December 19, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30430 Filed 11–25–11; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65794; File No. SR–OPRA–2011–03]

Options Price Reporting Authority; Notice of Filing and Immediate Effectiveness of Proposed Amendment to the Plan To Implement New Policies Regarding Reporting and Usage-Based Vendor Fees

November 21, 2011.

Pursuant to Section 11A of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 608 thereunder,[2] notice is hereby given that on November 7, 2011, the Options Price Reporting Authority (''OPRA'') submitted to the Securities and Exchange Commission (''Commission'') an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (''OPRA Plan'').[3] The proposed amendment would implement a new set of policies entitled ''Policies with respect to Reporting and Usage-based Vendor Fees.'' The Commission is publishing this notice to solicit comments from interested persons on the proposed OPRA Plan amendment.

I. Description and Purpose of the Plan Amendment

OPRA's proposed ''Policies with respect to Reporting and Usage-based Vendor Fees'' (the ''Policies'') are comprised of three sections. The first section describes OPRA policies relating to the reports that OPRA requires in order to determine the fees that are payable to OPRA by Vendors' and Professional Subscribers. The second and third sections describe OPRA policies pertaining to ''Usage-based Vendor Fees.''[4] Usage-based Vendor Fees are one of the types of fees that are payable to OPRA by Vendors. OPRA is not proposing to change the amount of any of its fees, but rather to clarify its reporting requirements and the circumstances in which certain fees are payable.

(1) *Policies with Respect to Reporting.* Section 1 of the new Policies summarizes OPRA's reporting requirements for Vendors and for Professional Subscribers that have an obligation to report their usage of OPRA data directly to OPRA. (These Professional Subscribers are sometimes referred to as ''internal distributors.''[5] OPRA has not previously summarized its requirements in a single document. As described in Section 1, OPRA requires that a Vendor report to OPRA with respect to:

- The Professional Subscribers to which the Vendor is providing bulk data feeds of OPRA Data (enabling these Professional Subscribers to act as internal distributors).
- The Professional Subscribers that have entered into Professional Subscriber Agreements directly with OPRA and that have devices and/or User IDs entitled by the Vendors.[6]
- The Professional Subscribers to which the Vendor distributes OPRA data and for whose access it pays OPRA usage-based fees (*i.e.,* Professional Subscribers to which it distributes OPRA data on a ''Per Query'' or ''meter-based'' basis).
- The Non-Professional Subscribers to whom the Vendor distributes OPRA data on a ''Per Query'' or ''meter-based'' basis and for whose access it pays OPRA usage-based fees.
- The Non-Professional Subscribers to whom the Vendor distributes OPRA data and for whose access it pays OPRA Nonprofessional Subscriber Fees.[7]
- Any voice-synthesized market data service provided by the Vendor.

Also as described in Section 1, OPRA requires that a Professional Subscriber that is an internal distributor report to OPRA with respect to the devices and User IDs that have .been entitled by the Professional Subscriber to have access to OPRA data.

(2) *Policies Relating to Usage-Based Fees.* Section 2 of the Policies describes OPRA's longstanding policies with respect to three questions that Vendors occasionally ask relating to OPRA's usage-based fees.

Paragraph 2(a) states OPRA's policy with respect to a Vendor that wishes to have access to OPRA data other than in connection with its activities as a Vendor—that is, to have access to OPRA

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78k–1.

[2] 17 CFR 242.608.

[3] The OPRA Plan is a national market system plan approved by the Commission pursuant to Section 11A of the Act and Rule 608 thereunder (formerly Rule 11Aa3–2). *See* Securities Exchange Act Release No. 17638 (March 18, 1981), 22 S.E.C. Docket 484 (March 31, 1981). The full text of the OPRA Plan is available at *http://www.opradata.com.*

The OPRA Plan provides for the collection and dissemination of last sale and quotation information on options that are traded on the participant exchanges. The nine participants to the OPRA Plan are BATS Exchange, Inc., Chicago Board Options Exchange, Incorporated, C2 Options Exchange, Incorporated, International Securities Exchange, LLC, NASDAQ OMX BX, Inc., NASDAQ OMX PHLX, Inc., NASDAQ Stock Market LLC, NYSE Amex, Inc., and NYSE Arca, Inc.

[4] ''Usage-based Vendor Fees'' or ''usage-based fees'' are fees that are payable by each Vendor with respect to access to OPRA Data by the Vendor's Subscribers on a ''Per Query'' or ''meter-based'' basis. Usage-based fees are applicable, at the election of the Vendor, to queries for ''quote packets'' or ''options chains.'' The rates for usage-based fees are stated, and the terms ''quote packet'' and ''options chain'' are defined, in OPRA's Fee Schedule. OPRA's Fee Schedule is available on OPRA's Web site, *www.opradata.com.*

[5] Professional Subscribers that are obliged to report their usage of OPRA data directly to OPRA are sometimes referred to as ''internal distributors'' because they have the independent ability to entitle access to OPRA data by their employees. These Professional Subscribers must have entered into Professional Subscriber Agreements directly with OPRA, and must also have entered into either a Direct Circuit Connection Rider or an Indirect (Vendor Pass-Through) Circuit Connection Rider with OPRA. OPRA sometimes refers to the data service to a Professional Subscriber that enables the Professional Subscriber to act as an internal distributor as a ''bulk data feed,'' and that term is defined in the Policies for that purpose.

[6] OPRA uses these reports to generate invoices for ''Professional Subscriber Device-based Fees'' that it sends directly to these Professional Subscribers.

[7] OPRA's Fee Schedule permits a Vendor to pay fees with respect to the receipt of OPRA data by a Nonprofessional Subscriber in one of two ways: Either by counting quote packets or options chains and paying usage-based fees or by paying the ''Nonprofessional Subscriber Fee''. The usage-based fees for Nonprofessional Subscribers are subject to a monthly cap, currently $1.00/month/Nonprofessional, and the Nonprofessional Subscriber Fee is a flat fee, also currently $1.00/month/Nonprofessional.

data in a ''Subscriber'' capacity as well as in its ''Vendor'' capacity. Such a Vendor has two choices. First, the Vendor may enter into a Professional Subscriber Agreement with OPRA and pay ''device-based fees'' directly to OPRA with respect to its access to OPRA data. Alternatively, the Vendor may enter into a Subscriber Agreement with a second, unaffiliated, Vendor to permit employees of the first Vendor to have access to OPRA data on a metered usage basis. In that case, the second Vendor will be responsible for tracking and reporting the access to OPRA data by employees of the first Vendor. OPRA is occasionally asked whether a Vendor can track and report the internal usage on a metered basis of the Vendor itself or its affiliates and pay usage-based fees with respect to this internal usage. Paragraph 2(a) states OPRA's longstanding policy that this alternative is not permitted.

Paragraph 2(b) states OPRA's policy that a Vendor must report with respect to its dissemination of OPRA data to a Professional Subscriber entirely on either a ''meter-based'' basis (in which case, the Vendor is responsible for paying Usage-based Vendor Fees for its dissemination of OPRA data to the Professional Subscriber) or on a ''device-based'' basis (in which case, the Professional Subscriber is responsible for paying device-based fees with respect to the Vendor's dissemination of OPRA data to the Professional Subscriber).

The policy described in paragraph 2(c) states that, if a device or User ID is capable of receiving OPRA information from one Vendor for which a Professional Subscriber pays device-based fees and from a second Vendor for which the second Vendor pays usage-based fees, both types of fees must be paid by the respective payors. OPRA has had a longstanding policy—stated in OPRA's ''Policies with respect to Device-Based Fees,'' [8]—that a Professional Subscriber is not required to pay more than one device-based fee with respect to any device or User ID that is capable of receiving OPRA information, even if the device or User ID is capable of receiving OPRA information from more than one source or ''service.'' Paragraph 2(c) affirms that, if a device or User ID is capable of receiving OPRA information from one Vendor for which the Professional Subscriber pays device-based fees and from a second Vendor for which the second Vendor pays usage-based fees, OPRA requires that both types of fees be paid by the respective payors.

(3) *Guidelines for Vendors' Quote Counting Systems.* Section 3 describes OPRA's guidelines with respect to Vendors' quote counting systems or ''quote meters.'' This section replaces a Policy currently on the OPRA Web site that, although it is entitled ''Auditing,'' actually describes OPRA's requirements with respect to quote meters. Section 3 states that a quote meter must comply with the following requirements:

- The quote meter must be able to recognize and count ''quote packets'' and/or ''options chains'' [9] for all data service of the Vendor that is provided to Subscribers on a usage basis, except that:
  - If the Vendor is ''capping'' the fee payable by the Vendor for any Nonprofessional Subscriber at the monthly maximum amount stated in OPRA's Fee Schedule, the quote meter needs to be able to count usage only up to the maximum amount.
  - If the Vendor is ''capping'' the fee payable by the Vendor for any Professional Subscriber at the monthly maximum amount stated in OPRA's Fee Schedule, the quote meter needs to be able to count usage only up to the maximum amount.
- The quote meter must not count usage for any Nonprofessional Subscriber for which the Vendor is paying the Nonprofessional Subscriber Fee. (The service to these Nonprofessional Subscribers is not on a usage basis.) [10]
- The quote meter must count usage separately for each option listed in a portfolio format or a market minder service. (For example, quote packets for a portfolio with five options series would constitute five quote packets.)
- The quote meter must count all ''current'' OPRA market data (*i.e.,* all OPRA data that was sent to the Vendor within the preceding 15 minutes). (Data that is no longer current—*i.e.,* that is delayed data—is not subject to reporting and payment of usage-based fees to OPRA.)

A Vendor's quote counting system must be able to comply with these requirements if the system is to be able to count quotes in a manner that results in an accurate determination of the Usage-based Vendor Fees that the Vendor owes to OPRA. Section 3 of the Policies provides a more accurate description of these requirements than OPRA's current policy entitled ''Auditing'' does.

The text of the proposed amendment to the OPRA Plan is available at OPRA, the Commission's Public Reference Room, on OPRA's Web site at *http://opradata.com*, and on the Commission's Web site at *http://www.sec.gov*.

II. Implementation of the OPRA Plan Amendment

OPRA designated this amendment as qualified to be put into effect upon filing with the Commission in accordance with clause (i) of paragraph (b)(3) of Rule 608 under the Act.[11] The Policies describe and refine longstanding OPRA technical policies with respect to the applicability of its fees, particularly its Usage-based Vendor Fee and Nonprofessional Subscriber Fee. Accordingly, OPRA will implement the Policies upon filing with the Commission.

The Commission may summarily abrogate the amendment within sixty days of its filing and require refiling and approval of the amendment by Commission order pursuant to Rule 608(b)(2) under the Act [12] if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Act.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed OPRA Plan amendment is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–OPRA–2011–03 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–OPRA–2011–03. This file

[8] OPRA's Policies with respect to Device-Based Fees are available on OPRA's Web site, *www.opradata.com.*

[9] These terms are defined in OPRA's Fee Schedule.

[10] OPRA's systems and Fee Schedule treat Nonprofessional Subscriber Fees and Usage-based Vendor Fees that are paid by Vendors with respect to access to OPRA data by Nonprofessionals separately.

[11] 17 CFR 242.608(b)(3)(i).

[12] 17 CFR 242.608(b)(2).

number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed plan amendment that are filed with the Commission, and all written communications relating to the proposed plan amendment 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 OPRA. 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–OPRA–2011–03 and should be submitted on or before December 19, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30425 Filed 11–25–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65800; File No. SR–C2–2011–035]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to a Temporary Quote Risk Monitor Mechanism Rule

November 21, 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 November 18, 2011, the C2 Options Exchange, Incorporated (''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] 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

The Exchange proposes to adopt Rule 8.12A *Pilot Quote Risk Monitor Mechanism.* The text of the proposed rule change is available on the Exchange's Web site (*http://www.c2exchange.com/Legal/RuleFilings.aspx*), at the Exchange's Office of the Secretary and at the Commission.

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 Statutory Basis for, the Proposed Rule Change

1. Purpose

On November 7, 2011, the Exchange filed to adopt a Quote Risk Monitor (QRM) rule.[5] That rule change was immediately effective upon filing, but will not be operative until December 7, 2011. C2 submitted the filing to codify C2's QRM functionality which has been available and in use on C2 since C2 commenced trading listed options.[6] On November 17, 2011 C2 announced that it would be deactivating the QRM functionality until December 7, 2011 when the new rule becomes operational.[7] The anticipated deactivation has caused considerable concern among C2 Market-Makers, and some have taken steps to cease acting as C2 Market-Makers. Out of concern that a decrease in quoters and a decrease in quote quality will have an adverse effect on the C2 market, this filing proposes to adopt a temporary C2 QRM rule that would be immediately effective and operative until December 7, 2011 when the above-referenced QRM rule will become operative.

C2 Rules require Market-Makers to maintain continuous electronic quotes.[8] To comply with this requirement, each Market-Maker can employ its own proprietary quotation and risk management systems to determine the prices and sizes at which it quotes.

A Market-Maker's risk in an options class is not limited to the risk in a single series of that class. Rather, a Market-Maker typically is active in quoting in multiple option classes, and each such option class can comprise dozens of individual option series. On C2, trades are automatically effected against a Market-Maker's then current quote. As a result, a Market-Maker faces exposure in all series of a class, requiring that the Market-Maker off-set or otherwise hedge its overall position in a class. The QRM functionality helps Market-Makers limit this overall exposure and risk. Specifically, the functionality permits a Market-Maker to establish parameters in the system to cancel its electronic quotes in all series of an option class until the Market-Maker refreshes those electronic quotes.

Under proposed Rule 8.12A, each Market-Maker that elects to use the functionality would be required to specify two parameters that the QRM Mechanism would use to determine when that Market-Maker's quotes should be cancelled. In particular, each Market-Maker is required to specify a maximum number of contracts for each option class (the ''Contract Limit'') and a rolling time period in seconds during which such Contract Limit is to be measured (the ''Measurement Interval'').

When the QRM Mechanism determines that the Market-Maker has traded more than the Contract Limit for any option class during any rolling Measurement Interval, the QRM Mechanism automatically cancels all of the Market-Maker's quotes in any series of that option class. By limiting its exposure across series, a Market-Maker is better able to quote aggressively in an option, knowing that the QRM

[13] 17 CFR 200.30–3(a)(29).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities Exchange Act Release No. 65744 (November 14, 2011) (SR–C2–2011–034).

[6] The Exchange inadvertently did not include a QRM rule in its initial rulebook and did not realize the omission until very recently.

[7] See C2 Regulatory Circular RG11–035.

[8] See C2 Rule 8.5(a)(1).

Mechanism will automatically cancel all its quotations in a class when its exposure limit is hit.

The Exchange notes that the proposed rule would not relieve a Market-Maker of its obligations to provide continuous electronic quotes under the Exchange rules [9] nor to provide ''firm'' quotes pursuant to the requirements of Exchange Rule 8.6. The Exchange also notes that the proposed rule is based on Chicago Board Options Exchange, Incorporated (''CBOE'') Rule 8.18 (Quote Risk Monitor Mechanism).

2. Statutory Basis

The basis under the Securities Exchange Act of 1934 (the ''Act'') for this proposed rule change is the requirement under Section 6(b)(5) [10] that an exchange have rules that are designed to promote just and equitable principles of trade, and to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest. In particular, the Exchange believes the proposed change is designed to promote just and equitable principles of trade, and to remove impediments to and perfect the mechanism for a free and open market and national market system because the rule change would provide a mechanism that would allow C2 Market-Makers to more effectively and efficiently manage their quotations. Knowing that a helpful quote management tool is in place would, in turn, allow those Market-Makers to quote more aggressively which removes impediments to a free and open market and benefits all C2 users.

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

The Exchange neither solicited nor received comments on the proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6) thereunder.[12]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [13] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Waiver of the operative delay will allow market makers to continue to use the QRM to manage risk associated with providing continuous quotes across a multitude of series and classes and thereby avoid a potentially adverse effect on the C2 market. For these reasons, the Commission designates that the proposed rule change become operative immediately upon filing.[15]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–C2–2011–035 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 No. SR–C2–2011–035. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the C2. 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 No. SR–C2–2011–035 and should be submitted on or before December 19, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30447 Filed 11–25–11; 8:45 am]

BILLING CODE 8011–01–P

[9] See C2 Rule 8.5(a)(1).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). Pursuant to Rule 19b–4(f)(6)(iii) under the Act, the Exchange is required to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. C2 has requested that the Commission waive the five-day pre-filing notice requirement in Rule 19b–4(f)(6)(iii). The Commission has determined to waive the five day pre-filing notice requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] 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. 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65796; File No. SR–OPRA–2011–05]

Options Price Reporting Authority; Notice of Filing and Immediate Effectiveness of Proposed Amendment to the Plan To Adopt a Policy Named ''Policy With Respect to Disaster Recovery Facilities''

November 21, 2011.

Pursuant to Section 11A of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 608 thereunder,[2] notice is hereby given that on November 7, 2011, the Options Price Reporting Authority (''OPRA'') submitted to the Securities and Exchange Commission (''Commission'') an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (''OPRA Plan'').[3] The proposed amendment adopts a policy named ''Policy with respect to Disaster Recovery Facilities'' (the ''Policy''). The Commission is publishing this notice to solicit comments from interested persons on the proposed OPRA Plan amendment.

I. Description and Purpose of the Plan Amendment

The purpose of OPRA's Policy with respect to Disaster Recovery Facilities is to address the fees that are payable to OPRA for a disaster recovery facility (a ''DR facility'') maintained by an OPRA Vendor or Professional Subscriber.

The Policy states that a Vendor or Professional Subscriber that operates a DR facility at which it needs to have access to OPRA data should be certain that its agreements with OPRA accommodate the DR facility. The Policy states that, if a Vendor or Professional Subscriber operates multiple sites that act as ''hot'' back-up sites for each other, OPRA will consider the sites not to be DR facilities.

The Policy states that, if a Vendor is operating a DR facility and uses OPRA data at the site for purposes solely associated with operating the DR facility in furtherance of the Vendor's activities as a Vendor, OPRA does not charge fees specifically for the DR facility, with one exception: If the Vendor has a live direct circuit connection to receive OPRA data from OPRA's processor at the DR facility, OPRA's Direct Access Fee is applicable.[4]

With respect to a Professional Subscriber, the Policy states that OPRA's standard Device-Based Fees will be applicable if a Professional Subscriber is operating a DR facility and has devices that are enabled to receive current OPRA data at the facility even when the site is not in actual use, but that these fees will not be applicable if devices at the site are not enabled to receive current OPRA data when the site is inactive. The Policy states that OPRA would not consider a device to be subject to fees if the device is temporarily enabled for current OPRA data solely for testing purposes. The Policy states that, as is the case for a Vendor that has a live direct circuit connection at its DR facility, if a Professional Subscriber has a live direct circuit connection at its DR facility, OPRA's Direct Access Fee will be applicable. Finally, the Policy states that, if devices at a DR facility are enabled to receive current OPRA data during an emergency, those devices will become fee-liable, but that OPRA will provide offsetting credits for devices that are unable to receive current OPRA data at the affected primary site as reasonably demonstrated by the Professional Subscriber to be appropriate in the circumstances.[5]

The text of the proposed amendment to the OPRA Plan is available at OPRA, the Commission's Public Reference Room, on OPRA's Web site at *http://opradata.com,* and on the Commission's Web site at *http://www.sec.gov.*

II. Implementation of the OPRA Plan Amendment

OPRA designated this amendment as qualified to be put into effect upon filing with the Commission in accordance with clause (i) of paragraph (b)(3) of Rule 608 under the Act.[6] The Policies describe and refine longstanding OPRA technical policies with respect to obligations of Vendors and Professional Subscribers to pay the fees described in OPRA's Fee Schedule with respect to their disaster recovery sites. Accordingly, OPRA will implement the Policies upon filing with the Commission.

The Commission may summarily abrogate the amendment within sixty days of its filing and require refiling and approval of the amendment by Commission order pursuant to Rule 608(b)(2) under the Act[7] if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Act.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed OPRA Plan amendment is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–OPRA–2011–05 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–OPRA–2011–05. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's

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[1] 15 U.S.C. 78k–1.

[2] 17 CFR 242.608.

[3] The OPRA Plan is a national market system plan approved by the Commission pursuant to Section 11A of the Act and Rule 608 thereunder (formerly Rule 11Aa3–2). *See* Securities Exchange Act Release No. 17638 (March 18, 1981), 22 S.E.C. Docket 484 (March 31, 1981). The full text of the OPRA Plan is available at *http://www.opradata.com.*

The OPRA Plan provides for the collection and dissemination of last sale and quotation information on options that are traded on the participant exchanges. The nine participants to the OPRA Plan are BATS Exchange, Inc., Chicago Board Options Exchange, Incorporated, C2 Options Exchange, Incorporated, International Securities Exchange, LLC, NASDAQ OMX BX, Inc., NASDAQ OMX PHLX, Inc., NASDAQ Stock Market LLC, NYSE Amex, Inc., and NYSE Arca, Inc.

[4] OPRA's base Direct Access Fee is currently, and for many years has been, $1000/month. (See the OPRA Fee Schedule, available on OPRA's Web site, *http://www.opradata.com.*) The base Direct Access Fee includes one backup circuit connection. OPRA's Direct Access Fee is payable by Vendors and Professional Subscribers that have direct circuit connections to OPRA's processor.

[5] Footnote 3 of the Policy notes that many OPRA Professional Subscribers count ''User IDs'' that are enabled to receive OPRA information as a surrogate for counting ''devices,'' and pay Device-based Fees on the basis of their ''User IDs'' rather than their ''devices.'' (See OPRA's ''Policies with respect to Device-based Fees'' for more information about counting User IDs instead of devices; these Policies are also available on OPRA's Web site.) Footnote 3 of the Policy notes that a disaster would probably not affect a Professional Subscriber's User ID count, and therefore would not affect the Device-based Fees payable by a Professional Subscriber that counts User IDs.

[6] 17 CFR 242.608(b)(3)(i).

[7] 17 CFR 242.608(b)(2).

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 plan amendment that are filed with the Commission, and all written communications relating to the proposed plan amendment 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 OPRA. 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–OPRA–2011–05 and should be submitted on or before December 19, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30427 Filed 11–25–11; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12934 and #12935]

Virginia Disaster #VA–00041

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Virginia (FEMA–4045–DR), dated 11/17/2011.

Incident: Remnants of Tropical Storm Lee.

Incident Period: 09/08/2011 through 09/09/2011.

Effective Date: 11/17/2011.

Physical Loan Application Deadline Date: 01/16/2012.

Economic Injury (EIDL) Loan Application Deadline Date: 08/17/2012.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 11/17/2011, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Alexandria City, Caroline, Essex, Fairfax, King And Queen, King George, Prince William, Westmoreland.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere ...	3.250
Non-Profit Organizations Without Credit Available Elsewhere	3.000
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	3.000

The number assigned to this disaster for physical damage is 12934B and for economic injury is 12935B.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2011–30494 Filed 11–25–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12879 and #12880]

Pennsylvania Disaster Number PA–00045

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Pennsylvania (FEMA—4030—DR), dated 10/07/2011.

Incident: Tropical Storm Lee.

Incident Period: 09/03/2011 through 10/15/2011.

DATES: *Effective Date:* 11/17/2011.

Physical Loan Application Deadline Date: 12/06/2011.

Economic Injury (EIDL) Loan Application Deadline Date: 07/09/2012.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Pennsylvania, dated 10/07/2011, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Chester, Northampton, Lackawanna, Mifflin, Adams.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2011–30496 Filed 11–25–11; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law (Pub. L.) 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections and new information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

[8] 17 CFR 200.30–3(a)(29).

(OMB)

Office of Management and Budget, *Attn:* Desk Officer for SSA, *Fax:* (202) 395–6974, *Email address: OIRA_Submission@omb.eop.gov*.

(SSA)

Social Security Administration, DCRDP, *Attn:* Reports Clearance Officer, 107 Altmeyer Building, 6401 Security Blvd., Baltimore, MD 21235, *Fax:* (410) 966–2830, *Email address: OPLM.RCO@ssa.gov*.

I. The information collection below is pending at SSA. SSA will submit it to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than January 27, 2012. Individuals can obtain copies of the collection instrument by calling the SSA Reports Clearance Officer at (410) 965–8783 or by writing to the above email address.

Workers' Compensation/Public Disability Questionnaire—20 CFR 404.408—0960–0247. Section *224* of the *Social Security Act (Act)* provides for the reduction of disability insurance benefits (DIB) when the combination of DIB and any worker's compensation (WC) or certain Federal, State, or local public disability benefits (PDB) exceeds 80 percent of the worker's pre-disability earnings. SSA uses Form SSA–546 to collect the data necessary to determine if the worker's receipt of WC or PDB payments will cause a reduction of DIB. The respondents are applicants for title II DIB.

Type of Request: Revision of an OMB-approved information collection.

Collection instrument	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–546	2,000	1	15	500
Modernized Claims System	248,000	1	15	62,000
Totals	250,000			62,500

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding the information collections would be most useful if OMB and SSA receive them within 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than December 28, 2011. Individuals can obtain copies of the OMB clearance packages by calling the SSA Reports Clearance Officer at (410) 965–8783 or by writing to the above email address.

1. *Application for Access to SSA Systems—20 CFR 401.45—0960–NEW.* SSA uses Form SSA–120 to allow limited access to SSA's information resources for SSA employees and non-Federal employees (contractors). SSA requires supervisory approval and local or component Security Officer review prior to granting this access. The respondents are SSA employees and non-Federal Employees (contractors) who require access to SSA systems to perform their jobs. Note: Because SSA employees are Federal workers exempt from the requirements of the Paperwork Reduction Act, the burden below is only for SSA contractors.

Note: Because SSA employees are Federal workers exempt from the requirements of the PRA, the burden below is only for SSA contractors.

Type of Request: In use without OMB approval.

Collection instrument	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–120	4,313	1	2	144

2. *Screen Pop—20 CFR 401.45—0960–NEW.* Section 205(a) of the Act requires SSA to verify the identity of individuals who request a record or information pertaining to themselves, and to establish procedures for disclosing personal information. SSA established Screen Pop, an automated telephone process, to speed up verification for such individuals. Accessing Screen Pop, callers enter their Social Security number (SSN) using their telephone keypad or speech technology prior to speaking with a National 800 Number Network (N8NN) agent. The automated Screen Pop application collects the SSN and routes it to the ''Start New Call'' Customer Help and Information (CHIP) screen. Functionality for the Screen Pop application ends once the SSN connects to the CHIP screen and the SSN routes to the agent's screen. When the call connects to the SSA agent, the agent can use the SSN to access the caller's record as needed. The respondents for this collection are individuals who contact SSA's N8NN to speak with an agent.

Type of Request: Request for a new information collection.

Collection instrument	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Screen Pop	34,000,000	1	1	566,667

3. *Marital Relationship Questionnaire—20 CFR 416.1826–0960–0460.* SSA uses Form SSA–4178 to determine if unrelated individuals of the opposite sex who live together are misrepresenting themselves as husband and wife. SSA needs this information to determine whether we are making correct payments to couples and

individuals applying for or currently receiving Supplemental Security Income (SSI) payments. The respondents are applicants for and recipients of SSI payments.

Type of Request: Revision of an OMB-approved information collection.

Collection instrument	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–4178	5,100	1	5	425

Dated: November 18, 2011.

Faye Lipsky,

Reports Clearance Officer, Center for Reports Clearance, Social Security Administration.

[FR Doc. 2011–30475 Filed 11–25–11; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 7695]

60-Day Notice of Proposed Information Collection: Form DS–7007, Summer Work Travel Job Placement Verification Form

ACTION: Notice of request for public comments.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. The purpose of this notice is to allow 60 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995.

- *Title of Information Collection:* Exchange Visitor Program—Summer Work Travel Job Placement Verification Form.
- *OMB Control Number:* None.
- *Type of Request:* New Collection.
- *Originating Office:* Bureau of Educational and Cultural Affairs, ECA/EC.
- *Form Number:* Form DS–7007.
- *Respondents:* Entities designated by the Department of State as Exchange Visitor Program sponsors in the Summer Work Travel category, and U.S. businesses that provide the employment opportunity.
- *Estimated Number of Respondents:* 51.
- *Estimated Number of Responses:* 120,000.
- *Average Hours per Response:* 1 hour.
- *Total Estimated Burden:* 120,000.
- *Frequency:* On occasion.
- *Obligation to Respond:* Mandatory.

DATES: The Department will accept comments from the public up to 60 days from November 28, 2011.

ADDRESSES: You may submit comments identified by any of the following methods:

- Persons with access to the Internet may view and comment on this notice by going to the regulations.gov Web site at *http://www.regulations.gov/#!home.* You can search by selecting ''Notice'' under Document Type, enter the Public Notice number, and check ''Open for Comment''. Search, and then to view the document, select an Agency.
- *Mail (paper, disk, or CD–ROM submissions):* U.S. Department of State, Office of Exchange Coordination and Designation, SA–5, 2200 C Street NW., Floor 5, Washington, DC 20522–0505
- *Email: jexchanges@state.gov.*

You must include the DS form number (if applicable), information collection title, and OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Rick A. Ruth, Deputy Assistant Secretary, Acting, for Private Sector Exchange, U.S. Department of State, SA–5, Floor 5, 2200 C Street NW., Washington, DC 20522–0505; or email at *jexchanges@state.gov.*

SUPPLEMENTARY INFORMATION:

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the effective administration of the Summer Work Travel category of the Exchange Visitor Program.
- Evaluate the accuracy of our estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of technology.

Abstract of Proposed Collection

This collection of information is needed by the Bureau of Educational and Cultural Affairs in administering the Exchange Visitor Program (J–Visa) under the provisions of the Mutual Educational and Cultural Exchange Act, as amended. Summer Work Travel Job Placement Verification Forms are to be completed by designated program sponsors. A Job Placement Verification Form is required for each Summer Work Travel participant. It will set forth the employer, address of employment site, duties required by the job, whether the Summer Work Travel participant will receive any remuneration for housing and living expenses (and if so, the amount), and estimates of the living expenses and other costs the participants are likely to incur while in the United States. The Form must be signed by the participant, the sponsor, and the third party employer, if a third party organization is used in the conduct of the Summer Work Travel program.

Upon request, Summer Work Travel applicants must present fully executed Job Placement Verification Forms (Form DS–7007) to any Consular Official interviewing them in connection with the issuance of J–1 visas.

Methodology

The collection will be submitted to the Department by mail or fax as requested by the Department of State during the review of program sponsor files, re-designations, incidents, etc.

Dated: October 20, 2011.

Rick A. Ruth,

Deputy Assistant Secretary, Acting, Office of Private Sector Exchange, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2011–30521 Filed 11–25–11; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Eleventh Meeting: RTCA Special Committee 223 Airport Surface Wireless Communications

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

ACTION: Notice of RTCA Special Committee 223 Airport Surface Wireless Communications Eleventh Meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of

RTCA Special Committee 223, Airport Surface Wireless Communications Eleventh Meeting

DATES: The meeting will be held December 6–7th, 2011, from 9 a.m.–5 p.m.

ADDRESSES: The meeting will be held at Booz Allen Hamilton, 1201 Maryland Avenue SW., Suite 5121B, Washington, DC 20024

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC, 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a Special Committee 223, Airport Surface Wireless Communications Meeting. The agenda will include the following:

December 6th, 2011

- Plenary
- Welcome, Introductions, Administrative Remarks by Special Committee Leadership
  - Designated Federal Official (DFO): Mr. Brent Phillips
  - Co-Chair: Mr. Aloke Roy, Honeywell International
  - Co-Chair: Mr. Ward Hall, ITT Corporation
- Agenda Overview
- Review/Approve Joint EUROCAE WG–82/RTCA SC–223 Plenary meeting Summary—RTCA Paper No. 220–11/SC223–023, and action item status
- Review action items
- General Presentations of Interest
  - WiMAX Forum status—WiMAX Forum
  - RTCA SC–206 Communiqué on Attributes Capability Matrix
  - ICAO Working Group S (plans/proposals/actions???)
  - AEEC SAI Action Regarding AeroMACS Standards—Continental Airlines

Afternoon—MOPS WG Breakout Session

- MOPS Outline—Rockwell Collins
  - Introduction Sections
- Discussion of Chapters 5,6,8—EUROCONTROL
  - SESAR P15.2.7 Profiles Definition for AeroMACS
  - Chap 8—Physical Layer—Updates per WiMAX Forum
  - Chap 5—Service Specific CS
  - Chap 6—Media Access Control

December 7, 2011

- MOPS WG Breakout Session
  - Discussion of Security Sub-layer—Honeywell
  - Review draft of Environmental (DO–160G)—Rockwell Collins
  - Review draft PICS—EUROCAE (Thales)
  - Review draft CSRL Appendix—Rockwell Collins
  - MOPS Schedule/Logistics—Rockwell Collins
- Wednesday Afternoon—Reconvene Plenary:
  - Discuss Work Program for 2012
  - Establish Agenda, Date and Place for RTCA plenary meetings #13 and #14
  - Review of Meeting summary report
  - Adjourn—Expected by 15:00
- Review all action items
- Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 17, 2011.

Robert L. Bostiga,

Manager, Business Operations Group, Federal Aviation Administration.

[FR Doc. 2011–30497 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2000–7257; Notice No. 68]

Railroad Safety Advisory Committee (RSAC); Working Group Activity Update

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Announcement of Railroad Safety Advisory Committee (RSAC) Working Group activities.

SUMMARY: The FRA is updating its announcement of RSAC's Working Group activities to reflect its current status.

FOR FURTHER INFORMATION CONTACT: Larry Woolverton, RSAC Designated Federal Officer/Administrative Officer, FRA, 1200 New Jersey Avenue SE., Mailstop 25, Washington, DC 20590, (202) 493–6212; or Robert Lauby, Deputy Associate Administrator for Regulatory and Legislative Operations, FRA, 1200 New Jersey Avenue SE., Mailstop 25, Washington, DC 20590, (202) 493–6474.

SUPPLEMENTARY INFORMATION: This notice serves to update FRA's last announcement of working group activities and status reports of December 7, 2010 (75 FR 76070). The 44th full RSAC meeting was held May 20, 2011, and the 45th meeting is scheduled for December 8, 2011, at the National Association of Home Builders, National Housing Center, located at 1201 15th Street NW., Washington, DC 20005.

Since its first meeting in April of 1996, the RSAC has accepted 36 tasks. Status for each of the open tasks (neither completed nor terminated) is provided below:

Open Tasks

Task 96–4—Tourist and Historic Railroads. Reviewing the appropriateness of the agency's current policy regarding the applicability of existing and proposed regulations to tourist, excursion, scenic, and historic railroads. This task was accepted on April 2, 1996, and a working group was established. The working group monitored the steam locomotive regulation task. Planned future activities involve the review of other regulations for possible adaptation to the safety needs of tourist and historic railroads. Contact: Robert Lauby, (202) 493–6474.

Task 03–01—Passenger Safety. This task includes updating and enhancing the regulations pertaining to passenger safety, based on research and experience. This task was accepted on May 20, 2003, and a working group was established. Prior to embarking on substantive discussions of a specific task, the working group set forth in writing a specific description of the task. The working group reports planned activity to the full RSAC at each scheduled full RSAC meeting, including milestones for completion of projects and progress toward completion. At the first meeting held on September 9–10, 2003, a consolidated list of issues was completed. At the second meeting, held on November 6–7, 2003, four task groups were established: Emergency Preparedness, Mechanical, Crashworthiness, and Track/Vehicle Interaction. The task forces met and reported on activities for working group consideration at the third meeting, held on May 11–12, 2004, and a fourth meeting was held October 26–27, 2004. The working group met on March 21–22, 2006, and again on September 12–13, 2006, at which time the group agreed to establish a task force on General Passenger Safety. The full Passenger Safety Working Group met on

April 17–18, 2007; December 11–12, 2007; November 13, 2008; and June 8, 2009. On August 5, 2009, the working group was requested to establish an Engineering Task Force (ETF) to consider technical criteria and procedures for qualifying alternative passenger equipment designs as equivalent in safety to equipment meeting the design standards in the Passenger Equipment Safety Standards. The working group met last on September 16, 2010, and no additional meetings are currently scheduled. Contact: Charles Bielitz, (202) 493–6314.

Engineering Task Force. The Passenger Safety Working Group approved a request from FRA to establish an ETF under the Passenger Safety Working Group in August 2009. The mission of the task force is to produce a set of technical evaluation criteria and procedures for passenger rail equipment built to alternative designs. The technical evaluation criteria and procedures would provide a means of establishing whether an alternative design would result in performance at least equal to the structural design standards set forth in the Passenger Equipment Safety Standards (Title 49 Code of Federal Regulations (CFR) part 238). The initial focus of this effort will be on Tier I standards. When completed, the criteria and procedures would form a technical basis for making determinations concerning equivalent safety pursuant to 49 CFR Section 238.201, and provide a technical framework for presenting evidence to FRA in support of any request for waiver of the compressive (buff) strength requirement, as set forth in 49 CFR 238.203. *See* 49 CFR part 211, Rules of Practice. The criteria and procedures could be incorporated into Part 238 at a later date after notice and opportunity for public comment. The ETF was formed and a kickoff meeting was held on September 23–24, 2009. The group held follow-on meetings November 3–4, 2009; January 7–8, 2010; and March 9–10, 2010. A followup GoTo/Webinar meeting was held on July 12, 2010. The ETF developed a draft ''*Criteria and Procedures Report,''* that was approved by the Passenger Safety Working Group during the September 16, 2010, meeting and by the RSAC Committee during the September 23, 2010, meeting. The document has been placed on the FRA Web site at the following address: *http://www.fra.dot.gov/downloads/safety/RSAC_REPORT-%209–16–10.pdf.*

Engineering Task Force II. To build on the success of the ETF in developing a set of alternative technical criteria and procedures for evaluating the crashworthiness and occupant protection performance of passenger rail equipment in service at conventional operating speeds, the FRA requested that the Passenger Safety Working Group re-task the group to concentrate on developing crashworthiness and occupant protection safety recommendations for high-speed passenger trains. The Passenger Safety Working Group accepted the task on July 28, 2010, by electronic vote. Under the new task, the task force may address any safety features of the equipment, including but not limited to crashworthiness, interior occupant protection, glazing, emergency egress, and fire safety features. Any type of equipment may be addressed, including conventional locomotives, high-speed power cars, cab cars, multiple-unit (MU) locomotives, and coach cars. The equipment addressed may be used in any type of passenger service, from conventional-speed to high-speed. Recommendations may take the form of criteria and procedures, revisions to existing regulations, or adoption of new regulations, including rules of particular applicability. The work of the re-tasked ETF is intended to assist FRA in developing appropriate safety standards for the high-speed rail projects planned for California. The Engineering Task Force II held a kickoff meeting on October 21–22, 2010, to begin work on the new high-speed task, and had follow-on meetings on January 11–12, 2011, February 14–15 2011, March 30–31, 2011, and June 16–17, 2011. Consensus Tier III recommendations of the ETF have been developed and were accepted by vote during a scheduled meeting on October 6–7, 2011. The ETF II has formed two additional Task Groups to work in the areas of track worthiness and brakes. The Track worthiness Task Group is tasked to identify potential safety issues related to operation of high-speed train sets on conventional track and to make recommendations on how best to mitigate any consequences. The Task Group includes experts and key stakeholders such as international operators of high-speed equipment, car builders, wheel/rail interaction dynamics specialists, and other RSAC working group members involved in vehicle/track interaction. The Brakes Task Group is tasked to review braking system requirements and international braking system requirements verses existing U.S. requirements including inspection and maintenance and identify common features, determine basic parameters and consider use of service proven braking systems. The Task Group will also consider performance based provisions/requirements with consideration for operator's to develop maintenance, inspection, and service plans and make recommendations regarding brakes to the ETF II as related to Tier III. Contact: Robert Lauby, (202) 493–6474.

Emergency Preparedness Task Force. At the working group meeting on March 9–10, 2005, the working group received and approved the consensus report of the Emergency Preparedness Task Force related to emergency communication, emergency egress, and rescue access. These recommendations were presented to and approved by the full RSAC on May 18, 2005. The working group met on September 7–8, 2005, and additional, supplementary recommendations were presented to and accepted by the full RSAC on October 11, 2005. The Notice of Proposed Rulemaking (NPRM) was published on August 24, 2006 (71 FR 50275), and was open for comment until October 23, 2006. The working group agreed upon recommendations for the final rule, including resolution of final comments received, during the April 17–18, 2007, meeting. The recommendations were presented to and approved by the full RSAC on June 26, 2007. The Passenger Train Emergency Systems final rule, focusing on emergency communication, emergency egress, and rescue access, was published on February 1, 2008 (73 FR 6370). The task force met on October 17–18, 2007, and reached consensus on the draft rule text for a followup NPRM on Passenger Train Emergency Systems, focusing on low location emergency exit path marking, emergency lighting, and emergency signage. The task force presented the draft rule text to the Passenger Safety Working Group on December 11–12, 2007, and the consensus draft rule text was presented to, and approved by full RSAC vote during the February 20, 2008, meeting. During the May 13–14, 2008, meeting, the task force recommended clarifying the applicability of back-up emergency communication system requirements in the February 1, 2008, final rule, and FRA announced its intention to exercise limited enforcement discretion for a new provision amending instruction requirements for emergency window exit removal. The working group ratified these recommendations on June 19, 2008. The task force met again on March 31, 2009, to clarify issues related to the followup NPRM raised by members. The modified rule text was presented to and approved by the Passenger Safety Working Group on June 8, 2009. The working group requested that FRA draft

the rule text requiring daily inspection of removable panels or windows in vestibule doors and entrust the Emergency Preparedness Task Force with reviewing the text. FRA sent the draft text to the task force for review and comment on August 4, 2009. The draft rule text was approved by the Passenger Safety Working Group by mail ballot on December 23, 2009. The target timeframe for the NPRM publication has been pushed back to November 2012 due to competing Rail Safety Improvement Act of 2008 (RSIA) priorities. No additional task force meetings are currently scheduled. Contact: Brenda Moscoso, (202) 493–6282.

Mechanical Task Force—Completed. Initial recommendations on mechanical issues (revisions to 49 CFR Part 238) were approved by the full RSAC on January 26, 2005. At the working group meeting of September 7–8, 2005, the task force presented additional perfecting amendments and the full RSAC approved them on October 11, 2005. An NPRM was published in the **Federal Register** on December 8, 2005 (70 FR 73070). Public comments were due by February 17, 2006. The final rule was published in the **Federal Register** on October 19, 2006 (71 FR 61835), effective December 18, 2006.

Crashworthiness Task Force—Completed. Among its efforts, the Crashworthiness Task Force provided consensus recommendations on static-end strength that were adopted by the working group on September 7–8, 2005. The full RSAC accepted the recommendations on October 11, 2005. The front-end strength of cab cars and MU locomotives NPRM was published in the **Federal Register** on August 1, 2007 (72 FR 42016), with comments due by October 1, 2007. A number of comments were entered into the docket, and a Crashworthiness Task Force meeting was held September 9, 2008, to resolve comments on the NPRM. Based on the consensus language agreed to at the meeting, FRA has prepared the text of the final rule incorporating the resolutions made at the task force meeting and the final rule language was adopted at the Passenger Safety Working Group meeting held on November 13, 2008. The language was presented and approved at the December 10, 2008, full RSAC meeting. The final rule was issued on December 31, 2009, and published on January 8, 2010 (75 FR 1180). Contact: Gary Fairbanks, (202) 493–6322.

Vehicle/Track Interaction Task Force. The task force is developing proposed revisions to 49 CFR Parts 213 and 238, principally regarding high-speed passenger service. The task force met on October 9–11, 2007, and again on November 19–20, 2007, in Washington, DC, and presented the final task force report and final recommendations and proposed rule text for approval by the Passenger Safety Working Group at the December 11–12, 2007, meeting. The final report and the proposed rule text were approved by the working group and were presented to and approved by full RSAC vote during the February 20, 2008, meeting. The group met on February 27–28, 2008, and by teleconference on March 18, 2010, to address unresolved issues, and the NPRM was published on May 10, 2010 (75 FR 25928). The task force was called back into session on August 5–6, 2010, to review and consider NPRM comments. The final rule will amend the Track Safety Standards and Passenger Equipment Safety Standards for high-speed train operations and train operations at high cant deficiencies to promote the safe interaction of rail vehicles with the track over which they operate. It will revise both the safety limits for these operations and the process to qualify them. It accounts for a range of vehicle types that are currently used and may likely be used on future high-speed or high cant deficiency rail operations, and would provide safety assurance for train operations in all classes of track. It is based on the results of simulation studies designed to identify track geometry irregularities associated with unsafe wheel forces and acceleration, thorough reviews of vehicle qualification and revenue service test data, and consideration of international practices. The draft final rule was sent to the task force for final consensus on November 11, 2011. The target date set for the final rule is April 2012. Contact: John Mardente, (202) 493–1335.

General Passenger Safety Task Force. At the Passenger Safety Working Group meeting on April 17–18, 2007, the task force presented a progress report to the working group. The task force met on July 18–19, 2007, and afterwards it reported proposed reporting cause codes for injuries involving the platform gap, which were approved by the Working Group by mail ballot in September 2007. The full RSAC approved the recommendations for changes to 49 CFR Part 225 accident/incident cause codes on October 25, 2007. The General Passenger Safety Task Force presented draft guidance material for management of the gap that was considered and approved by the Working Group during the December 11–12, 2007, meeting and was presented to and approved by full RSAC vote during the February 20, 2008, meeting. The group met April 23–24, 2008, December 3–4, 2008, April 21–23, 2009, October 7–8, 2009, and July 30, 2010 by GoTo/Webinar teleconference. The task force continues work on passenger train door securement, ''second train in station,'' trespasser incidents, and System Safety-based solutions by developing a regulatory approach to System Safety. The task force has created two task groups to focus on these issues.

The Door Safety Task Group has reached consensus on 47 out of 48 safety issues and had five items that have been remanded to the task force for vote. The issues are addressed in the area of passenger train door mechanical and operational requirements and presented draft regulatory language to the Passenger Safety Working Group at the September 16, 2010, meeting. More work remains to ensure the 49 CFR Part 238 door rule consensus document and the proposed American Public Transit Association (APTA) door standard (APTA SS–M–18–10) use uniform language. The document was approved by the Passenger Safety Working Group by electronic vote on March 31, 2011, and approved by the RSAC on May 20, 2011. This rulemaking would amend the passenger equipment safety standards to enhance safety standards as they relate to passenger door securement while a passenger train is in service based on research and experiences of FRA safety inspectors. Specifically, FRA would incorporate by reference APTA standard: ''APTA SS–M–18–10 Standard for Powered Exterior Side Door System Design for New Passenger Cars.'' A draft NPRM is currently under development with a target publication date of May 2012. No additional Door Task Group meetings are currently scheduled. Contact: Brian Hontz, (610) 521–8220.

The System Safety Task Group has produced draft regulatory language for a System Safety Rule, but further work on this rulemaking is delayed until a study of legal protections for Risk Reduction Program (RRP) and System Safety Program (SSP) risk analysis data that is required by the RSIA is complete. The legal study is expected to be complete by December 2012. The System Safety rulemaking would improve passenger railroad safety through structured, proactive processes and procedures developed by passenger railroad operators. It would require passenger railroads to establish an SSP that would systematically evaluate and manage risks in order to reduce the number and rates of railroad accidents, incidents, injuries, and fatalities. The target date

for NPRM publication is May 2012. No additional System Safety Task Group meetings are currently scheduled. Contact: Dan Knote, (631) 567–1596.

Task 05–01—Review of Roadway Worker Protection Issues. This task was accepted on January 26, 2005, to review 49 CFR part 214, Subpart C, Roadway Worker Protection (RWP), and related sections of Subpart A; to recommend consideration of specific actions to advance the on-track safety of railroad employees and contractors engaged in maintenance-of-way activities throughout the general system of railroad transportation, including clarification of existing requirements. A working group was established and reported to the RSAC any specific actions identified as appropriate. The first meeting of the working group was held on April 12–14, 2005. Over the course of 2 years, the group drafted and reached consensus on regulatory language for various revisions, clarifications, and additions to 32 separate items in 19 sections of the rule. However, two parties raised technical concerns regarding one of those items, namely, the draft language concerning electronic display of track authorities. The working group presented and received approval on all of its consensus recommendations for draft rule text to the full RSAC at the June 26, 2007, meeting. FRA will address the electronic display of track authorities issue, along with eight additional items that the working group was unable to reach consensus, through the traditional NPRM process. In early 2008, the external working group members were solicited to review the consensus rule text for errata review. In order to address the heightened concerns raised with the current regulations for adjacent-track, on-track safety, FRA decided to issue, on an accelerated basis, a separate NPRM that would focus on this element of the RWP rule alone. An NPRM with an abbreviated comment period regarding adjacent-track, on-track safety was published on July 17, 2008, but was later withdrawn on August 13, 2008, to permit further consideration of the RSAC consensus language. A second NPRM concerning adjacent-controlled-track, on-track safety was published on November 25, 2009, and comments were due to the docket by January 25, 2010. Comments have been reviewed and considered by FRA, and the target publication date for the final rule is November 2011. Due to the ongoing work of this separate rulemaking, the remaining larger NPRM relating to the various revisions, clarifications, and additions to 31 separate items in 19 sections of the rule, and FRA's recommendations for nine nonconsensus items is now planned for early 2012. Contact: Joe Riley, (202) 493–6357.

Task 05–02—Reduce Human Factor-Caused Train Accident/Incidents. This task was accepted on May 18, 2005, to reduce the number of human factor-caused train accidents/incidents and related employee injuries. The Railroad Operating Rules Working Group was formed, and the working group extensively reviewed the issues presented. The final working group meeting devoted to developing a proposed rule was held February 8–9, 2006. The working group was not able to deliver a consensus regulatory proposal, but it did recommend that it be used to review comments on FRA's NPRM, which was published in the **Federal Register** on October 12, 2006 (FR 71 60372), with public comments due by December 11, 2006. Two reviews were held, one on February 8–9, 2007, and one on April 4–5, 2007. Consensus was reached on four items and those items were presented and accepted by the full RSAC at the June 26, 2007, meeting. A final rule was published in the **Federal Register** on February 13, 2008 (73 FR 8442), with an effective date of April 14, 2008. FRA received four petitions for reconsideration of that final rule. The final rule that responded to the petitions for consideration was published in the **Federal Register** on June 16, 2008, and concluded the rulemaking. Working group meetings were held September 27–28, 2007; January 17–18, 2008; May 21–22, 2008; and September 25–26, 2008. The working group has considered issues related to issuance of Emergency Order No. 26 (prohibition on use of certain electronic devices while on duty), and ''after arrival mandatory directives,'' among other issues. The working group continues to work on after arrival orders, and at the September 25–26, 2008, meeting voted to create a Highway-Rail Grade Crossing Task Force to review highway-rail grade crossing accident reports regarding incidents of grade crossing warning systems providing ''short or no warning'' resulting from or contributed to ''by train operational issues'' with the intent to recommend new accident/incident reporting codes that would better explain such events, and which may provide information for remedial action going forward. A followup task is to review and provide recommendations regarding supplementary reporting of train operations-related, no-warning or short-warning incidents that are not technically warning system activation failures, but that result in an accident/incident or a near miss. The task force has been formed and will begin work after other RSIA priorities are met. Contact: Douglas Taylor, (202) 493–6255.

Task 06–01—Locomotive Safety Standards. This task was accepted on February 22, 2006, to review 49 CFR part 229, Railroad Locomotive Safety Standards, and revise as appropriate. A working group was established with the mandate to report any planned activity to the full Committee at each scheduled full RSAC meeting, to include milestones for completion of projects and progress toward completion. The first working group meeting was held May 8–10, 2006. Working group meetings were held on August 8–9, 2006; September 25–26, 2006; October 30–31, 2006; and the working group presented recommendations regarding revisions to requirements for locomotive sanders to the full RSAC on September 21, 2006. The NPRM regarding sanders was published in the **Federal Register** on March 6, 2007 (72 FR 9904). Comments received were discussed by the working group for clarification, and FRA published a final rule on October 19, 2007 (72 FR 59216). The working group met on January 9–10, 2007; November 27–28, 2007; February 5–6, 2008; May 20–21, 2008; August 5–6, 2008; October 22–23, 2008; January 6–7, 2009; and April 15–16, 2009. The working group has now completed the review of 49 CFR Part 229 and was unable to reach consensus regarding locomotive cab temperature standards, locomotive alerters, and remote control locomotives. The group reached consensus regarding critical locomotive electronic standards, updated annual/biennial air brake standards, clarification of the ''air brakes operate as intended'' requirement, locomotive pilot clearance within hump classification yards, clarification of the ''high voltage'' warning requirement, an update of ''headlight lamp'' requirements, and language to allow locomotive records to be stored electronically. The working group presented a draft 49 CFR part 229 rule text revision covering these items to the RSAC for consideration at the September 10, 2009, meeting and received approval. The NPRM was delayed due to competing RSIA priorities and the need for additional language. The NPRM was published on January 12, 2011 (76 FR 2200), and the final rule is scheduled to be published in December 2011. This rulemaking would amend the rules pertaining to the Locomotive Safety Standards. The

proposed amendments would update, consolidate, and clarify existing rules, and adopt existing industry and engineering best practices. The proposed amendments include: Updating locomotive inspection recordkeeping requirements by permitting electronic records; consolidating locomotive air brake maintenance into a single provision; clarifying locomotive headlight requirements to address new technology; and establishing locomotive electronics standards based on existing industry and engineering best practices, as well as other existing Federal electronics standards. This action is taken by FRA in an effort to improve its safety regulator program. The working group may be called back to address comments received on the final rule after publication. Contact: Steve Clay, (202) 493–6259.

Task 06–03—Medical Standards for Safety-Critical Personnel. This task was accepted on September 21, 2006, to enhance the safety of persons in the railroad operating environment and the public by establishing standards and procedures for determining the medical fitness for duty of personnel engaged in safety-critical functions. A working group was established by the full RSAC and reports its activities and progress toward completion of this task to the full RSAC during each meeting of the full RSAC. The first working group meeting was held December 12–13, 2006, and the working group has held follow-on meetings on February 20–21, 2007; July 24–25, 2007; August 29–30, 2007; October 31–November 1, 2007; December 4–5, 2007; February 13–14, 2008; March 26–27, 2008; April 22–23, 2008; December 8–9, 2009; February 16–17, 2010; March 11–12, 2010; May 24–26, 2010; August 31–September 1, 2010; November 18–19, 2010; February 16–17, 2010; March 11–12, 2010; May 24–26, 2010; August 31–September 1, 2010; November 18–19, 2010; and September 27–28, 2011. During the working group's September 2011 meeting, the working group discussed stakeholder positions on the draft rule text and draft medical qualification criteria and protocols, and a preliminary cost-benefit analysis was presented to the working group by the FRA economist. The working group tentatively agreed to proceed to revise its draft recommendations to include a proposed option that the medical qualification criteria be issued as medical qualification guidelines rather than standards. The working group established a task force to draft proposed revisions to working draft documents to be presented to the working group for review and comment. The next working group meeting is scheduled to be held February 1–2, 2012, in Washington, DC. Contact: Dr. Bernard Arseneau, (202) 493–6002.

Physicians Task Force. A Physicians Task Force was established by the working group in May 2007, and tasked to draft recommended medical qualification criteria and protocols for locomotive engineers and conductors. The Physicians Task Force has had meetings or conference calls on July 24, 2007; August 20, 2007; October 15, 2007; October 31, 2007; June 23–24, 2008; September 8–10, 2008; October 8, 2008; November 12–13, 2008; December 8–10, 2008; January 27–28, 2009; February 24–25, 2009; March 11–12, 2009; March 31–April 1, 2009; April 15, 2009; April 22, 2009; May 13, 2009; May 20, 2009; June 17, 2009; January 21–22, 2010; March 3, 2010; August 16–17, 2010; and October 25–26, 2010; December 17, 2010; January 11, 2011; March 3–4, 2011; May 16–17, 2011; August 18, 2011; August 25, 2011; August 31, 2011. On September 1, 2011, the task force notified working group members that it had made significant progress in completing its task and requested that the working group participate in clarifying a limited number of remaining operational issues relevant to the task that merited review by industry management, labor, and other stakeholders. No further meetings of the Physicians Task Force are currently scheduled. Contact: Dr. Bernard Arseneau, (202) 493–6002.

Critical Incident Task Force. The Medical Standards Working Group accepted RSAC Task 2009–02, Critical Incident Response, during the December 8–9, 2010, meeting. The working group has been tasked to provide advice regarding development of implementing regulations for critical incident stress plans as required by the RSIA. A Critical Incident Task Force was established by the working group during the May 24–26, 2010, Medical Standards Working Group meeting. The scheduled kickoff meeting for the Critical Incident Task Force scheduled for September 2, 2010, was postponed at the request of industry participants. In late March 2011, FRA leadership decided to request that the RSAC be asked to amend the Critical Incident task statement to remove reference to the Medical Standards Working Group and to allow the group to assume full working group status to expedite the work. The Committee approved the revised task statement with a target date for recommendations to the Committee of December 2011 and the task force transitioned to the Critical Incident Working Group. (See Critical Incident Working Group entry.) Contact: Dr. Bernard Arseneau, (202) 493–6002.

Task 07–01—Track Safety Standards. This task was accepted on February 22, 2007, to consider specific improvements to the Track Safety Standards or other responsive actions, supplementing work already underway on continuous welded rail (CWR) specifically to: Review controls applied to the re-use of rail in CWR ''plug rail''; review the issue of cracks emanating from bond wire attachments; consider improvements in the Track Safety Standards related to fastening of rail to concrete ties; and ensure a common understanding within the regulated community concerning requirements for internal rail flaw inspections. The tasks were assigned to the Track Safety Standards Working Group. The working group will report any planned activity to the full Committee at each scheduled full RSAC meeting, including milestones for completion of projects and progress toward completion. The first working group meeting was held on June 27–28, 2007, and the group met again on August 15–16, 2007, and October 23–24, 2007. Two task forces were created under the working group: Concrete Ties Task Force and Rail Integrity Task Force. The Concrete Ties Task Force met on November 26–27, 2007; February 13–14, 2008; April 16–17, 2008; July 9–10, 2008; and September 17–18, 2008. The Concrete Ties Task Force finalized consensus language regarding concrete crossties (49 CFR Part 213) and presented a recommendation to the Track Standards Working Group at the November 20, 2008, working group meeting. The language was approved by both the working group and the December 10, 2008, RSAC meeting and the task force was dissolved. The Concrete Crossties NPRM was published on August 26, 2010 (75 FR 52490). The Track Standards Working Group met on October 26–27, 2010, to discuss the outstanding issue of plug rail. The working group reached consensus on regulatory language regarding the reuse of plug rail and the consensus language was presented to and approved by the RSAC Committee during the December 14, 2010 meeting. RSAC Task 07–01 will be complete once the final rule is issued. Contact: Carlo Patrick, (202) 493–6399.

Task 08–03—Track Safety Standards Rail Integrity. This task was accepted on September 10, 2008, to consider specific improvements to the Track Safety Standards or other responsive actions designed to enhance rail integrity. The Rail Integrity Task Force was created in October 2007 under Task 07–01 and

first met on November 28–29, 2007. The task force met on February 12–13, 2008; April 15–16, 2008; July 8–9, 2008; September 16–17, 2008; February 3–4, 2009; June 16–17, 2009; October 29–30, 2009; January 20–21, 2010; March 9–11, 2010; and April 20, 2010. Consensus has been achieved on bond wires and a common understanding on internal rail flaw inspections has been reached. The task force has reached consensus to recommend to the working group that the item regarding ''the effect of rail head wear, surface conditions and other relevant factors on the acquisition and interpretation of internal rail flaw test results'' be closed. The task force does not recommend regulatory action concerning head wear. Surface conditions and their effect on test integrity has been discussed and understood during dialogue concerning common understanding on internal rail flaw inspections. The task force believes that new technology has been developed that improves test performance and will impact the effect of head wear and surface conditions on interpretation of internal rail flaw test results. Consensus text was developed on recommended changes that would approach a performance-based approach to flaw detection scheduling. However, the group did not reach consensus on what length of segment of track is practical to use on determining test cycles. Consensus text has been finalized for recommended changes to 49 CFR 213.113, Defective rails; 213.237, Rail inspection; and 213.241, Inspection records. The task force has developed a new 49 CFR 213.238, Qualified operator language, that defines the minimum requirements for the training of a rail flaw detector car operator. The task force presented the consensus language to the Track Standards Working Group during the July 28–30, 2010, meeting and the Track Standards Working Group presented its consensus recommendations to the RSAC Committee for approval during the September 23, 2010, Committee meeting. By majority vote, the RSAC accepted the recommendations of the Track Standards Working Group and forwarded those recommendations to the Administrator completing RSAC Task 08–03. The associated NPRM is currently in development and RSAC Task 08–03 will be complete once the final rule is issued. Contact: Carlo Patrick, (202) 493–6399.

Task No. 08–04—Positive Train Control. This task was accepted on December 10, 2008, to provide advice regarding development of implementing regulations for Positive Train Control (PTC) systems and their deployment under the RSIA. The task included a requirement to convene an initial meeting no later than January 2009, and to report recommendations back to RSAC no later than April 24, 2009. The PTC Working Group was created in December 2008 by working group member nominations from committee member organizations under Task 08–04 and the kickoff meeting was held on January 26–27, 2009. The group met again on February 11–13, 25–27; March 17–18, 2009; and March 31–April 1, 2009. On April 2, 2009, the RSAC approved the request by the working group for agreement to vote on the draft rule text recommendations from the working group by mail ballot. On May 11, 2009, by majority vote via mail ballot, the RSAC accepted the recommendations of the PTC Working Group and forwarded those recommendations to the Administrator, with the understanding that there are other issues that FRA would be making proposals with respect to their resolution. The NPRM was published on July 21, 2009 (74 FR 36152), with comments due by August 20, 2009. In addition, a public hearing was held on August 13, 2009 (74 FR 36152). The PTC Working Group was reconvened on August 31–September 2, 2009, to discuss comments received on the NPRM and the PTC Working Group presented consensus rule text items to the RSAC for approval at the September 10, 2009, meeting. The PTC consensus rule text was approved by majority RSAC vote by electronic ballot on September 24, 2009, and the final rule was published on January 15, 2010 (75 FR 2598). Final rule amendments were published on September 27, 2010 (75 FR 59108). An NPRM proposing amendments to the PTC Final Rule that would remove various regulatory requirements that require railroads to either conduct further analyses or meet certain risk-based criteria in order to avoid PTC system implementation on track segments that do not transport poison- or toxic-by-inhalation hazardous materials traffic, and are not used for intercity or commuter rail passenger transportation, as of December 31, 2015, was published on August 24, 2011 (76 FR 52918) with comments due by October 24, 2011. The PTC Working Group met on October 21, 2011, to provide input for an additional NPRM intended to address further rule considerations. FRA did not seek consensus from the RSAC or PTC Working Group on the substance of this NPRM, but requested the working group's valued assistance and input in its development. No additional meetings are scheduled at this time. Contact: Tom McFarlin, (202) 493–6203.

PTC Implementation Plan Task Force. A task force was formed to assist FRA in developing a model template for a successful PTC Implementation Plan (PTCIP), and in development of an example associated Risk Prioritization Methodology. PTCIPs are required to be submitted by April 16, 2010, under the mandate of the RSIA. FRA posted a final version of a PTCIP template and an example risk prioritization methodology model for prioritization of line segment implementation to the FRA public Web site on January 12, 2010, the same day the final rule was made available for public review. No further meetings of this task force are currently scheduled. Contact: Tom McFarlin, (202) 493–6203.

PTC Risk Evaluation Task Force. The creation of the PTC Risk Evaluation Task Force was approved by the PTC Working Group on April 1, 2010, to develop a computer model to estimate the risk of PTC-preventable accidents on a line segment basis. The group was formed by nominations from members of the PTC Working Group and the kickoff meeting was held via GoTo/Webinar on June 17, 2010. A followup meeting was held on August 3, 2010, and an additional followup GoTo/Webinar meeting was held on September 7, 2010. No additional meetings are scheduled at this time. Contact: Mark Hartong, (202) 493–1332.

Task No. 08–07—Conductor Certification. This task was accepted on December 10, 2008, to develop regulations for certification of railroad conductors, as required by the RSIA, and to consider any appropriate related amendments to existing regulations and report recommendations for proposed or interim final rule (as determined by FRA in consultation with the Office of the Secretary of Transportation and the Office of Management and Budget) by October 16, 2009. The Conductor Certification Working Group was officially formed by nominations from member organizations in April 2009, and the first meeting was held on July 21–23, 2009. Additional meetings were held on August 25–27, 2009; September 15–17, 2009; October 20–22, 2009; November 17–19, 2009; and December 16–18, 2009. Tentative consensus was reached on the vast majority of the regulatory text. The working group approved the draft rule text by electronic ballot and the consensus draft language was approved by the RSAC on March 18, 2010, by unanimous vote as the recommendation from the Committee to the FRA Administrator. The resulting NPRM was published in

the **Federal Register** on November 10, 2010 (75 FR 69166) and the working group was called back to meet and review comments received on May 12, 2011, and the final rule is currently under development with a target publication date of November 2012. This rulemaking would provide rules and guidance for requisite train conductor certification to ensure that individuals have the knowledge and skills necessary to perform the duties of a train conductor. This rulemaking may propose that each railroad adopt and comply with a written program for certifying and recertifying the qualifications of conductors. After the final rule is published, the working group will reconvene to make conforming amendments to the locomotive engineer certification regulation as appropriate. Contact: Mark McKeon, (202) 493–6350.

Task No. 09—01—Passenger Hours of Service. This task was accepted on April 2, 2009, to provide advice regarding development of implementing regulations for the hours of service of operating employees of commuter and intercity passenger railroads under the RSIA. The group has been tasked to review available data concerning the effects of fatigue on the performance of subject employees and consider the role of fatigue prevention in determining maximum hours of service. The group has also been tasked to consider the potential for alternative approaches to hours of service using available tools for evaluating the impact of various crew schedules and determine the effect of alternative approaches on the availability of employees to support passenger service. The group is charged to report whether existing hours of service restrictions are effective in preventing fatigue among subject employees, whether an alternative approach to hours of service for the subject employees would enhance safety and whether alternative restrictions on hours of service could be coupled with other fatigue countermeasures to promote the fitness of employees for safety-critical duties. The Passenger Hours of Service Working Group was officially formed through the formal Committee member nomination process in May 2009, and the first meeting was held on June 24, 2009. Followup working group meetings were held on February 2–3, 2010; March 4–5, 2010; April 6, 2010; May 20, 2010; and June 29, 2010. Consensus has been reached on a majority of the issues and the draft rule text has been matured. A Passenger Hours of Service Task Force was formed to review collected data and provide recommendations to the working group. The task force met on January 14–15, 2010; March 30–31, 2010; and June 16, 2010. The working group approved the draft rule text by electronic ballot on September 22, 2010, and the consensus draft language was approved by the RSAC on October 15, 2010, by unanimous electronic vote as the recommendation from the Committee to the FRA Administrator. The working group met on December 9, 2010, to discuss the approved consensus language and the NPRM preamble and the resulting NPRM was published on March 22, 2011 (76 FR 16200), and the final rule was published on August 12, 2011 (76 FR 50360), with an effective date of October 15, 2011. Contact: Mark McKeon, (202) 493–6350.

Task No. 09–02—Critical Incident Programs. This task was accepted on September 10, 2009, to provide advice regarding development of implementing regulations for Critical Incident Stress Plans as required by the RSIA. The group has been tasked to define what a ''critical incident'' is that requires a response; review available data, literature, and standards of practice concerning critical incident programs to determine appropriate action when a railroad employee is involved in or directly witnesses a critical incident; review any evaluation studies available for existing railroad critical incident programs; describe program elements appropriate for the rail environment, including those requirements set forth in the RSIA; provide an example of a suitable plan (template); and assist in the preparation of an NPRM no later than December 2010. In late March 2011, FRA leadership decided to request that the RSAC be asked to amend the Critical Incident task statement to remove reference to the Medical Standards Working Group and to allow the group to assume full working group status to expedite the work. The Committee approved the revised task statement with a target date for recommendations to the Committee of December 2011. The Critical Incident Working Group kickoff meeting was held on June 24, 2011. The draft report assessing current knowledge of post-traumatic interventions and to advance evidence-based recommendations for controlling the risks associated with traumatic exposure in the railroad setting was completed and distributed to the working group prior to the September 8–9, 2011, working group meeting. Due to the aggressive timeline, the working group held its second meeting on October 11–12, 2011 with a follow-on meeting scheduled for December 13–14, 2011. Contact: Ron Hynes, (202) 493–6404.

Task No. 10–01—Minimum Training Standards and Plans. This task was accepted on March 18, 2010, to establish minimum training standards for each class and craft of safety-related railroad employee and their railroad contractor and subcontractor equivalents, as required by RSIA. The group has been tasked to assist FRA in developing regulations responsive to the legislative mandate, while ensuring generally accepted principles of adult learning are employed in training and development and delivery; determine a reasonable method for submission and FRA review of training plans which takes human resource limitations into account; establish reasonable oversight criteria to ensure training plans are effective, using the operational tests and inspections requirements of 49 CFR Part 217 as a model. The Training Standards Working Group was officially formed through the formal Committee member nomination process in March 2010, and the first meeting was held on April 13–14, 2010. A followup working group meeting was held on June 2–3, 2010, and additional followup meetings were scheduled for August 17–18 and September 21–22, 2010. A Task Analysis Task Force was formed under the working group to develop a task analysis template and met in Florence, KY, on June 22–23, 2010, with CSX Transportation hosting the event. The group developed a 21-page task analysis document for an outbound train yard carman position, which is complete regarding FRA railroad safety laws, regulations, and orders. The working group met August 17–18, and October 19–20, 2010, and by GoTo/Webinar on November 15–16, 2010. The working group reached consensus and the resulting training standards draft regulatory language was presented to and approved by the RSAC Committee on December 14, 2010. This rulemaking will (1) Establish minimum training standards for each class or craft of safety-related employee and equivalent railroad contractor and subcontractor employee that require railroads, contractors, and subcontractors to qualify or otherwise document the proficiency of such employees in each such class and craft regarding their knowledge and ability to comply with Federal railroad safety laws and regulations and railroad rules and procedures intended to implement those laws and regulations, etc.; (2) require submission of railroads', contractors', and subcontractors' training and qualification programs for FRA approval; and (3) establish a

minimum training curriculum and ongoing training criteria, testing, and skills evaluation measures for track and equipment inspectors employed by railroads and railroad contractor and subcontractors. The resulting NPRM is under development with a target publication date of January 2012. No additional working group meetings are scheduled at this time. Contact: Michael Logue, (202) 493–6301.

Task No. 10–02—Safety Technology in Dark Territory. This task was accepted on September 23, 2010, to provide advice regarding development of standards, guidance, regulations, or orders governing the development, use, and implementation of rail safety technology in dark territory, as required by Section 406 of the RSIA. Specifically, to assist FRA in developing regulations responsive to the legislative mandate and to report recommendations to the FRA Administrator for proposed or interim final rule (as determined by FRA in consultation with the Office of the Secretary of Transportation and the Office of Management and Budget) by September 30, 2011. This rulemaking would issue standards or guidance governing development and deployment of technology to promote safe operation in non-signaled territory in arrangements not defined in signal inspection law. The delay in starting this effort was caused by the PTC rulemaking, which required the same key personnel both in government and industry. With the PTC effort maturing, resources became available and the Dark Territory Working Group was formed to assist FRA in developing regulations responsive to the legislative mandate and to report recommendations to the FRA Administrator for proposed or interim final rule (as determined by FRA in consultation with OST and OMB). The working group met on March 3–4, 2011, May 9–10, 2011, and September 6–7, 2011 and created four task forces to investigate specific subject areas. A follow-on meeting is scheduled for November 17–18, 2011, and the target date for reporting recommendations to the RSAC Committee is December 2011. Contact: Olga Cataldi, (202) 493–6321.

Task No. 11–01—Preventing Railroad Employee Distractions Caused by Personal Electronic Devices. This task was accepted on May 20, 2011, to prescribe mitigation strategies, programs and processes for governing the use of personal electronic devices that could cause distractions to railroad employees engaged in safety-critical activities. This working group will explore additional methods to achieve compliance through education, peer-to-peer intervention, counseling and other cooperative, non-regulatory/punitive methods. The Electronic Device Distraction Working Group was formed and held its kickoff meeting on October 25–26, 2011. The group is scheduled to meet next on January 11–12, 2011. Contact: Miriam Kloeppel, (202) 493–6224.

Task No. 11–02—Track Inspection Time Study. This task was accepted by the Committee electronically on August 16, 2011, to consider specific improvements to the Track Safety Standards or other responsive actions related to the Track Inspection Time Study required by Sections 403 (a)–(c) of the RSIA and other relevant studies and resources. Sections 403(a) and (b) of the RSIA required a study of inspection practices and the amount of time required for inspections under the Track Safety Standards, and another set of revisions to those regulations. The report was due by October 16, 2010, on the results of a specified track inspection time and track safety study. FRA is expected to make recommendations for rule changes and, under Section 403(c), not later than 2 years after completion of the study, prescribe regulations based on its results. FRA organized an independent study by an outside contractor and developed a questionnaire used to get information from railroad track inspectors throughout the country; interviews with railroad and union officials were also conducted for additional perspectives. The Track Inspection Time Study was completed and signed by the Secretary on May 2, 2011, starting the 2-year timeline for rulemaking. The task was given to the Track Standards Working Group and it held a kickoff meeting on October 20, 2011, and follow-on meetings are scheduled for December 20–21, 2011; February 7–8, and April 26–27, 2012. Contact: Ken Rusk, (202) 493–6236.

Completed Tasks

Task 96–1—(Completed) Revising the freight power brake regulations.

Task 96–2—(Completed) Reviewing and recommending revisions to the Track Safety Standards (49 CFR Part 213).

Task 96–3—(Completed) Reviewing and recommending revisions to the Radio Standards and Procedures (49 CFR Part 220).

Task 96–5—(Completed) Reviewing and recommending revisions to Steam Locomotive Inspection Standards (49 CFR Part 230).

Task 96–6—(Completed) Reviewing and recommending revisions to miscellaneous aspects of the regulations addressing locomotive engineer certification (49 CFR Part 240).

Task 96–7—(Completed) Developing roadway maintenance machines (on-track equipment) safety standards.

Task 96–8—(Completed) This planning task evaluated the need for action responsive to recommendations contained in a report to Congress titled, Locomotive Crashworthiness & Working Conditions.

Task 97–1—(Completed) Developing crashworthiness specifications (49 CFR Part 229) to promote the integrity of the locomotive cab in accidents resulting from collisions.

Task 97–2—(Completed) Evaluating the extent to which environmental, sanitary, and other working conditions in locomotive cabs affect the crew's health and the safe operation of locomotives, proposing standards where appropriate.

Task 97–3—(Completed) Developing event recorder data survivability standards.

Task 97–4 and *Task 97–5*—(Completed) Defining PTC functionalities, describing available technologies, evaluating costs and benefits of potential systems, and considering implementation opportunities and challenges, including demonstration and deployment.

Task 97–6—(Completed) Revising various regulations to address the safety implications of processor-based signal and train control technologies, including communications-based operating systems.

Task 97–7—(Completed) Determining damages qualifying an event as a reportable train accident.

Task 00–1—(Completed—task withdrawn) Determining the need to amend regulations protecting persons who work on, under, or between rolling equipment and persons applying, removing, or inspecting rear end marking devices (Blue Signal Protection).

Task 01–1—(Completed) Developing conformity of FRA's regulations for accident/incident reporting (49 CFR Part 225) to revised regulations of the Occupational Safety and Health Administration, U.S. Department of Labor, and to make appropriate revisions to the FRA Guide for Preparing Accident/Incident Reports (Reporting Guide).

Task 08–01—(Completed) Report on the Nation's railroad bridges. Report to FRA on the current state of railroad bridge safety management; update the findings and conclusions of the 1993 Summary Report of the FRA Railroad Bridge Safety Survey.

Task No. 08–06—(Completed) Hours of Service Recordkeeping and Reporting. Develop revised recordkeeping and reporting requirements for hours of service of railroad employees. Final rule published May 27, 2009, with an effective date of July 16, 2009. (74 FR 25330).

Task No. 08–05—(Completed) Railroad Bridge Safety Assurance. Develop a rule encompassing the requirements of Section 417 of the RSIA (Railroad Bridge Safety Assurance), of RSIA bridge failure. Final rule published July 15, 2010 (75 FR–41282).

Task 06–02—(Completed) Track Safety Standards and CWR. Issue requirements for inspection of joint bars in CWR to detect cracks that could affect the integrity of the track structure published a final rule on August 25, 2009, with correcting amendment published on October 21, 2009.

Please refer to the notice published in the **Federal Register** on March 11, 1996, (61 FR 9740) for more information about the RSAC.

Issued in Washington, DC, on November 21, 2011.

Brenda J. Moscoso,

Director, Office of Safety Analysis, Risk Reduction, and Crossing/Trespasser Programs.

[FR Doc. 2011–30476 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket Number MARAD 2011 0152]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel DAUNTLESS; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

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.

DATES: Submit comments on or before December 28, 2011.

ADDRESSES: Comments should refer to docket number MARAD–2011–0152. 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, Email *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel DAUNTLESS is:

Intended Commercial Use of Vessel: ''Coastal sightseeing.''

Geographic Region: ''ME, NH, MA, RI, CT, NY.''

The complete application is given in DOT docket MARAD–2011–0152 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.

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: November 17, 2011.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2011–30609 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2010–0143; Notice 2]

JCA Corporation, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of Petition Grant.

SUMMARY: JCA Corporation (JCA)[1], has determined that certain Trail America brand Special Trailer ''ST'' tires that it imported failed to meet the requirements of paragraph S6.5(d) of Federal Motor Vehicle Safety Standard (FMVSS) No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of more than 4,536 Kilograms (10,000 Pounds) and Motorcycles.* JCA has filed an appropriate report pursuant to 49 CFR Part 573, *Defect and Noncompliance Responsibility and Reports* (dated October 19, 2009).

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), JCA has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

Notice of receipt of JCA's petition was published, with a 30-day public comment period, on November 9, 2010, in the **Federal Register** (75 FR 68854). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System Web site at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2010–0143.''

For further information on this decision, contact Mr. George Gillespie, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–5299, facsimile (202) 366–7002.

JCA estimates that approximately 899,804 Trail America brand Special Trailer ''ST'' tires that were

[1] JCA Corporation (JCA) is a State of Washington corporation that imports replacement motor vehicle equipment.

manufactured from January 1, 2008, through October 15, 2009, by Tianjin Kings Glory Tire Company, LTD. of Qiaosandao, Yangliuqing, Xiqing Tianjin, China 300380, and imported by JCA are affected.

JCA states that the noncompliance is that the maximum single load labeling and maximum inflation pressures on the sidewalls of the tires are in English units of ''lb'' and ''psi'' only; no Metric units are included as required by paragraph S6.5(d) of FMVSS No. 119.

JCA explained that no property damage or accidents have been reported to it or its customers as a result of the subject noncompliance.

JCA further explains that it has taken steps to correct the noncompliance in future production.

JCA also states that it believes the noncompliance is inconsequential to motor vehicle safety because the affected tires fulfill all other relevant requirements of FMVSS No. 119.

In summation, JCA believes that the described noncompliance 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.

NHTSA Decision: The agency agrees with JCA that the noncompliance is inconsequential to motor vehicle safety. The agency believes that the true measure of inconsequentiality to motor vehicle safety in this case is that there is no effect on the operational safety of vehicles on which these tires are mounted.

While the correct tire inflation pressure is included on the subject tire sidewalls, it is not marked in both English and Metric unit systems on each sidewall as required by S6.5(d). However, because the tire inflation pressure is available and stated correctly on each tire in English units, it is unlikely that a consumer will not find or will misread pressure units due to the noncompliance. Therefore, the tires, as labeled, are likely to achieve the safety purpose of the standard. In the agency's judgment, the subject incorrect labeling of the tire inflation pressure information will have an inconsequential effect on motor vehicle safety.

NHTSA notes that the statutory provisions (49 U.S.C. 30118 (d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the 899,804 [2] tires that JCA no longer controlled at the time that it determined that a noncompliance existed in the subject tires.

In consideration of the foregoing, NHTSA has decided that JCA has met its burden of persuasion that the subject FMVSS No. 119 labeling noncompliances are inconsequential to motor vehicle safety. Accordingly, JCA's petition is granted and the petitioner is exempted from the obligation of providing notification of, and a remedy for, the subject noncompliance under 49 U.S.C. 30118 and 30120.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at CFR 1.50 and 501.8)

Issued on: November 18, 2011.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2011–30562 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2010–0137; Notice 2]

General Motors, LLC, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of Petition Grant.

SUMMARY: General Motors, LLC (GM),[1] has determined that certain 2008 through 2010 Model Year Chevrolet Malibu passenger cars equipped with automatic transmissions and manufactured May 2007 through March 2010 do not fully meet the requirements of paragraph S3.1.4.1 of Federal Motor Vehicle Safety Standard (FMVSS) No. 102, *Transmission Shift Position Sequence, Starter Interlock, and Transmission Braking Effect.* GM filed an appropriate report pursuant to 49 CFR Part 573 *Defect and Noncompliance Responsibility and Reports,* dated March 30, 2010.

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), GM has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

Notice of receipt of GM's petition was published, with a 30-day public comment period, on October 21, 2010, in the **Federal Register** (75 FR 65054). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System Web site at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2010–00137.''

Contact Information: For further information on this decision, contact Mr. Vincent J. Williams, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–2319, facsimile (202) 366–7002.

Summary of GM's Petition: A total of 462,227 model year 2008, 2009 and 2010 Chevrolet Malibu passenger cars manufactured during the period May 2007 through March 2010 are potentially affected by the subject noncompliance.

GM described the noncompliance as the absence of the required transmission shift position display for a certain ignition key cylinder position. GM explained that while the key is in the ignition there is a narrow ignition key cylinder position between the ''ACC'' and ''OFF'' positions within which the transmission shift lever can be moved and the indicator light that illuminates the transmission shift position display is inoperative. The Company added that this noncompliance only occurs when the engine is not running.

GM additionally stated that in all other ignition activation and operation positions, all of the subject vehicles comply with paragraph S3.1.4.1 of FMVSS No. 102.

GM argued its belief that the subject noncompliance is inconsequential to motor vehicle safety because:

> As NHTSA recognized in proposing the standard (53 FR 32409–32411 (August 25, 1988)), the purpose of the display requirement for PRNDM information is to ''provide the driver with transmission position information for the vehicle conditions where such information can reduce the likelihood of shifting errors.'' Thus, in all but the rarest circumstances, the primary function of the PRNDM display is to inform the driver of gear selection and

[2] JCA's petition, which was filed under 49 CFR part 556, requests an agency decision to exempt JCA as a manufacturer from the notification and recall responsibilities of 49 CFR Part 573 for 899,804 of the affected tires. However, the decision on this petition does not relieve distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after JCA notified them that the subject noncompliance existed.

[1] General Motors, LLC (GM) is a Michigan corporation that manufactures motor vehicles.

relative position of the gears while the engine is running. All of the subject vehicles display PRNDM information whenever the ignition switch is in the ''On'' or ''Run'' position.

With the exception of the absence of the required transmission shift position display for one narrow ignition key cylinder position, the system meets all other applicable requirements of FMVSS No. 102.

GM has no record of any incidents, injuries, owner complaints or field reports related to this noncompliance. GM added that if a customer reports this problem to them and requests a remedy, the Company will replace the ignition switch with a conforming component.

Since this noncompliance only occurs during an atypical operation, the noncompliance is not likely to occur under normal driving conditions. The only circumstance where the noncompliance would appear is if the ignition switch is in the intermediary position between the ''OFF'' and ''ACC'' detent positions prior to the interlock. In order for this condition to be present, a driver would have to first move the transmission control to ''PARK.'' In such a case, there are two possible scenarios for the driver: 1) leaving the vehicle with the key in the ignition or 2) remaining in the vehicle. GM provides the following analysis for both scenarios:

1. The driver exits the vehicle while leaving the key in the ignition:

If the driver attempted to remove the key before exiting the vehicle, the key would not be capable of removal. The doors may also still be locked if they are in the factory default setting to unlock in the ''PARK'' position.

As required by S5.1.3 of FMVSS No. 114, GM provides an audible warning to the driver that activates whenever the key has been left in the ignition locking system and the driver's door is opened.

The Owner's Manual supplied with the vehicle provides specific warnings and instructions on ensuring the vehicle is in ''PARK'' and the key is removed before exiting the vehicle.

2. The driver remains in the vehicle:

If the driver remains in the vehicle, he or she would likely either restart the vehicle's engine or attempt to remove the key to exit the vehicle.

If the driver attempts to restart the engine, paragraph S3.1.3 of FMVSS No. 102 requires that the starter be inoperative whenever the vehicle's transmission shift position is in a forward or reverse drive position. The driver rotating the ignition switch forward attempting to start the engine will definitely activate the PRNDM display. Therefore, the PRNDM information will be available to the driver who can see that the vehicle did not start because the transmission was not in ''Park'' or ''Neutral.''

GM says that because both of these situations are addressed by FMVSS requirements, a lack of a transmission shift position display in either of these cases may constitute a minor inconvenience, but will have no consequence to safety. In addition, GM stated that NHTSA has previously granted similar petitions on 3 occasions.

Furthermore, GM also stated the following:

GM recognizes that there may be isolated non-driving situations in which a person may desire to know gear selection or the relative position of the gears with the engine off, such as when placing the vehicle in tow. However, these cases occur infrequently and do not occur during normal ignition activation and vehicle operation. If the subject condition [noncompliance] is present during these infrequent non-driving situations when PRNDM information may be desired, gear selection and relative positioning can easily be determined by rotating the ignition switch slightly clockwise past the accessory ''ACC'' detent to activate the shift indicator display without starting the vehicle's engine. Given the nature of these non-driving situations and since the information can be readily obtained with a slight key rotation, GM believes that the subject condition [noncompliance] will have no real or implied degradation of motor vehicle safety.

GM also indicated that it has corrected the problem that caused the subject noncompliance so that it cannot reoccur in future production.

In view of the above, GM believes that the described noncompliance is inconsequential and does not present a risk to motor vehicle safety. Thus, GM requests that its petition, to exempt it from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120, should be granted.

NHTSA Decision: NHTSA agrees with GM that the noncompliance is inconsequential to motor vehicle safety. As the agency noted in the past (53 FR 32409, August 25, 1988), the purpose of the PRNDL information display requirement is to ''provide the driver with transmission position information for the vehicle conditions where such information can reduce the likelihood of shifting errors.'' In all but the rarest circumstances, the primary function of the transmission display is to inform the driver of gear selection and relative position of the gears while the engine is running. In this case, the selected gear position and PRNDL display are always visible when the engine is running. Therefore, as GM stated, the vehicles will be in compliance with FMVSS No. 102 during normal ignition activation and vehicle operation.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the 462,227 [2] vehicles that GM no longer controlled at the time that it determined that a noncompliance existed in the subject vehicles.

In consideration of the foregoing, NHTSA has decided that GM has met its burden of persuasion that the subject FMVSS No. 102 noncompliance is inconsequential to motor vehicle safety. Accordingly, GM's petition is granted and the petitioner is exempted from the obligation of providing notification of, and a remedy for, the subject noncompliance under 49 U.S.C. 30118 and 30120.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at CFR 1.50 and 501.8)

Issued on: November 18, 2011.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2011–30563 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2010–0080; Notice 2]

Goodyear Tire and Rubber Company, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Grant of Petition for Decision of Inconsequential Noncompliance.

SUMMARY: Goodyear Tire and Rubber Company, (Goodyear),[1] has determined that approximately 14,826 passenger car replacement tires manufactured between August of 2007 and May of 2009, do not fully comply with paragraph S5.5(f) of Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New Pneumatic Radial Tires for Light Vehicles.* Goodyear has filed an appropriate report pursuant to 49 CFR part 573, *Defect and Noncompliance*

[2] GM's petition, which was filed under 49 CFR part 556, requests an agency decision to exempt GM from the notification and recall responsibilities of 49 CFR part 573 for as many as 462,227 of the affected vehicles. However, the granting of this petition does not relieve GM's distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after GM recognized that the subject noncompliance existed.

[1] Goodyear Tire and Rubber Company (Goodyear) a replacement equipment manufacturer is incorporated in the state of Ohio.

Responsibility and Reports (Dated July 8, 2009).

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Goodyear has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

Notice of receipt of Goodyear's petition was published, with a 30-day public comment period, on June 25, 2010, in the **Federal Register** (75 FR 36472). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System Web site at: *http://www.regulations.gov/*. Then follow the online search instructions to locate docket number ''NHTSA–2010–0080.''

For further information on this decision, contact Mr. George Gillespie, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–5299, facsimile (202) 366–7002.

Affected are approximately 14,826 sizes P195/55R15 84V and P225/60R16 97H Goodyear brand Arizonian Silver Edition Plus model passenger car tires manufactured between August of 2007 and May of 2009 at Goodyear's plant located in Otrokovice, Czech Republic.

Goodyear explains that the noncompliance is that, due to a mold labeling error, the sidewall marking on the reference side of the tires incorrectly describes the actual number of plies in the tread area of the tires as required by paragraph S5.5(f). Specifically, the tires in question were inadvertently manufactured with ''Tread Plies: 2 Polyester + 2 steel.'' The labeling should have been ''Tread Plies: 2 Polyester + 1 polyamide + 2 steel.

Goodyear also explains that while the non-compliant tires are mislabeled ''the tires meet or exceed all applicable Federal Motor Vehicle Safety Standards.''

Goodyear argues that this noncompliance is inconsequential to motor vehicle safety because the noncompliant sidewall marking does not create an unsafe condition and all other labeling requirements have been met.

Goodyear points out that NHTSA has previously granted similar petitions for noncompliances in sidewall marking.

Goodyear additionally states that it has corrected the affected tire molds and all future production will have the correct material shown on the sidewall.

In summation, Goodyear believes that the described noncompliance of its tires to meet the requirements of FMVSS No. 139 is inconsequential to motor vehicle safety, and that its petition, to exempt 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, and should be granted.

NHTSA Decision: The agency agrees with Goodyear that the noncompliances are inconsequential to motor vehicle safety. The agency believes that the true measure of inconsequentiality to motor vehicle safety in this case is that there is no effect of the noncompliances on the operational safety of the vehicles on which these tires are mounted. The safety of people working in the tire retread, repair, and recycling industries must also be considered. Although tire construction affects the strength and durability, neither the agency nor the tire industry provides information relating tire strength and durability to the number of plies and types of ply cord material in the tread and sidewall. Therefore, tire dealers and customers should consider the tire construction information along with other information such as load capacity, maximum inflation pressure, and tread wear, temperature, and traction ratings, to assess performance capabilities of various tires. In the agency's judgment, the incorrect labeling of the tire construction information will have an inconsequential effect on motor vehicle safety because most consumers do not base tire purchases or vehicle operation parameters on the ply material in a tire.

The agency also believes the noncompliance will have no measurable effect on the safety of the tire retread, repair, and recycling industries. The use of steel cord construction in the sidewall and tread is the primary safety concern of these industries. In this case, since the tire sidewalls do not contain steel plies, this potential safety concern does not exist.

NHTSA notes that the statutory provisions (49 U.S.C. 30118 (d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the 14,826 [2] tires that Goodyear no longer controlled at the time that it determined that a noncompliance existed in the subject tires.

In consideration of the foregoing, NHTSA has decided that Goodyear has met its burden of persuasion that the subject FMVSS No. 139 labeling noncompliances are inconsequential to motor vehicle safety. Accordingly, Goodyear's petition is granted and the petitioner is exempted from the obligation of providing notification of, and a remedy for, the subject noncompliance under 49 U.S.C. 30118 and 30120.

Authority: (49 U.S.C. 30118, 30120: Delegations of authority at CFR 1.50 and 501.8).

Issued on: November 18, 2011.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2011–30569 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–59–P

[2] Goodyear's petition, which was filed under 49 CFR part 556, requests an agency decision to exempt Goodyear as a manufacturer from the notification and recall responsibilities of 49 CFR part 573 for the affected vehicles. However, a decision on this petition cannot relieve distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Goodyear notified them that the subject noncompliance existed.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2010–0152]

Technical Report on Fatality Risk, Mass, and Footprint of Model Year 2000–2007 Passenger Cars and LTVs

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Request for comments on technical report.

SUMMARY: This notice announces NHTSA's publication of a technical report describing relationships between a vehicle's mass, footprint (size), and body type and its rate of involvement in fatal crashes. The report's title is: *Relationships Between Fatality Risk, Mass, and Footprint in Model Year 2000–2007 Passenger Cars and LTVs—Preliminary Report.*

DATES: Comments must be received no later than January 27, 2012.

ADDRESSES:

Report: The technical report is available on the Internet for viewing on line or downloading in PDF format at the Federal eRulemaking Portal. It is item no. 0023 in Docket No. NHTSA–2010–0152. You may access it by going to *http://www.regulations.gov*, typing NHTSA–2010–0152–0023 in the box under ''Enter Keyword or ID'' and

clicking on ''Search,'' clicking on ''U.S. DOT/NHTSA—Report: Relationships Between Fatality Risk, Mass, and Footprint in Model Years 2000–2007—Preliminary Report,'' and then clicking on the small orange box labeled ''PDF.'' Or you may go directly to *http://www.regulations.gov/#!documentDetail;D=NHTSA-2010-0152-0023* and then click on the small orange box labeled ''PDF.'' You may obtain a copy of the report free of charge by sending a self-addressed mailing label to Charles J. Kahane (NVS–431), National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590.

Comments: You may submit comments [identified by Docket Number NHTSA–2010–0152] 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 Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except Federal holidays.

You may call Docket Management at (202) 366–9826.

Instructions: For detailed instructions on submitting comments, see the Procedural Matters section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Charles J. Kahane, Chief, Evaluation Division, NVS–431, National Center for Statistics and Analysis, National Highway Traffic Safety Administration, Room W53–312, 1200 New Jersey Avenue SE., Washington, DC 20590. *Telephone:* (202) 366–2560. *Email: chuck.kahane@dot.gov*.

SUPPLEMENTARY INFORMATION: Mass reduction while holding a vehicle's footprint (size) constant is a potential strategy for meeting footprint-based CAFE and GHG standards. An important corollary issue is the possible effect of mass reduction that maintains footprint on fatal crashes. One way to estimate these effects is statistical analyses of societal fatality rates per VMT, by vehicles' mass and footprint, for the current on-road vehicle fleet. Societal fatality rates include occupants of all vehicles in the crash as well as pedestrians. The analyses comprised MY 2000–2007 cars and LTVs in CY 2002–2008 crashes. Fatality rates were derived from FARS data, 13 State crash files, and registration and mileage data from R.L. Polk. The table presents the estimated percent increase in societal fatality rates per 100-pound mass reduction while holding footprint constant for five classes of vehicles:

MY 2000–2007 CY 2002–2008	Fatality increase (%) per 100-pound mass reduction while holding footprint constant	
	Point estimate	95% Confidence bounds
Cars < 3,106 pounds	1.44	+.29 to +2.59
Cars ≥ 3,106 pounds	.47	−.58 to +1.52
CUVs and minivans	−.46	−1.75 to +.83
Truck-based LTVs < 4,594 pounds	.52	−.43 to +1.46
Truck-based LTVs ≥ 4,594 pounds	−.39	−1.06 to +.27

Only the 1.44 percent risk increase in the lighter cars is statistically significant. There are non-significant increases in the heavier cars and the lighter truck-based LTVs and non-significant societal benefits for mass reduction in CUVs, minivans, and the heavier truck-based LTVs. Based on these results, potential combinations of mass reductions that maintain footprint and are proportionately somewhat higher for the heavier vehicles may be safety-neutral or better as point estimates and, in any case, unlikely to significantly increase fatalities. The primarily non-significant results are not due to a paucity of data, but because the societal effect of mass reduction while maintaining footprint, if any, is small.

This preliminary report is currently undergoing peer review. Information about the review is available in Docket No. NHTSA–2010–0152, including the peer-review charge at NHTSA–2010–0152–0024 and the names of the reviewers at NHTSA–2010–0152–0025.

This report updates and supersedes earlier NHTSA reports on vehicle mass, size and fatality risk issued in 2010 (75 FR 25324, Docket No. NHTSA–2010–0152, report available at *http://www.nhtsa.gov/staticfiles/rulemaking/pdf/cafe/CAFE_2012-2016_FRIA_04012010.pdf*, pp. 464–542); 2003 (68 FR 66153, Docket No. NHTSA–2003–16318, report available at *http://www-nrd.nhtsa.dot.gov/Pubs/809662.PDF*); and 1997 (62 FR 34491, Docket No. NHTSA–1997–3725, report available at *http://www-nrd.nhtsa.dot.gov/Pubs/808570.PDF*).

Procedural Matters

How can I influence NHTSA's thinking on this subject?

NHTSA welcomes public review of the evaluation plan and invites the reviewers to comment about the selection, priority, and schedule of the regulations to be evaluated. The agency is interested in learning of any additional data that may be useful in the evaluations. NHTSA will submit to the Docket a response to the comments and, if appropriate, will supplement or revise the evaluation plan.

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the Docket number of this document (NHTSA–2010–0152) in your comments.

Your primary comments must not be more than 15 pages long (49 CFR 553.21). However, you may attach additional documents to your primary comments. There is no limit on the length of the attachments.

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 (65 FR 19477) or you may visit *http://regulations.gov*.

Please send two paper copies of your comments to Docket Management, fax

them, or use the Federal eRulemaking Portal. The mailing address is U.S. Department of Transportation, Docket Management Facility, M–30, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The fax number is 1–(202) 493–2251. To use the Federal eRulemaking Portal, go to *http://www.regulations.gov* and follow the online instructions for submitting comments.

We also request, but do not require you to send a copy to Charles J. Kahane, Chief, Evaluation Division, NVS–431, National Highway Traffic Safety Administration, Room W53–312, 1200 New Jersey Avenue SE., Washington, DC 20590 (or email them to *chuck.kahane@dot.gov*). He can check if your comments have been received at the Docket and he can expedite their review by NHTSA.

How can I be sure that my comments were received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, send three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. Include a cover letter supplying the information specified in our confidential business information regulation (49 CFR Part 512).

In addition, send two copies from which you have deleted the claimed confidential business information to U.S. Department of Transportation, Docket Management Facility, M–30, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, or submit them via the Federal eRulemaking Portal.

Will the agency consider late comments?

In our response, we will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

How can I read the comments submitted by other people?

You may read the materials placed in the docket for this document (e.g., the comments submitted in response to this document by other interested persons) at any time by going to *http://www.regulations.gov*. Follow the online instructions for accessing the dockets. You may also read the materials at the Docket Management Facility by going to the street address given above under **ADDRESSES**. The Docket Management Facility is open between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except Federal holidays.

Authority: 49 U.S.C. 30111, 30168; delegation of authority at 49 CFR 1.50 and 501.8.

James F. Simons,

Director, Office of Regulatory Analysis and Evaluation.

[FR Doc. 2011–30561 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2011–0168]

Technical Report Evaluating the 1999–2003 Head Impact Upgrade of FMVSS No. 201, Upper-Interior Components

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Request for comments on technical report.

SUMMARY: This notice announces NHTSA's publication of a Technical Report reviewing and evaluating its existing Safety Standard 201, *Occupant Protection in Interior Impact. The report's title is: Evaluation of the 1999–2003 Head Impact Upgrade of FMVSS No. 201—Upper-Interior Components: Effectiveness of Energy-Absorbing Materials Without Head-Protection Air Bags.*

DATES: Comments must be received no later than March 27, 2012.

ADDRESSES:

Report: The technical report is available on the Internet for viewing in PDF format at *http://www-nrd.nhtsa.dot.gov/Pubs/811538.PDF.* You may obtain a copy of the report free of charge by sending a self-addressed mailing label to Charles J. Kahane (NVS–431), National Highway Traffic Safety Administration, Room W53–312, 1200 New Jersey Avenue SE., Washington, DC 20590.

Comments: You may submit comments [identified by Docket Number NHTSA–2011–0168] 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 Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except Federal holidays.

You may call Docket Management at (202) 366–9826.

Instructions: For detailed instructions on submitting comments, see the Procedural Matters section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Charles J. Kahane, Chief, Evaluation Division, NVS–431, National Center for Statistics and Analysis, National Highway Traffic Safety Administration, Room W53–312, 1200 New Jersey Avenue SE., Washington, DC 20590. *Telephone:* (202) 366–2560. *Email: chuck.kahane@dot.gov.*

For information about NHTSA's evaluations of the effectiveness of existing regulations and programs: You may see a list of published evaluation reports at *http://www-nrd.nhtsa.dot.gov/cats/listpublications.aspx?Id=226&ShowBy=Category* and if you click on any report you will be able to view it in PDF format.

SUPPLEMENTARY INFORMATION: Federal Motor Vehicle Safety Standard (FMVSS) No. 201—Occupant Protection in Interior Impact—was upgraded in 1995, with a 1998–2003 phase-in, to reduce occupants' risk of head injury from contact with a vehicle's upper interior, including its pillars, roof headers and side rails, and the upper roof. Initially, energy-absorbing materials alone were used to meet the standard. NHTSA

statistically analyzed the effect of these materials on head injuries due to upper-interior contact in cars and light trucks in the Crashworthiness Data System of the National Automotive Sampling System for 1995–2009 and the effect on head injuries in fatal crashes in the Fatality Analysis Reporting System—Multiple Cause of Death files for 1999–2007. FMVSS No. 201 without head-protection air bags reduces AIS 4-to-6 head injuries due to contact with upper-interior components by an estimated 24 percent (95% confidence bounds, 11 to 35%), based on the average of the analysis results for the two databases. That is equivalent to a 4.3-percent reduction of overall fatality risk (confidence bounds 2.0 to 6.2%). When all vehicles on the road meet FMVSS No. 201, it will save an estimated 1,087 to 1,329 lives per year. At a cost of $25.52 (in 2010 dollars) over the life of a vehicle, that amounts to an annual cost, depending on new-vehicle sales, ranging from $301 to $424 million for certifying all new vehicles to FMVSS No. 201. It is a very cost-effective regulation, costing less than $1 million per life saved.

NHTSA issued previous evaluation reports on FMVSS No. 201 in 2006 (72 FR 9074, Docket No. NHTSA–2007–27371, report available at *http://www-nrd.nhtsa.dot.gov/Pubs/810739.PDF*) and in 1988 (53 FR 2516, report available at *http://www-nrd.nhtsa.dot.gov/Pubs/807203.PDF*).

Procedural Matters

How can I influence NHTSA's thinking on this subject?

NHTSA welcomes public review of the technical report. NHTSA will submit to the Docket a response to the comments and, if appropriate, will supplement or revise the report.

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the Docket number of this document (NHTSA–2011–0168) in your comments.

Your primary comments must not be more than 15 pages long (49 CFR 553.21). However, you may attach additional documents to your primary comments. There is no limit on the length of the attachments.

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 (65 FR 19477) or you may visit *http://www.regulations.gov.*

Please send two paper copies of your comments to Docket Management, fax them, or use the Federal eRulemaking Portal. The mailing address is U.S. Department of Transportation, Docket Management Facility, M–30, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The fax number is 1–(202) 493–2251. To use the Federal eRulemaking Portal, go to *http://www.regulations.gov* and follow the online instructions for submitting comments.

We also request, but do not require you to send a copy to Charles J. Kahane, Chief, Evaluation Division, NVS–431, National Highway Traffic Safety Administration, Room W53–312, 1200 New Jersey Avenue SE., Washington, DC 20590 (or email them to *chuck.kahane@dot.gov*). He can check if your comments have been received at the Docket and he can expedite their review by NHTSA.

How can I be sure that my comments were received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, send three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. Include a cover letter supplying the information specified in our confidential business information regulation (49 CFR Part 512).

In addition, send two copies from which you have deleted the claimed confidential business information to U.S. Department of Transportation, Docket Management Facility, M–30, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, or submit them via the Federal eRulemaking Portal.

Will the agency consider late comments?

In our response, we will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

How can I read the comments submitted by other people?

You may read the materials placed in the docket for this document (e.g., the comments submitted in response to this document by other interested persons) at any time by going to *http://www.regulations.gov.* Follow the online instructions for accessing the dockets. You may also read the materials at the Docket Management Facility by going to the street address given above under **ADDRESSES**. The Docket Management Facility is open between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except Federal holidays.

Authority: 49 U.S.C. 30111, 30168; delegation of authority at 49 CFR 1.50 and 501.8.

James F. Simons,

Director, Office of Regulatory Analysis and Evaluation.

[FR Doc. 2011–30560 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Office of Hazardous Materials Safety; Actions on Special Permit Applications

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on Special Permit Applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given of the actions on special permits applications in (January to November 2011). The mode

of transportation involved are identified by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft. Application numbers prefixed by the letters EE represent applications for Emergency Special Permits. It should be noted that some of the sections cited were those in effect at the time certain special permits were issued.

Issued in Washington, DC, on November 17, 2011.

Donald Burger,

Chief, Special Permits and Approvals Branch.

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
		MODIFICATION SPECIAL PERMIT GRANTED	
11924–M	Packgen Corporation, Auburn, ME.	49 CFR 173.12(b)(2)(i)	To modify the special permit to authorize an additional non-bulk packaging.
11911–M	Transfer Flow, Inc., Chico, CA.	49 CFR 178.700 thru 178.819	To modify the special permit to authorize new part numbers; to add several new refueling systems; to add two new fuel caps; and to add several new fuel tanks to the special permit.
13997–M	Maritime Helicopers, Homer, AK.	49 CFR 172.101(9b); 172.302(c)	To reissue the exemption originally issued on an emergency basis for the transportation of a Division 2.1 material in DOT Specification 51 portable tanks that exceed the quantities limitation by cargo aircraft.
13199–M	Carrier Corporation, Houston, TX.	49 CFR 173.302(c); 173.306(e)(1)	To modify the special permit to authorize a broader range for the amount of refrigerant gas.
7765–M	Carleton Technologies, Inc., Orchard Park, NY.	49 CFR 173.302(a)(4); 175.3	To modify the special permit to authorize a new pressure vessel for use as part of a missile gas storage system.
10511–M	Schlumberger Technology, Sugar Land, TX.	49 CFR 173.304; 173.310	To modify the special permit to authorize the transportation in commerce of Division 2.2 Corporation gases in non specification packaging.
15118–M	Mystery Creek Resources Inc., McGrath, AK.	49 CFR 172.101 Column (9B)	To reissue the special permit originally issued as an emergency as a permanent special permit.
10698–M	Worthington Cylinders, Chilton, WI.	49 CFR 173.304(a)(2); 178.50	To modify the special permit to authorize additional Division 2.2 materials.
14157–M	Worthington Cylinders of Canada, Tilbury, Ontario.	49 CFR 173.302a	To modify the special permit to change the test criteria for Hot-Dip Galvanized cylinders from the ratio rejection in § 180.209 to elastic expansion of the REE marked on the cylinder.
9758–M	Coleman Company, Inc., The, Wichita, KS.	49 CFR 173.304(d)(3)(ii); 178.33	To modify the special permit to authorize the transportation in commerce of an additional Division 2.1 material.
12332–M	Toyota Motor Sales, U.S.A., Inc., Torrance, CA.	49 CFR 173.166 (c) and (e)	To modify the special permit to add cargo vessel as an authorized mode of transportation and to allow consolidation of recycling parts from U.S. territories to be transported with recycling parts from the continental U.S.
15092–M	Tatonduk Outfitters Limited dba Everts Air Alaska, Fairbanks, AK.	49 CFR § 173.302(f) (3)(4), and (5), § 173.304(f) (3), (4), (5), and § 172.301(c).	To modify the special permit to bring it in line with all the other Alaska air carrier special permits.
14574–M	KMG Electronic Chemicals, Houston, TX.	49 CFR 180.407(c), (e) and (f)	To modify the special permit to authorize the addition of additional Class 8 hazardous materials and to add 16 new cargo tanks.
12247–M	Weldship Corporation, Bethlehem, PA.	49 CFR 172.301, 173.302a(b)(2), (b)(3) and (b)(4); 180.205(c) and (g) and 180.209(a).	To modify the special permit to authorize ultrasonic testing of DOT–SP 9001, 9370, 9421, 9706, 9791, 9909, 10047, 10869, and 11692 cylinders.
10704–M	Spray Products Corporation, Plymouth Meeting, PA.	49 CFR 173.302(a); Part 172, Subpart C, E and F; Part 172; Part 174; Part 177.	To modify the special permit to authorize additional end uses of the product.
15250–M	DOE/National Nuclear Security Administration, Albuquerque, NM.	49 CFR 173.56(b)(3)(i)	To reissue the special permit originally issued on an emergency basis for the transportation in commerce of certain explosives that are tested to a revision of the Department of Defense Ammunition and Explosive Hazard Classification Procedures TB 700–2 that has not been incorporated by reference.
15097–M	US Consumer Product Safety Commission, Denver, CO.	49 CFR 173.56	To reissue the special permit originally issued on an emergency basis for the transportation of unapproved fireworks to the CPSC laboratory in Gaithersburg, MD for testing.
14924–M	Explosive Service International Ltd., Baton Rouge, LA.	49 CFR 176.144(e), 176.145(b), 176.137(b)(7), 176.63(e), 176.83 and 176.138(b).	To modify the special permit to authorize the transportation in commerce of certain Division 1.1D and 1.4B explosives by vessel in an alternative stowage configuration.
10597–M	Thermo King Corporation, Minneapolis, MN.	49 CFR 177.834(l)(2)(i)	To modify the special permit to authorize a new series of heaters containing Class 3 liquids and/or Division 2.1 gases.

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
12092–M	KMR Industries, LLC, Columbia, MD.	49 CFR 173.34(e)	To modify the special permit to authorize additional modes of transportation (rail and cargo vessel.)
		NEW SPECIAL PERMIT GRANTED	
15279–N	University Of Colorado at Boulder, Boulder, CO.	49 CFR Parts 171–180	To authorize the transportation in commerce of Division 6.2 materials without being subject to the Hazardous Materials Regulations when transported for short distances by motor vehicle (less than 2 miles). (mode 1)
15304–N	Hillsboro Aviation, Hillsboro, OR.	49 CFR 172.101, Column (9B), 172.204(c)(3), 173.27(b)(2), 175.30(a)(1), 172.200, 172.300, and 172.400.	To authorize the transportation in commerce of certain hazardous materials by external load on helicopters in remote areas of the U.S. without being subject to hazard communication requirements and quantity limitations where no other means of transportation is available. (mode 4)
15284–N	Solvay Fluorides, LLC Houston, TX.	49 CFR 179.15(a), 173.31(e)(2)(ii) and 173.244(a)(2).	To authorize the transportation in commerce of anhydrous hydrogen fluoride in a DOT 112S5001 car with a minimum shell thickness of 1.263″ and full height headshields. (mode 2)
15335–N	Seastar Chemicals Inc., Sidney, BC.	49 CFR 173.158(f)(3)	To authorize the transportation in commerce of nitric acid up to 70% concentration in an alternative packaging configuration. (modes 1, 2, 3)
15343–N	Bush Air Cargo Inc., Anchorage, AK.	49 CFR 173.241 and 173.242	To authorize the transportation in commerce of Class 3 liquid fuels in non-DOT specification collapsible, rubber containers up to 500 gallon capacity by cargo aircraft within and to only remote Alaska locations. (mode 4)
15351–N	Cooper-Atkins Corporation, Middlefield, CT.	49 CFR 173.4a	To authorize certain Division 2.1 and 2.2 materials to be transported as excepted quantities. (modes 3, 5)
15370–N	Tatonduk Outfitters Limited, Fairbanks, AK.	49 CFR 172.101, § 172.301(c), § 172.62(c), 172.101 Column (9B).	To authorize the transportation in commerce of certain Class 1 explosive materials which are forbidden for transportation by air, to be transported by cargo aircraft within the State of Alaska when other means of transportation are impracticable or not available. (mode 4)
15364–N	Winco Fireworks International, LLC, Lone Jack, MO.	49 CFR 172.302 and 173.60–173.62	To authorize the transportation in commerce of Fireworks 1.4G, UNO336 in alternative packaging by motor vehicle. (mode 1)
15368–N	Shannon & Wilson Inc., Fairbanks, AK.	49 CFR 173.4 and 173.4a	To authorize the transportation in commerce of methanol mixtures as small quantities when the amount of material exceeds 30 ml. (modes 1, 4, 5, 6)
15388–N	Alpine Air Alaska, Inc., Girdwood, AK.	49 CFR 172.101 Column (9B), 172.204(c)(3), 173.27(b)(2), 175.30(a)(1), 172.200, 172.300 and 172.400.	To authorize the transportation in commerce of certain hazardous materials by cargo aircraft in remote areas of the U.S. without being subject to hazard communication requirements and quantity limitations where no other means of transportation is available. (mode 4)
15372–N	Takata de Mexico, S.A. de C.V. Ciudad Frontera.	49 CFR 173.301(a), 173.302(a), 178.65(f)(2).	To authorize the manufacture, marking, sale and use of non-DOT specification pressure vessels for use as components of safety systems. (modes 1, 2, 3, 4, 5)
15392–N	Brim Equipment Leasing, Inc. dba Brim Aviation, Ashland, OR.	49 CFR Parts 106, 107, and 171–180	To authorize the transportation in commerce of certain hazardous materials by cargo aircraft including by external load in remote areas of the U.S. without being subject to hazard communication requirements and quantity limitations where no other means of transportation is available. (mode 4)
15397–N	Northern Pioneer Helicopters, LLC, Big Lake, AK.	49 CFR 172.101 Column (9B), 172.204(c)(3), 173.27(b)(2), 175.30(a)(1), 172.200, 172.300 and 172.400.	To authorize the transportation in commerce of certain hazardous materials by cargo aircraft including by external load in remote areas of Alaska without being subject to hazard communication requirements and quantity limitations where no other means of transportation is available. (mode 4)
15425–N	National Aeronautics & Space Administration (NASA), Washington, DC.	49 CFR 177.848	To authorize the transportation in commerce of certain hydrazine fuels on the same motor vehicle without regard to segregation requirements. (mode 1)
15428–N	Space Exploration Technologies Corp., Hawthorne, CA.	49 CFR Part 172 and 173	To authorize the transportation in commerce of certain hazardous material as part of the Dragon space capsule without requiring shipping papers, marking and labeling. (mode 1)

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
15446–N	Arkema, Inc., King of Prussia, PA.	49 CFR 172.427	To authorize the transportation in commerce of organic peroxides in packaging with labeling allowed prior to changes promulgated under HM–215I. (mode 1)
15440–N	Mountain Air Helicopters, Inc., Los Lunas, NM.	49 CFR 172.101, Column (9B), 172.204(c)(3), 173.27(b)(2), 175.30 (a)(1).	To authorize the transportation in commerce of certain hazardous materials by cargo aircraft including by external load in remote areas of the U.S. without being subject to hazard communication requirements and quantity limitations where no other means of transportation is available. (mode 4)
EMERGENCY SPECIAL PERMIT GRANTED			
15192–M	Korean Air Lines Co. Ltd. (KAL), Arlington, VA.	49 CFR 172.101 Column (9B)	To authorized transportation of additional Class 1 materials and a Division 4.2 that are forbidden for transportation by cargo only aircraft. (mode 4)
15270–M	Security Signals, Cordova, TN.	49 CFR 173.56(b)(1)	To modify the special permit to authorize an additional three months use. (mode 1)
15365–M	Lantis Productions Inc., Draper, UT.	49 CFR 172.300, 172.400 and 173.56	To modify the special permit to remove the quantity limitation. (mode 1)
15455–M	United States Environmental Protection Agency Region II, Edison, NJ.	49 CFR Parts 171–180	To add disaster areas affected by Tropical Storm Lee (modes 1, 2, 3)
15462–M	United States Environmental Protection Agency Region 9, Signal Hill, CA.	49 CFR 173.21	To authorize the one-time, one-way transportation in commerce of an additional 19 DOT Specification 3A cylinders containing an experimental gas by motor vehicle for destruction. (mode 1)
15462–M	United States Environmental Protection Agency Region 9, Signal Hill, CA.	49 CFR 173.21	To authorize the one-time, one-way transportation in commerce of an additional 19 DOT Specification 3A cylinders containing an experimental gas by motor vehicle for destruction. (mode 1)
11077–M	U.S. Department of Defense, Scott AFB, IL.	49 CFR 173.226(b); 173.227(b)	To modify the special permit by removing one Division 6.1 hazardous materials and adding an additional Division 6.1 hazardous material. (mode 1)
15462–M	United States Environmental Protection Agency Region 9, Signal Hill, CA.	49 CFR 173.21	To authorize the one-time, one-way transportation in commerce of an additional 19 DOT Specification 3A cylinders containing an experimental gas by motor vehicle for destruction. (mode 1)
15277–N	Delta Air Lines, Inc., Atlanta, GA.	49 CFR 173.34(e); 173.304(a)(1); 173.305; 173.309; 175.3.	To authorize the transportation in commerce of fire extinguishers to be shipped with an alternative proper shipping name as specified in several exemptions. (modes 1, 2, 4, 5)
15250–N	DOE/National Nuclear Security Administration, Albuquerque, NM.	49 CFR 173.56(b)(3)(i)	To authorize the transportation in commerce of certain explosives that are tested to a revision of the Department of Defense Ammunition and Explosive Hazard Classification Procedures TB 700–2 that has not been incorporated by reference. (modes 1, 4)
15292–N	Air Supply Alaska, Inc., Kenai, AK.	49 CFR 172.101 Column (8C), 173.242, and 175.310(c)(1)(i) through 175.310(c)(1)(iii).	Authorizes the transportation in commerce of certain liquid fuels, Class 3 materials, contained in non-DOT specification packaging seal drums or rollagons of up to 500 gallon capacity by cargo aircraft to remote locations within the state of Alaska and Bronson Creek, British Columbia, Canada. (mode 4)
15326–N	Chemtura Corporation, Middlebury, CT.	49 CFR 178.337–8(a)(3)	To authorize the transportation of certain hazardous materials in DOT Specification 331 cargo tank motor vehicles that are not equipped with remote self-closing internal stop valves. (mode 1)
15330–N	Lynden Air Cargo LLC, Anchorage, AK.	49 CFR 172.101, § 172.301(c), § 172.62(c).	This special permit authorizes the transportation in commerce of certain Class 1 explosive materials which are forbidden for transportation by air, to be transported by cargo aircraft within the State of Alaska when other means of transportation are impracticable or not available.
15324–N	Bristow Alaska Inc. (Former Grantee: Air Logistics of Alaska, Inc.), Fairbanks, AK.	49 CFR § 172.101 Column (8C); § 173.242 and § 175.310(c)(1)(i) through § 175.310(c)(1)(iii).	This special permit authorizes the transportation in commerce of certain liquid fuels, Class 3 materials, contained in non-DOT specification packaging seal drums or rollagons of up to 500 gallon capacity by cargo aircraft to remote locations only within the state of Alaska. (mode 4)
15347–N	Raytheon Missile Systems Company, Tucson, AZ.	49 CFR 173.301, 173.302 and 173.306 ..	To authorize the transportation in commerce of helium in non-DOT specification packaging (cryoengines and assemblies of Maverick Missiles, Guidance Control Sections and Training Guidance Missiles containing cryoengines). (modes 1, 3, 5)

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
15357–N	Pacific Airways Inc., Ketchikan, AK.	49 CFR 172.101 Column (9b), 172.301(c), 172.62(c).	To authorize the transportation in commerce of certain Class 1 explosive materials which are forbidden for transportation by air, to be transported by cargo aircraft within and around the State of Alaska when other means of transportation are impracticable or not available. (mode 4)
15355–N	BST Manufacturing, Minden, LA.	49 CFR 173.56(a) and 173.62(b)	To authorize the one-time, one-way transportation in commerce of an unapproved explosive in 5 gallon plastic pails by motor vehicle for disposal. (mode 1)
15380–N	US DOT (PHMSA) Field Operations, Washington, DC.	49 CFR 173.56	To authorize the one-way transportation in commerce of unapproved fireworks for testing. (mode 1)
15378–N	Ameriflight, Inc., Burbank, CA.	49 CFR 172.203(a), the 200 TI per cargo aircraft limitation in § 175.700(b)(2)(ii), and the separation distance requirements of § 175.702(6), except as specified herein.	To authorize the carriage of radioactive materials aboard cargo aircraft only, under any combination of the following conditions: when the combined transport index exceeds the authorized limit of 200 per aircraft (as specified in § 175.700(b)(2)(ii)), or the separation distance criteria of § 175.702(b) cannot be met. (mode 4)
15365–N	Lantis Productions Inc., Draper, UT.	49 CFR 172.300, 172.400 and 173.56	To authorize the one-time, one-way transportation in commerce of 10845 kg of unapproved fireworks from Carson, CA to the Lantis Fireworks & Lasers facility in Fairfield, UT for destruction by motor vehicle. (mode 1)
15389–N	AMETEK Ameron LLC d/b/a MASS Systems, Baldwin Park, CA.	49 CFR 173.301(a)(1), 173.301(a)(1), 173.302a(a)(1), and 173.304a(a)(1).	To authorize the manufacture, marking, sale and use of non-DOT specification high pressure longitudinal welded and drawn cylinder for transportation of compressed oxygen, flammable or non-flammable gases. (modes 1, 2, 3, 4, 5)
15420–N	USA Jet Airlines, Inc., Belleville, MI.	49 CFR 172.203(a), the 200 TI per cargo aircraft limitation in § 175.700(b)(2)(ii), and the separation distance requirements of § 175.702(a)(2)(ii), except as specified herein.	To authorize the carriage of radioactive materials aboard cargo aircraft only, under any combination of the following conditions: when the combined transport index exceeds the authorized limit of 200 per aircraft (as specified in § 175.700(b)(2)(ii)), or the separation distance criteria of § 175.702(a)(2)(ii) cannot be met. (mode 4)
15431–N	Praxair, Inc., Danbury, CT	49 CFR 171.23(a) and 173.304(d)	To authorize the transportation in commerce of 23 non-DOT specification cylinders containing a residue of Phosphine for export to Canada. (mode 1)
15430–N	Lockheed Martin Missiles and Fire Control, Orlando, FL.	49 CFR 178.503(a)(6)	To authorize the transportation in commerce of approximately 742 packages containing a Class 1 hazardous material that may be mismarked regarding the year of manufacture. (mode 1)
15394–N	INVISTA Sarl, Charlotte, NC.	49 CFR 173.32(0)(5)	To authorize the transportation in commerce of a portable tank that is not filled to 80% capacity for 10 miles by motor vehicle so that the hazardous materials can be repackaged. (mode 1)
15424–N	Antonov Company, t/a Antonov Airlines, Kiev, NH.	49 CFR § 172.101 Column (9B), 172.204(c)(3), 173.27, and 175.30(a)(1).	This emergency special permit authorizes the one-time transportation in commerce of certain cartridges for weapons, inert projectile that are forbidden for transportation by cargo only aircraft.
15408–N	Bald Mountain Air Service Inc., Homer, AK.	49 CFR 172.101 Column (8C); § 173.241; § 173.242 and § 175.320(a) in that non-DOT specification packaging is not authorized, except as specified herein.	To authorize the transportation in commerce of certain liquid fuels, Class 3 materials, contained in non-DOT specification packaging seal drums or rollagons of up to 500 gallon capacity by cargo aircraft to remote locations within the state of Alaska and Bronson Creek, British Columbia, Canada. (mode 4)
15455–N	United States Environmental Protection Agency Region II, Edison, NJ.	49 CFR Parts 171–180	To authorize the emergency transportation of hazardous materials in support of the recovery and relief efforts to, from and within the Hurricane Irene disaster areas of New York and New Jersey under conditions that may not meet the Hazardous Materials Regulations. (modes 1, 2, 3)
15462–N	United States Environmental Protection Agency Region 9, Signal Hill, CA.	49 CFR 173.21	To authorize the one-time, one-way transportation in commerce of three DOT Specification 3A cylinders containing an experimental gas by motor vehicle for destruction. (mode 1)
15450–N	Wal-Mart Stores, Inc., Bentonville, AR.	49 CFR part 172, part 173 and part 177	To authorize the one-time, one-way transportation in commerce of certain hazardous materials from damaged or stucturally-impaired retail stores impacted by Hurricane Irene to a temporary warehousing facility for approximately 10 miles by motor vehicle. (mode 1)

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
15459–N	Antonov Company, t/a Antonov Airlines, Kiev, NH.	49 CFR § 172.101 Column (9B)	To authorize the emergency transportation of hazardous materials in support of the recovery and relief efforts to, from and within the Hurricane Irene disaster areas of New York and New Jersey under conditions that may not meet the Hazardous Materials Regulations. (modes 1, 2, 3)
15441–N	Zapata Incorporated, Charlotte, NC.	49 CFR 173.201	To authorize the transportation in commerce of a slurry mixture as Class 3 in alternative packaging by motor vehicle. (mode 1)
15442–N	Linde Gas North America LLC, Murray Hill, NJ.	49 CFR 180.212(a) and 180.212(b)(2)	To authorize the transportation in commerce of hydrogen fluoride, anhydrous in a non-DOT specification cylinder. (modes 1, 2, 3)
15445–N	Jiangxi Lidu Fireworks, Co, Ltd., Jianxain County, Jiangxi Province.	49 CFR 173.52, 49 CFR 173.50	To authorize the transportation in commerce of certain unapproved Division 1.3G fireworks to a storage facility for the purpose of destruction. (mode 1)
		MODIFICATION SPECIAL PERMIT WITHDRAWN	
14778–M	Metalcraft/Sea-Fire Marine Inc., Baltimore, MD.	49 CFR 173.301(f)	To modify the special permit to authorize the transportation in commerce of additional non-DOT specification cylinders containing a Division 2.2 compressed gas for export only.
		NEW SPECIAL PERMIT WITHDRAWN	
15282–N	Lockheed Martin Space Systems Company, Denver, CO.	49 CFR 172.101 Column (9B), 173.301(f), 173.302a(a)(1) and 173.304a(a)(2).	To authorize the transportation in commerce of anhydrous ammonia in heat pipes. (modes 1, 2, 3, 4)
15276–N	Ecotec Manufacturing Inc. d.b.a. Yiwu City Machine Factory, Okeechobee, FL.	49 CFR 173.304a and 178.33	To authorize the manufacture, marking, sale and use of a non-refillable, non-DOT specification inside metal container similar to a DOT specification 2Q for the transportation in commerce of Division 2.2 compressed gases. (mode 1)
15297–N	American Eagle Airlines, Inc., DFW Airport, TX.	49 CFR 180.209; 173.304(a)(1); 173.305; 173.309.	To authorize the transportation in commerce of fire extinguishers to be shipped with an alternative proper shipping name. (modes 1, 2, 4, 5)
15323–N	Kidde-Fenwal Inc., Ashland, MA.	49 CFR 171.23	To authorize the manufacture, marking, sale and use of non-DOT specification cylinders meeting EN 13322–1, containing nitrogen, to be used in fire suppression systems. (mode 1)
15402–N	Benchmark River and Rail Terminals, LLC, Cincinnati, OH.	49 CFR 174.67	Benchmark River and Rail Terminals, LLC is requesting a Special Permit to allow tank cars, containing hazardous materials, to remain standing with unloading connections attached when no product is being transferred, provided that a minimal level of monitoring is maintained with an operator/employee within the vicinity. (mode 2)
15413–N	QSA Global, Inc., Burlington, MA.	49 CFR 173.301, 173.302a	To authorize the one-way transportation in commerce of non-DOT specification cylinders containing Helium from QSA Global in Burlington, MA to Linde Gas in Stewartsville, NJ for transfer of gas to DOT authorized cylinders. (mode 1)
15382–N	Lockheed Martin Space Systems Company, Sunnyvale, CA.	49 CFR 177.834(l)(1)	To authorize the transportation in commerce of certain Division 1.4 explosives in a motor vehicle equipped with a cargo heater that has not been rendered inoperable. (mode 1)
15453–N	HRD Aero Systems Inc., Valencia, CA.	49 CFR 173.302a and 173.304a	To authorize the transportation in commerce of certain cylinders manufactured under DOT–SP 7971 which contain bromochlorodifluoro methane and nitrogen. (modes 1, 2, 3, 4, 5)
15434–N	Qal-Tek Associates, Idaho Falls, ID.	49 CFR 173.431	Request for a special permit to transport expired sealed source capsules enclosed in Portable Nuclear density gauges. (modes 1, 4)
		EMERGENCY SPECIAL PERMIT GRANTED	
15320–N	Halliburton Energy Services, Broussard, LA.	49 CFR 173.401, 173.403, 173.410, 173.412, 173.41, 173.422, 173.465, and 173.466.	To authorize the one-time, one-way transportation in commerce of a well logging tool containing radioactive material (sealed source) in alternative packaging by motor vehicle. (mode 1)
15352–N	TEM Enterprises dba Xtra Airways, Boise, ID.	49 CFR 175.10(15)	To authorize the transportation of wheelchairs or other battery-powered mobility aids equipped with a non-spillable battery in checked baggage of passenger aircraft without disconnecting the batter. (mode 5)

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
15495–N	Dow Corning Corp., Midland, MI.	49 CFR 180.407	To authorize the transportation in commerce of a MC331 cargo tank motor vehicle containing hydrogen chloride, refrigerated liquid that is passed its test date. (mode 1)

DENIED

12995–M	Request by Dow Chemical Company Midland, MI, August 10, 2011. To modify the special permit to reduce the sample size from 1 in 2,000 to 1 in 10,000.
11329–M	Request by Degesch America, Inc., Weyers Cave, VA, May 18, 2011.
15138–N	Request by Transportation Systems Solutions, Crystal Lake, IL, April 21, 2011. To authorize the transportation in commerce of certain combustible liquids in bulk packagings that are also marine pollutants in the port area without placards.
15296–N	Request by ATK Launch Systems Inc., Brigham City, UT June 14, 2011. To authorize the transportation in commerce of a Division 4.1 material in alternative packaging by motor vehicle.
15314–N	Request by Mohawk Electrical Systems, Inc., Milford, DE June 22, 2011. To authorize the transportation in commerce of three (3) Mines, 1.1D in alternative packaging by motor vehicle and cargo vessel.
15411–N	Request by Vexxel Composites LLC Brigham City, UT, October 27, 2011. To authorize the manufacturing, mark, sale and use of Carbon and Glass fiber reinforced, Stainless Steel lined composite pressure vessels per DOT–CFFC specification.
15399–N	Request by Cheyenne Light Fuel and Power Company, Rapid City, SD, October 19, 2011. To authorize the transportation in commerce of a Type 4 cylinder, resin impregnated, and fully wrapped continuous filament with a non-metallic liner containing methane.
15415–N	Request by Vexxel Composites LLC, Brigham City, UT, October 27, 2011. To authorize the manufacture, mark, sale, and use of non-DOT specification fully wrapped carbon-fiber reinforced aluminum lined cylinders per DOT–CFFC for the U.S. Army as a survival egress air support cylinder.
15454–N	Request by Hoke, Inc., Spartanburg, SC, September 28, 2011. To authorize the re-manufacturing of specific DOT Specification 3BN cylinders by reducing the volume from 4500 cc to 3000 cc.
15409–N	Request by Jiangxi Lidu Fireworks, Co, Ltd., Toronto, on August 24, 2011. Re exportation back to China via rail from Chicago to Long Beach and then via vessel to Shanghai, PR China.
15410–N	Request by Flashing Thunder Fireworks, Inc., Osage, IA, August 24, 2011. To authorize the transportation in commerce of Division 1.4G fireworks from the customs warehouse in Kentucky approximately 30 miles to a warehouse facility in West Harrison, IN to hold until issues regarding the EX numbers are resolved.

[FR Doc. 2011–30253 Filed 11–25–11; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

November 22, 2011.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before December 28, 2011, to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or e-mail at *OIRA_Submission@OMB.EOP.GOV* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave., NW., Suite 11020, Washington, DC 20220, or online at *http://www.PRAComment.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov,* or the entire information collection request maybe found at *http://www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Number: 1545–0090.

Type of Review: Revision of a currently approved collection.

Title: Form 1040–SS, U.S. Self-Employment Tax Return; Form 1040–PR, Planilla Para La Declaracion De La Contribucion Federal Sobre El Trabajo Por Cuenta Propia-Puerto Rico; and Anejo H–PR.

Forms: 1040–SS, 1040–PR, ANEXO H–PR.

Abstract: Form 1040–S (Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands) and 1040–PR (Puerto Rico) are used by self-employed individuals to figure and report self-employment tax under IRC chapter 2 of Subtitle A, and provide credit to the taxpayer's social security account. Anejo H–PR is used to compute household employment taxes. Form 1040–SS and Form 1040–PR are also used by bona-fide residents of Puerto Rico to claim the additional child tax credit.

Respondents: Individuals and Households.

Estimated Total Burden Hours: 2,801,605.

OMB Number: 1545–0096.

Type of Review: Revision of a currently approved collection.

Title: Form 1042, Annual Withholding Tax Return for U.S. Source Income of Foreign Persons; Form 1042–S, Foreign Person's U.S. Source Income Subject to Withholding, Form 1042–T, Annual Summary and Transmittal of Forms 1042–S.

Forms: 1042, 1042–S, 1042–T.

Abstract: Form 1042 is used by withholding agents to report tax withheld at source on certain income paid to nonresident alien individuals, foreign partnerships, and foreign corporations to the IRS. Form 1042–S is used by withholding agents to report income and tax withheld to payees. A copy of each 1042–S is filed magnetically or with Form 1042 for information reporting purposes. The IRS uses this information to verify that the correct amount of tax has been withheld and paid to the United States. Form 1042–T is used by withholding agents to transmit Forms 1042–S to the IRS.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 2,705,594.

OMB Number: 1545–0110.

Type of Review: Revision of a currently approved collection.

Title: Dividends and Distributions.

Form: 1099–DIV.

Abstract: The form is used by the Service to insure that dividends are properly reported as required by Code section 6042 and that liquidation distributions are correctly reported as required by Code section 6043, and to determine whether payees are correctly reporting their income.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 34,695,867.

OMB Number: 1545–0119.

Type of Review: Revision of a currently approved collection.

Title: Distributions From Pensions, Annuities, Retirement or Profit-Sharing Plans, IRAs, Insurance Contracts, *etc.*

Form: 1099–R.

Abstract: Form 1099–R is used to report distributions from pensions, annuities, profit-sharing or retirement plans, IRAs, and the surrender of insurance contracts. This information is used by IRS to verify that income has been properly reported by the recipient.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 39,247,614.

OMB Number: 1545–1008.

Type of Review: Revision of a currently approved collection.

Title: Passive Activity Loss Limitations.

Form: 8582.

Abstract: Under Internal Revenue Code section 469, losses from passive activities, to the extent that they exceed income from passive activities, cannot be deducted against nonpassive income. Form 8582 is used to figure the passive activity loss allowed and the loss to be reported on the tax return.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 8,451,989.

OMB Number: 1545–1027.

Type of Review: Revision of a currently approved collection.

Title: U.S. Property and Casualty Insurance Company Income Tax Return.

Forms: 1020–PC, Schedule M to 1020–PC.

Abstract: Property and casualty insurance companies are required to file an annual return of income and pay the tax due. The data is used to insure that companies have correctly reported income and paid the correct tax.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 672,246.

OMB Number: 1545–1204.

Type of Review: Revision of a currently approved collection.

Title: Low-Income Housing Credit Agencies Report of Noncompliance or Building Disposition.

Form: 8823.

Abstract: Form 8823 is used by housing agencies to report noncompliance with the low-income housing provisions of Code section 42.

Respondents: State, Local, and Tribal Governments.

Estimated Total Burden Hours: 303,200.

OMB Number: 1545–1257.

Type of Review: Revision of a currently approved collection.

Title: Credit for Prior Year Minimum Tax—Corporations.

Form: 8827.

Abstract: Section 53(d), as revised, allows corporations a minimum tax credit based on the full amount of alternative minimum tax incurred in tax years beginning after 1989, or a carryforward for use in a future year.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 298,000.

OMB Number: 1545–1424.

Type of Review: Revision of a currently approved collection.

Title: Cancellation of Debt.

Form: 1099–C.

Abstract: Form 1099–C is used for reporting canceled debt, as required by section 6050P of the Internal Revenue Code. It is used to verify that debtors are correctly reporting their income.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 854,892.

OMB Number: 1545–1632.

Type of Review: Extension without change of a currently approved collection.

Title: T.D. 8873—New Technologies in Retirement Plans.

Abstract: This document contains amendments to the regulations governing certain notices and consents required in connection with distributions from retirement plans. Specifically, these regulations set forth applicable standards for the transmission of those notices and consents through electronic media and modify the timing requirements for providing certain distribution-related notices. The regulations provide guidance to plan sponsors and administrators by interpreting the notice and consent requirements in the context of the electronic administration of retirement plans. The regulations affect retirement plan sponsors, administrators, and participants.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 477,563.

OMB Number: 1545–1648.

Type of Review: Extension without change of a currently approved collection.

Title: Low-Income Taxpayer Clinic 2012 Grant Application Package and Guidelines.

Abstract: Publication 3319 is the grant application and program requirements for our external customers, non-profits, legal aid societies, universities, law schools, and will be used by anyone in the US and territories to apply for a low income taxpayer grant.

Respondents: Private Sector: Not-for-profit institutions.

Estimated Total Burden Hours: 6,000.

OMB Number: 1545–1772.

Type of Review: Revision of a currently approved collection.

Title: User Fee for Employee Plan Determination Letter Request.

Form: 8717.

Abstract: The Omnibus Reconciliation Act of 1990 requires payment of a ''user fee'' with each application for a determination letter. Because of this requirement, the Form 8717 was created to provide filers the means to make payment and indicate the type of request.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 369,720.

OMB Number: 1545–1796.

Type of Review: Extension without change of a currently approved collection.

Title: REG–106879–00 (Final) Consolidated Loss Recapture Events.

Abstract: This document contains final regulations under section 1503(d) regarding the events that require the recapture of dual consolidated losses. These regulations are issued to facilitate compliance by taxpayers with the dual consolidated loss provisions. The regulations generally provide that certain events will not trigger recapture of a dual consolidated loss or payment of the associated interest charge. The regulations provide for the filing of certain agreements in such cases.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 60.

OMB Number: 1545–1934.

Type of Review: Revision of a currently approved collection.

Title: TD 9394 (REG–108524–00) (Final)—Section 1446 Regulations; Form 8804–C—Certificate of Partner-Level Items to Reduce Section 1446 Withholding.

Form: 8804–C.

Abstract: This regulation implements withholding regime on partnerships conducting business in the United States that have foreign partners. Such partners are required to pay withholding tax in installments on each foreign partner's allocable share of the partnership's U.S. Business taxable income. Special rules for publicly traded partnerships such that these partnerships pay withholding tax on distributions to foreign partners.

Respondents: Private Sector: Not-for-profit institutions.

Estimated Total Burden Hours: 18,701.

OMB Number: 1545–1936.

Type of Review: Extension without change of a currently approved collection.

Title: Revenue Procedure 2005–24, Waiver of Spousal Election.

Abstract: This revenue procedure provides guidance on the procedures for waiving a spousal election right with respect to charitable remainder annuity trusts under section 664(d)(1) and charitable remainder unitrusts under section 664(d)(2) that are established after the date that is 90 days after the date the Rev. Proc. is published in the IRB.

Respondents: Individuals and Households.

Estimated Total Burden Hours: 150,000.

OMB Number: 1545–2099.

Type of Review: Revision of a currently approved collection.

Title: Excise Tax on Certain Transfers of Qualifying Geothermal or Mineral Interests.

Form: 8924.

Abstract: Form 8924, Excise Tax on Certain Transfers of Qualifying Geothermal or Mineral Interests, is required by Section 403 of the Tax Relief and Health Care Act of 2006 which imposes an excise tax on certain transfers of qualifying mineral or geothermal interests.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 111.

OMB Number: 1545–2129.

Type of Review: Revision of a currently approved collection.

Title: Exercise of an Incentive Stock Option Under * * *; Transfer of Stock Acquired Through an * * *; REG–103146–08–Information Reporting Requirements Under Code Sec. 6039.

Forms: 3922, 3921.

Abstract: Form 3921 is a copy of the information return filed with the IRS which transferred shares of stock to a recipient through exercise of an incentive stock option under section 422(b). Form 3922 is used to record a transfer of the legal title of a share of stock acquired by the employee where the stock was acquired pursuant to the exercise of an option described in section 423(c). REG–103146–08—reflects the changes to section 6039 of the Internal Revenue Code made by section 403 of the Tax Relief and Health Care Act of 2006.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 25,205.

Bureau Clearance Officer: Yvette Lawrence, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224; (202) 927–4374.

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. 2011–30538 Filed 11–25–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

United States Mint

Citizens Coinage Advisory Committee November 29, 2011; Public Meeting

ACTION: Notice.

SUMMARY: Pursuant to United States Code, Title 31, section 5135(b)(8)(C), the United States Mint announces the Citizens Coinage Advisory Committee (CCAC) public meeting scheduled for November 29, 2011.

Date: November 29, 2011.

Time: 9 a.m. to 5 p.m.

Location: Conference Room A, United States Mint, 801 9th Street NW., Washington, DC 20220.

Subject: Review and consideration of reverse candidate designs for the 2013 America the Beautiful Quarters® Program Coins; review and consideration of candidate designs for the 2012 First Spouse Gold Coins and Bronze Medals honoring Alice Paul (with a reverse representative of the suffrage movement), Frances Cleveland and Caroline Harrison; review and consideration of reverse candidate designs for 2012 American Eagle Platinum Coin program; and discussion of the 2011 Annual Report.

Interested persons should call the CCAC HOTLINE at (202) 354–7502 for the latest update on meeting time and room location.

In accordance with 31 U.S.C. § 5135, the CCAC:

- Advises the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals.
- Advises the Secretary of the Treasury with regard to the events, persons, or places to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made.
- Makes recommendations with respect to the mintage level for any commemorative coin recommended.

FOR FURTHER INFORMATION CONTACT: Andy Fishburn, United States Mint Liaison to the CCAC; 801 9th Street NW., Washington, DC 20220; or call (202) 354–6700.

Any member of the public interested in submitting matters for the CCAC's consideration is invited to submit them by fax to the following number: (202) 756–6525.

Authority: 31 U.S.C. 5135(b)(8)(C).

Dated: November 16, 2011.

Richard A. Peterson,

Deputy Director, United States Mint.

[FR Doc. 2011–30469 Filed 11–25–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0678]

Proposed Information Collection (Agreement To Train on the Job Disabled Veterans) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to assure that on the job training establishments are providing veterans with the appropriate rehabilitation training.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 27, 2012.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *http://www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0678'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 461–9769 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501—3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Agreement to Train on the Job Disabled Veterans, VA Form 28–1904.

OMB Control Number: 2900–0678.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 28–1904 is a written agreement between an on the job training (OJT) establishments and VA. The agreement is necessary to ensure that OJT is providing claimants with the appropriate training and supervision, and VA's obligation to provide claimants with the necessary tools, supplies, and equipment for such training.

Affected Public: Business or other for-profit.

Estimated Annual Burden: 150 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 600.

Dated: November 22, 2011.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–30507 Filed 11–25–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0677]

Proposed Information Collection (Contract for Training and Employment) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to ensure contracts between VA and training facilities/vendors are consistent with the Federal Procurement Regulations.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 27, 2012.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *http://www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or email *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0677'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 461–9769 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Contract for Training and Employment (Chapter 31, Title 38 U.S. Code), VA Form 28–1903.

OMB Control Number: 2900–0677.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 28–1903 is used to standardize contracts agreements between VA and training facilities/vendors providing vocational rehabilitation training and employment to veterans. VA uses the data collected to ensure that veterans are receiving training and employment as agreed in the contract.

Affected Public: Business or other for-profit.

Estimated Annual Burden: 1,200 hours.

Estimated Average Burden per Respondent: 60 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 1,200.

Dated: November 22, 2011.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–30506 Filed 11–25–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0580]

Agency Information Collection (Request for Transportation Expense Reimbursement): Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before December 28, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0580'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, FAX (202) 461–0966 or email *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–0580.''

SUPPLEMENTARY INFORMATION:

Title: Request for Transportation Expense Reimbursement (38 CFR 21.8370).

OMB Control Number: 2900–0580.

Type of Review: Extension of a currently approved collection.

Abstract: Children of Vietnam veterans born with spina bifida and receiving vocational training or seeking employment may request reimbursement for transportation expenses. To be eligible, the child must provide supportive documentation of actual expenses incurred for the travel. VA uses the information collected to determine if the child is unable to pursue training or employment without travel assistance.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on September 21, 2011, at page 58567.

Affected Public: Individuals or households.

Estimated Annual Burden: 63 hours.

Estimated Average Burden per Respondent: 6 minutes.

Frequency of Response: Monthly.

Estimated Number of Respondents: 50.

Estimated Total Annual Responses: 600.

Dated: November 22, 2011.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–30508 Filed 11–25–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0721]

Agency Information Collection (Exam for Housebound Status or Permanent Need for Regular Aid and Attendance): Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before December 28, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0721'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–7485, FAX (202) 461–0966 or email *denise.mclamb@va.gov*. Please refer to ''OMB Control No. 2900–0721.''

SUPPLEMENTARY INFORMATION:

Title: Exam for Housebound Status or Permanent Need for Regular Aid and Attendance, VA Form 21–2680.

OMB Control Number: 2900–0721.

Type of Review: Extension of a currently approved collection.

Abstract: VA will use VA Form 21–2680 to gather medical information that is necessary to determine beneficiaries or claimants receiving treatment from private doctors or physicians, eligibility for aid and attendance or housebound benefit.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on September 21, 2011, at pages 58565–58566.

Affected Public: Business or other for-profit.

Estimated Annual Burden: 7,000 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 14,000.

Dated: November 22, 2011.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–30503 Filed 11–25–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0104]

Agency Information Collection (Report of Accidental Injury in Support of Claim for Compensation or Pension/ Statement of Witness to Accident): Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before December 28, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316.

Please refer to ''OMB Control No. 2900–0104'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–7485, FAX (202) 461–0966 or email *denise.mclamb@va.gov*. Please refer to ''OMB Control No. 2900–0104.''

SUPPLEMENTARY INFORMATION:

Title: Report of Accidental Injury in Support of Claim for Compensation or Pension/Statement of Witness to Accident, VA Form 21–4176.

OMB Control Number: 2900–0104.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 21–4176 is used to support a claim for disability benefits based on an accidental injury that a veteran incurred while in the line of duty. VA will use the data collected to determine whether the injury was accidental or a result of willful misconduct by the veteran.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on September 21, 2011, at pages 58566–58567.

Affected Public: Individuals or households.

Estimated Annual Burden: 2,200 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 4,400.

Dated: November 22, 2011.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–30504 Filed 11–25–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0108]

Agency Information Collection (Report of Income From Property or Business): Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before December 28, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0108'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–7485, FAX (202) 461–0966 or email *denise.mclamb@va.gov*. Please refer to ''OMB Control No. 2900–0108.''

SUPPLEMENTARY INFORMATION:

Title: Report of Income from Property or Business, VA Form 21–4185.

OMB Control Number: 2900–0108.

Type of Review: Extension of a currently approved collection.

Abstract: Claimants complete VA Form 21–4185 to report income and expenses that derived from rental property and/or operation of a business. VA uses the information to determine whether the claimant is eligible for VA benefits and, if eligibility exists, the proper rate of payment.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on September 21, 2011, at page 58566.

Affected Public: Individuals or households.

Estimated Annual Burden: 3,500 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 7,000.

Dated: November 22, 2011.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–30505 Filed 11–25–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0720]

Agency Information Collection (Operation Enduring Freedom/ Operation Iraqi Freedom Seriously Injured/Ill Service Member Veteran Worksheet): Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before December 28, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0720'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, FAX (202) 461–0966 or email *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–0720.''

SUPPLEMENTARY INFORMATION:

Title: Operation Enduring Freedom/ Operation Iraqi Freedom Seriously Injured/Ill Service Member Veteran Worksheet, VA Form 21–0773.

OMB Control Number: 2900–0720.

Type of Review: Extension of a currently approved collection.

Abstract: Veterans Service Representatives used VA Form 21–0773 as a checklist to ensure they provided Operation Enduring Freedom or Operation Iraqi Freedom service members who have at least six months remaining on active duty and may have suffered a serious injury or illness, with information, applications, and/or referral service regarding VA benefits.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on September 21, 2011, at page 58565.

Affected Public: Individuals or households.

Estimated Annual Burden: 7,000 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 14,000.

Dated: November 22, 2011.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–30502 Filed 11–25–11; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 415, et al.
Medicare Program; Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 415, and 495

[CMS–1524–FC and CMS–1436–F]

RINs 0938–AQ25 and 0938–AQ00

Medicare Program; Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It also addresses, implements or discusses certain statutory provisions including provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act) and the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. In addition, this final rule with comment period discusses payments for Part B drugs; Clinical Laboratory Fee Schedule: Signature on Requisition; Physician Quality Reporting System; the Electronic Prescribing (eRx) Incentive Program; the Physician Resource-Use Feedback Program and the value modifier; productivity adjustment for ambulatory surgical center payment system and the ambulance, clinical laboratory, and durable medical equipment prosthetics orthotics and supplies (DMEPOS) fee schedules; and other Part B related issues.

DATES: *Effective date:* These regulations are effective on January 1, 2012.

Implementation date: The 3-day payment window policy provisions specified in section V.B.3.a. of this final rule with comment period will be implemented by July 1, 2012.

Comment date: To be assured consideration, comments on the items listed in the ''Comment Subject Areas'' section of this final rule with comment period must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time on January 3, 2012.

ADDRESSES: In commenting, please refer to file code CMS–1524–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions for ''submitting a comment.''

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1524–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1524–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–1066 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Ryan Howe, (410) 786–3355 or Chava Sheffield, (410) 786–2298, for issues related to the physician fee schedule practice expense methodology and direct practice expense inputs.

Elizabeth Truong, (410) 786–6005, or Sara Vitolo, (410) 786–5714, for issues related to potentially misvalued services and interim final work RVUs.

Ken Marsalek, (410) 786–4502, for issues related the multiple procedure payment reduction and pathology services.

Sara Vitolo, (410) 786–5714, for issues related to malpractice RVUs.

Michael Moore, (410) 786–6830, for issues related to geographic practice cost indices.

Ryan Howe, (410) 786–3355, for issues related to telehealth services.

Elizabeth Truong, (410) 786–6005, for issues related to the sustainable growth rate, or the anesthesia or physician fee schedule conversion factors.

Bonny Dahm, (410) 786–4006, for issues related to payment for covered outpatient drugs and biologicals.

Glenn McGuirk, (410) 786–5723, for issues related to the Clinical Laboratory Fee Schedule (CLFS) signature on requisition policy.

Claudia Lamm, (410) 786–3421, for issues related to the chiropractic services demonstration budget neutrality issue.

Jamie Hermansen, (410) 786–2064, or Stephanie Frilling, (410) 786–4507 for issues related to the annual wellness visit.

Christine Estella, (410) 786–0485, for issues related to the Physician Quality Reporting System, incentives for Electronic Prescribing (eRx) and Physician Compare.

Gift Tee, (410) 786–9316, for issues related to the Physician Resource Use Feedback Program and physician value modifier.

Stephanie Frilling, (410) 786–4507 for issues related to the 3-day payment window.

Pam West, (410) 786–2302, for issues related to the technical corrections or the therapy cap.

Rebecca Cole or Erin Smith, (410) 786–4497, for issues related to physician payment not previously identified.

SUPPLEMENTARY INFORMATION:

Comment Subject Areas: We will consider comments on the following subject areas discussed in this final rule with comment period that are received by the date and time indicated in the DATES section of this final rule with comment period:

(1) The interim final work, practice expense, and malpractice RVUs (including the physician time, direct practice expense (PE) inputs, and the equipment utilization rate assumption) for new, revised, potentially misvalued, and certain other CY 2012 HCPCS codes. These codes and their CY 2012 interim final RVUs are listed in Addendum C to this final rule with comment period.

(2) The physician self-referral designated health services codes listed in Tables 83 and 84.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the regulations.gov Web site (*http://www.regulations.gov*) as soon as possible after they have been received. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–(800) 743–3951.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a table of contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR). Information on the regulations' impact appears throughout the preamble and, therefore, is not discussed exclusively in section IX. of this final rule with comment period.

Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order as follows:

AA Anesthesiologist assistant
AACE American Association of Clinical Endocrinologists
AACVPR American Association of Cardiovascular and Pulmonary Rehabilitation
AADE American Association of Diabetes Educators
AANA American Association of Nurse Anesthetists
ABMS American Board of Medical Specialties
ABN Advanced Beneficiary Notice
ACC American College of Cardiology
ACGME Accreditation Council on Graduate Medical Education
ACLS Advanced cardiac life support
ACP American College of Physicians
ACR American College of Radiology
ACS American Community Survey
ADL Activities of daily living
AED Automated external defibrillator
AFROC Association of Freestanding Radiation Oncology Centers
AFS Ambulance Fee Schedule
AHA American Heart Association
AHFS–DI American Hospital Formulary Service-Drug Information
AHRQ [HHS] Agency for Healthcare Research and Quality
AMA American Medical Association
AMA RUC [AMA's Specialty Society] Relative (Value) Update Committee
AMA–DE American Medical Association Drug Evaluations
AMI Acute Myocardial Infarction
AMP Average Manufacturer Price
AO Accreditation organization
AOA American Osteopathic Association
APA American Psychological Association
APC Administrative Procedures Act
APTA American Physical Therapy Association
ARRA American Recovery and Reinvestment Act (Pub. L. 111–5)
ASC Ambulatory surgical center
ASP Average Sales Price
ASPE Assistant Secretary of Planning and Evaluation (ASPE)
ASRT American Society of Radiologic Technologists
ASTRO American Society for Therapeutic Radiology and Oncology
ATA American Telemedicine Association
AWP Average Wholesale Price
AWV Annual Wellness Visit
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
BLS Bureau of Labor and Statistics
BMD Bone Mineral Density
BMI Body Mass Index
BN Budget Neutrality
BPM Benefit Policy Manual
CABG Coronary Artery Bypass Graft
CAD Coronary Artery Disease
CAH Critical Access Hospital
CAHEA Committee on Allied Health Education and Accreditation
CAP Competitive Acquisition Program
CARE Continuity Assessment Record and Evaluation
CBIC Competitive Bidding Implementation Contractor
CBP Competitive Bidding Program
CBSA Core-Based Statistical Area
CDC Centers for Disease Control and Prevention
CEM Cardiac Event Monitoring
CF Conversion Factor
CFC Conditions for Coverage
CFR Code of Federal Regulations
CKD Chronic Kidney Disease
CLFS Clinical Laboratory Fee Schedule
CMA California Medical Association
CMD Contractor Medical Director
CME Continuing Medical Education
CMHC Community Mental Health Center
CMPs Civil Money Penalties
CMS Centers for Medicare & Medicaid Services
CNS Clinical Nurse Specialist
CoP Condition of Participation
COPD Chronic Obstructive Pulmonary Disease
CORF Comprehensive Outpatient Rehabilitation Facility
COS Cost of Service
CPEP Clinical Practice Expert Panel
CPI Consumer Price Index
CPI–U Consumer Price Index for Urban Consumers
CPR Cardiopulmonary Resuscitation
CPT [Physicians] Current Procedural Terminology (4th Edition, 2002, copyrighted by the American Medical Association)
CQM Clinical Quality Measures
CR Cardiac Rehabilitation
CRF Chronic Renal Failure
CRNA Certified Registered Nurse Anesthetist
CROs Clinical Research Organizations
CRP Canalith Repositioning
CRT Certified Respiratory Therapist
CSC Computer Sciences Corporation
CSW Clinical Social Worker
CT Computed Tomography
CTA Computed Tomography Angiography
CWF Common Working File
CY Calendar Year
D.O. Doctor of Osteopathy
DEA Drug Enforcement Agency
DHHS Department of Health and Human Services
DHS Designated health services
DME Durable Medical Equipment
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DOJ Department of Justice
DOQ Doctors Office Quality
DOS Date of service
DOTPA Development of Outpatient Therapy Alternatives
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
DSMT Diabetes Self-Management Training Services
DXA CPT Dual energy X-ray absorptiometry
E/M Evaluation and Management Medicare Services
ECG Electrocardiogram
EDI Electronic data interchange
EEG Electroencephalogram
EGC Electrocardiogram
EHR Electronic health record
EKG Electrocardiogram
EMG Electromyogram
EMTALA Emergency Medical Treatment and Active Labor Act
EOG Electro-oculogram
EPO Erythopoeitin
EPs Eligible Professional
eRx Electronic Prescribing
ESO Endoscopy Supplies
ESRD End-Stage Renal Disease
FAA Federal Aviation Administration
FAX Facsimile
FDA Food and Drug Administration (HHS)
FFS Fee-for-service
FISH In Situ Hybridization Testing
FOTO Focus On Therapeutic Outcomes
FQHC Federally Qualified Health Center
FR **Federal Register**
FTE Full Time Equivalent
GAF Geographic Adjustment Factor
GAO Government Accountability Office
GEM Generating Medicare [Physician Quality Performance Measurement Results]
GFR Glomerular Filtration Rate
GME Graduate Medical Education
GPCIs Geographic Practice Cost Indices
GPO Group Purchasing Organization
GPRO Group Practice Reporting Option
GPS Geographic Positioning System
GSA General Services Administration
GT Growth Target
HAC Hospital-Acquired Conditions
HBAI Health and Behavior Assessment and Intervention
HCC Hierarchal Condition Category
HCPAC Health Care Professionals Advisory Committee
HCPCS Healthcare Common Procedure Coding System
HCRIS Healthcare Cost Report Information System
HDL/LDL High-Density Lipoprotein/Low-Density Lipoprotein
HDRT High Dose Radiation Therapy
HEMS Helicopter Emergency Medical Services
HH PPS Home Health Prospective Payment System
HHA Home Health Agency
HHRG Home Health Resource Group
HHS [Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HIT Health Information Technology
HITECH Health Information Technology for Economic and Clinical Health Act (Title IV of Division B of the Recovery Act, together with Title XIII of Division A of the Recovery Act)
HITSP Healthcare Information Technology Standards Panel
HIV Human Immunodeficiency Virus
HMO Health Maintenance Organization
HOPD Hospital Outpatient Department
HPSA Health Professional Shortage Area
HRA Health Risk Assessment
HRSA Health Resources Services Administration (HHS)
HSIP HPSA Surgical Incentive Program
HUD Department of Housing and Urban Development
HUD Housing and Urban Development
IACS Individuals Access to CMS Systems
IADL Instrumental Activities of Daily Living

ICD International Classification of Diseases
ICF Intermediate Care Facilities
ICF International Classification of Functioning, Disability and Health
ICR Intensive Cardiac Rehabilitation
ICR Information Collection Requirement
IDE Investigational Device Exemption
IDTF Independent Diagnostic Testing Facility
IFC Interim Rinal Rule with Comment Period
IGI IHS Global Insight, Inc.
IME Indirect Medical Education
IMRT Intensity-Modulated Radiation Therapy
INR International Normalized Ratio
IOM Institute of Medicine
IOM Internet Only Manual
IPCI Indirect Practice Cost Index
IPPE Initial Preventive Physical Examination
IPPS Inpatient Prospective Payment System
IRS Internal Revenue Service
ISO Insurance Services Office
IVD Ischemic Vascular Disease
IVIG Intravenous Immune Globulin
IWPUT Intra-service Work Per Unit of Time
JRCERT Joint Review Committee on Education in Radiologic Technology
KDE Kidney Disease Education
LCD Local Coverage Determination
LOPS Loss of Protective Sensation
LUGPA Large Urology Group Practice Association
M.D. Doctor of Medicine
MA Medicare Advantage Program
MAC Medicare Administrative Contractor
MA–PD Medicare Advantage-Prescription Drug Plans
MAV Measure Applicability Validation
MCMP Medicare Care Management Performance
MCP Monthly Capitation Payment
MDRD Modification of Diet in Renal Disease
MedCAC Medicare Evidence Development and Coverage Advisory Committee (formerly the Medicare Coverage Advisory Committee (MCAC))
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MGMA Medical Group Management Association
MIEA–TRHCA Medicare Improvements and Extension Act of 2006 (that is, Division B of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109–432)
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MMEA Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309)
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173)
MNT Medical Nutrition Therapy
MOC Maintenance of Certification
MP Malpractice
MPC Multispecialty Points of Comparison
MPPR Multiple Procedure Payment Reduction Policy
MQSA Mammography Quality Standards Act of 1992 (Pub. L. 102–539)
MRA Magnetic Resonance Angiography
MRI Magnetic Resonance Imaging
MSA Metropolitan Statistical Area
MSP Medicare Secondary Payer
MUE Medically Unlikely Edit
NAICS North American Industry Classification System
NBRC National Board for Respiratory Care
NCCI National Correct Coding Initiative
NCD National Coverage Determination
NCQA National Committee for Quality Assurance
NCQDIS National Coalition of Quality Diagnostic Imaging Services
NDC National Drug Codes
NF Nursing facility
NISTA National Institute of Standards and Technology Act
NP Nurse Practitioner
NPI National Provider Identifier
NPP Nonphysician Practitioner
NPPES National Plan & Provider Enumeration System
NQF National Quality Forum
NRC Nuclear Regulatory Commission
NSQIP National Surgical Quality Improvement Program
NTSB National Transportation Safety Board
NUBC National Uniform Billing Committee
OACT [CMS] Office of the Actuary
OBRA Omnibus Budget Reconciliation Act
OCR Optical Character Recognition
ODF Open Door Forum
OES Occupational Employment Statistics
OGPE Oxygen Generating Portable Equipment
OIG Office of the Inspector General
OMB Office of Management and Budget
ONC [HHS] Office of the National Coordinator for Health IT
OPPS Outpatient Prospective Payment System
OSCAR Online Survey and Certification and Reporting
PA Physician Assistant
PACE Program of All-inclusive Care for the Elderly
PACMBPRA Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (Pub. L. 111–192)
PAT Performance Assessment Tool
PC Professional Components
PCI Percutaneous Coronary Intervention
PCIP Primary Care Incentive Payment Program
PDP Prescription Drug Plan
PE Practice Expense
PE/HR Practice Expense per Hour
PEAC Practice Expense Advisory Committee
PECOS Provider Enrollment Chain and Ownership System
PERC Practice Expense Review Committee
PFS Physician Fee Schedule
PGP [Medicare] Physician Group Practice
PHI Protected Health Information
PHP Partial Hospitalization Program
PIM [Medicare] Program Integrity Manual
PLI Professional Liability Insurance
POA Present On Admission
POC Plan Of Care
PODs Physician Owned Distributors
PPATRA Physician Payment And Therapy Relief Act
PPI Producer Price Index
PPIS Physician Practice Expense Information Survey
PPPS Personalized Prevention Plan Services
PPS Prospective Payment System
PPTA Plasma Protein Therapeutics Association
PQRI Physician Quality Reporting Initiative
PR Pulmonary rehabilitation
PRA Paperwork Reduction Act
PSA Physician Scarcity Areas
PT Physical Therapy
PTA Physical Therapy Assistant
PTCA Percutaneous Transluminal Coronary Angioplasty
PVBP Physician and Other Health Professional Value-Based Purchasing Workgroup
QDCs (Physician Quality Reporting System) Quality Data Codes
RA Radiology Assistant
RAC Medicare Recovery Audit Contractor
RBMA Radiology Business Management Association
RFA Regulatory Flexibility Act
RHC Rural Health Clinic
RHQDAPU Reporting Hospital Quality Data Annual Payment Update Program
RIA Regulatory Impact Analysis
RN Registered Nurse
RNAC Reasonable Net Acquisition Cost
RPA Radiology Practitioner Assistant
RRT Registered Respiratory Therapist
RUC [AMA's Specialty Society] Relative (Value) Update Committee
RVRBS Resource-Based Relative Value Scale
RVU Relative Value Unit
SBA Small Business Administration
SCHIP State Children's Health Insurance Programs
SDW Special Disability Workload
SGR Sustainable Growth Rate
SLP Speech-Language Pathology
SMS [AMAs] Socioeconomic Monitoring System
SNF Skilled Nursing Facility
SOR System of Record
SRS Stereotactic Radiosurgery
SSA Social Security Administration
SSI Social Security Income
STARS Services Tracking and Reporting System
STATS Short Term Alternatives for Therapy Services
STS Society for Thoracic Surgeons
TC Technical Components
TIN Tax Identification Number
TJC Joint Commission
TRHCA Tax Relief and Health Care Act of 2006 (Pub. L. 109–432)
TTO Transtracheal Oxygen
UAF Update Adjustment Factor
UPMC University of Pittsburgh Medical Center
URAC Utilization Review Accreditation Committee
USDE United States Department of Education
USP–DI United States Pharmacopoeia-Drug Information
VA Department of Veterans Affairs
VBP Value-Based Purchasing
WAC Wholesale Acquisition Cost
WAMP Widely Available Market Price
WHO World Health Organization

Addenda Available Only Through the Internet on the CMS Web Site

In the past, the Addenda referred to throughout the preamble of our annual PFS proposed and final rules with comment period were included in the printed **Federal Register**. However, beginning with the CY 2012 PFS proposed rule, the PFS Addenda no longer appear in the **Federal Register**. Instead these Addenda to the annual proposed and final rules with comment period will be available only through the Internet. The PFS Addenda along with other supporting documents and tables referenced in this final rule with comment period are available through the Internet on the CMS Web site at *http://www.cms.gov/PhysicianFeeSched/*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2012 PFS final rule with comment period, refer to item CMS–1524–FC. For complete details on the availability of the Addenda referenced in this final rule with comment period, we refer readers to section X. of this final rule with comment period. Readers who experience any problems accessing any of the Addenda or other documents referenced in this final rule with comment period and posted on the CMS Web site identified above should contact Rebecca Cole at (410) 786–1589 or Erin Smith at (410) 786–4497.

CPT (Current Procedural Terminology) Copyright Notice

I. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians' Services.'' The Act requires that payments under the physician fee schedule (PFS) are based on national uniform relative value units (RVUs) based on the relative resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, practice expense (PE), and malpractice expense. Before the establishment of the resource-based relative value system, Medicare payment for physicians' services was based on reasonable charges. We note that throughout this final rule with comment period, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (such as physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, psychologists, or clinical social workers) that are permitted to furnish and bill Medicare under the PFS for their services.

A. Development of the Relative Value System

1. Work RVUs

The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (Pub. L. 101–239), and OBRA 1990, (Pub. L. 101–508). The final rule, published on November 25, 1991 (56 FR 59502), set forth the fee schedule for payment for physicians' services beginning January 1, 1992. Initially, only the physician work RVUs were resource-based, and the PE and malpractice RVUs were based on average allowable charges.

The physician work RVUs established for the implementation of the fee schedule in January 1992 was developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original physician work RVUs for most codes in a cooperative agreement with the Department of Health and Human Services (DHHS). In constructing the code-specific vignettes for the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the Federal government, and obtained input from numerous physician specialty groups.

Section 1848(b)(2)(B) of the Act specifies that the RVUs for anesthesia services are based on RVUs from a uniform relative value guide, with appropriate adjustment of the conversion factor (CF), in a manner to assure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. We established a separate CF for anesthesia services, and we continue to utilize time units as a factor in determining payment for these services. As a result, there is a separate payment methodology for anesthesia services.

We establish physician work RVUs for new and revised codes based, in part, on our review of recommendations received from the American Medical Association's (AMA's) Specialty Society Relative Value Update Committee (RUC).

2. Practice Expense Relative Value Units (PE RVUs)

Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432), enacted on October 31, 1994, amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians service beginning in 1998. We were to consider general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising PEs.

Section 4505(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), amended section 1848(c)(2)(C)(ii) of the Act to delay implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from charge-based PE RVUs to resource-based RVUs.

We established the resource-based PE RVUs for each physician's service in a final rule with comment period, published November 2, 1998 (63 FR 58814), effective for services furnished in 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, resource-based PE RVUs did not become fully effective until 2002.

This resource-based system was based on two significant sources of actual PE data: the Clinical Practice Expert Panel (CPEP) data and the AMA's Socioeconomic Monitoring System (SMS) data. The CPEP data were collected from panels of physicians, practice administrators, and nonphysician health professionals (for example, registered nurses (RNs)) nominated by physician specialty societies and other groups. The CPEP panels identified the direct inputs required for each physician's service in both the office setting and out-of-office setting. We have since refined and revised these inputs based on recommendations from the AMA RUC. The AMA's SMS data provided aggregate specialty-specific information on hours worked and PEs.

Separate PE RVUs are established for procedures that can be performed in both a nonfacility setting, such as a physician's office, and a facility setting, such as a hospital outpatient department (HOPD). The difference between the facility and nonfacility RVUs reflects the fact that a facility typically receives separate payment from Medicare for its costs of providing the service, apart from payment under the PFS. The nonfacility RVUs reflect all

of the direct and indirect PEs of providing a particular service.

Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules with comment period published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the calendar year (CY) 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007 and provided for a 4-year transition for the new PE RVUs under this new methodology. This transition ended in CY 2010 and direct PE RVUs are calculated in CY 2012 using this methodology, unless otherwise noted.

In the CY 2010 PFS final rule with comment period (74 FR 61749), we updated the PE/hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties. For this update, we used the Physician Practice Information Survey (PPIS) conducted by the AMA. The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) using a survey instrument and methods highly consistent with those of the SMS and the supplemental surveys used prior to CY 2010. We note that in CY 2010, for oncology, clinical laboratories, and independent diagnostic testing facilities (IDTFs), we continued to use the supplemental survey data to determine practice expense per hour (PE/HR) values (74 FR 61752). Beginning in CY 2010, we provided for a 4-year transition for the new PE RVUs using the updated PE/HR data. In CY 2012, the third year of the transition, PE RVUs are calculated based on a 75/25 blend of the new PE RVUs developed using the PPIS data and the previous PE RVUs based on the SMS and supplemental survey data.

3. Resource-Based Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require that we implement resource-based malpractice RVUs for services furnished on or after CY 2000. The resource-based malpractice RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs were based on malpractice insurance premium data collected from commercial and physician-owned insurers from all the States, the District of Columbia, and Puerto Rico. In the CY 2010 PFS final rule with comment period (74 FR 61758), we implemented the Second Five-Year Review and update of the malpractice RVUs. In the CY 2011 PFS final rule with comment period, we described our approach for determining malpractice RVUs for new or revised codes that become effective before the next Five-Year Review and update (75 FR 73208). Accordingly, to develop the CY 2012 malpractice RVUs for new or revised codes we crosswalked the new or revised code to the malpractice RVUs of a similar source code and adjusted for differences in work (or, if greater, the clinical labor portion of the fully implemented PE RVUs) between the source code and the new or revised code.

4. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review all RVUs no less often than every 5-years. The First Five-Year Review of Work RVUs was published on November 22, 1996 (61 FR 59489) and was effective in 1997. The Second Five-Year Review of Work RVUs was published in the CY 2002 PFS final rule with comment period (66 FR 55246) and was effective in 2002. The Third Five-Year Review of Work RVUs was published in the CY 2007 PFS final rule with comment period (71 FR 69624) and was effective on January 1, 2007. The Fourth Five-Year Review of Work RVUs was initiated in the CY 2010 PFS final rule with comment period where we solicited candidate codes from the public for this review (74 FR 61941). Proposed revisions to work RVUs and corresponding changes to PE and malpractice RVUs affecting payment for physicians' services for the Fourth Five-Year Review of Work RVUs were published in a separate **Federal Register** notice on June 6, 2011 (76 FR 32410). We have reviewed public comments, made adjustments to our proposals in response to comments, as appropriate, and included final values in this final rule with comment period, effective for services furnished beginning January 1, 2012.

In 1999, the AMA RUC established the Practice Expense Advisory Committee (PEAC) for the purpose of refining the direct PE inputs. Through March 2004, the PEAC provided recommendations to CMS for over 7,600 codes (all but a few hundred of the codes currently listed in the AMA's Current Procedural Terminology (CPT) codes). As part of the CY 2007 PFS final rule with comment period (71 FR 69624), we implemented a new bottom-up methodology for determining resource-based PE RVUs and transitioned the new methodology over a 4-year period. A comprehensive review of PE was undertaken prior to the 4-year transition period for the new PE methodology from the top-down to the bottom-up methodology, and this transition was completed in CY 2010. In CY 2010, we also incorporated the new PPIS data to update the specialty-specific PE/HR data used to develop PE RVUs, adopting a 4-year transition to PE RVUs developed using the PPIS data.

In the CY 2005 PFS final rule with comment period (69 FR 66236), we implemented the First Five-Year Review of the malpractice RVUs (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). The Second Five-Year Review and update of resource-based malpractice RVUs was published in the CY 2010 PFS final rule with comment period (74 FR 61758) and was effective in CY 2010.

In addition to the Five-Year Reviews, beginning for CY 2009, CMS and the AMA RUC have identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by section 3134 of the Affordable Care Act, which requires the agency to periodically identify, review and adjust values for potentially misvalued codes with an emphasis on the following categories: (1) Codes and families of codes for which there has been the fastest growth; (2) codes or families of codes that have experienced substantial changes in practice expenses; (3) codes that are recently established for new technologies or services; (4) multiple codes that are frequently billed in conjunction with furnishing a single service; (5) codes with low relative values, particularly those that are often billed multiple times for a single treatment; (6) codes which have not been subject to review

since the implementation of the RBRVS (the so-called 'Harvard valued codes'); and (7) other codes determined to be appropriate by the Secretary.

5. Application of Budget Neutrality to Adjustments of RVUs

Budget neutrality typically requires that expenditures not increase or decrease as a result of changes or revisions to policy. However, section 1848(c)(2)(B)(ii)(II) of the Act requires adjustment only if the change in expenditures resulting from the annual revisions to the PFS exceeds a threshold amount. Specifically, adjustments in RVUs for a year may not cause total PFS payments to differ by more than $20 million from what they would have been if the adjustments were not made. In accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

B. Components of the Fee Schedule Payment Amounts

To calculate the payment for every physician's service, the components of the fee schedule (physician work, PE, and malpractice RVUs) are adjusted by geographic practice cost indices (GPCIs). The GPCIs reflect the relative costs of physician work, PE, and malpractice in an area compared to the national average costs for each component.

RVUs are converted to dollar amounts through the application of a CF, which is calculated by CMS' Office of the Actuary (OACT).

The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

Payment = [(RVU work × GPCI work) + (RVU PE × GPCI PE) + (RVU Malpractice × GPCI Malpractice)] × CF.

C. Most Recent Changes to the Fee Schedule

The CY 2011 PFS final rule with comment period (75 FR 73170) implemented changes to the PFS and other Medicare Part B payment policies. It also finalized many of the CY 2010 interim RVUs and implemented interim RVUs for new and revised codes for CY 2011 to ensure that our payment systems are updated to reflect changes in medical practice and the relative values of services. The CY 2011 PFS final rule with comment period also addressed other policies, as well as certain provisions of the Affordable Care Act and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

In the CY 2011 PFS final rule with comment period, we announced the following for CY 2011: the total PFS update of −10.1 percent; the initial estimate for the sustainable growth rate of −13.4 percent; and the conversion factor (CF) of $25.5217. These figures were calculated based on the statutory provisions in effect on November 2, 2010, when the CY 2011 PFS final rule with comment period was issued.

On December 30, 2010, we published a correction notice (76 FR 1670) to correct several technical and typographical errors that occurred in the CY 2011 PFS final rule with comment period. This correction notice announced a revised CF for CY 2011 of $25.4999, which was in accordance with the statutory provisions in effect as of November 2, 2010, the date the CY 2011 PFS final rule with comment period was issued.

On November 30, 2010, the Physician Payment and Therapy Relief Act of 2010 (PPATRA) (Pub. L. 111–286) was signed into law. Section 3 of Pub. L. 111–286 modified the policy finalized in the CY 2011 PFS final rule with comment period (75 FR 73241), effective January 1, 2011, regarding the payment reduction applied to multiple therapy services provided to the same patient on the same day in the office setting by one provider and paid for under the PFS (hereinafter, the therapy multiple procedure payment reduction (MPPR)). The PPATRA provision changed the therapy MPPR percentage from 25 to 20 percent of the PE component of payment for the second and subsequent ''always'' therapy services furnished in the office setting on the same day to the same patient by one provider, and excepted the payment reductions associated with the therapy MPPR from budget neutrality under the PFS.

On December 15, 2010, the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309) was signed into law. Section 101 of the MMEA provided for a 1-year zero percent update for the CY 2011 PFS. As a result of the MMEA, the CY 2011 PFS conversion factor was revised to $33.9764.

II. Provisions of the Final Rule for the Physician Fee Schedule

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing the service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. Section 121 of the Social Security Amendments of 1994 (Pub. L. 103–432), enacted on October 31, 1994, required us to develop a methodology for a resource-based system for determining PE RVUs for each physician's service. We develop PE RVUs by looking at the direct and indirect physician practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. In addition, we note that section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs for a year may not cause total PFS payments to differ by more than $20 million from what they would have been if the adjustments were not made. Therefore, if revisions to the RVUs cause expenditures to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed history of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We use a bottom-up approach to determine the direct PE by adding the costs of the resources (that is, the clinical staff, equipment, and supplies) typically required to provide each service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are based on our review of recommendations received from the AMA RUC. For a detailed explanation of the bottom-up direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units Under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect practice expenses incurred per hour worked in developing the indirect

portion of the PE RVUs. Prior to CY 2010, we primarily used the practice expense per hour (PE/HR) by specialty that was obtained from the AMA's Socioeconomic Monitoring Surveys (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS), which was expanded (relative to the SMS) to include nonphysician practitioners (NPPs) paid under the PFS.

The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs using a consistent survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and healthcare professional groups. We believe the PPIS is the most comprehensive source of PE survey information available to date. Therefore, we used the PPIS data to update the PE/HR data for almost all of the Medicare-recognized specialties that participated in the survey for the CY 2010 PFS.

When we changed over to the PPIS data beginning in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we finalized a 4-year transition (75 percent old/25 percent new for CY 2010, 50 percent old/50 percent new for CY 2011, 25 percent old/75 percent new for CY 2012, and 100 percent new for CY 2013) from the previous PE RVUs to the PE RVUs developed using the new PPIS data.

Section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added section 1848(c)(2)(H)(i) of the Act, which requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

We do not use the PPIS data for reproductive endocrinology, sleep medicine, and spine surgery since these specialties are not separately recognized by Medicare, nor do we have a method to blend these data with Medicare-recognized specialty data.

Supplemental survey data on independent labs, from the College of American Pathologists, were implemented for payments in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments in CY 2007. Neither IDTFs nor independent labs participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for medical oncology, independent laboratories, and IDTFs were updated to CY 2006 using the MEI to put them on a comparable basis with the PPIS data.

Previously, we have established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead use the PPIS-based PE/HR. We continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable x-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other with respect to physician time.

For registered dietician services, the resource-based PE RVUs have been calculated in accordance with the final policy that crosswalks the specialty to the ''All Physicians'' PE/HR data, as adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) and discussed in more detail in the CY 2011 PFS final rule with comment period (75 FR 73183).

There are four specialties whose utilization data will be newly incorporated into ratesetting for CY 2012. We proposed to use proxy PE/HR values for these specialties by crosswalking values from other, similar specialties as follows: Speech Language Pathology from Physical Therapy; Hospice and Palliative Care from All Physicians; Geriatric Psychiatry from Psychiatry; and Intensive Cardiac Rehabilitation from Cardiology. Additionally, since section 1833(a)(1)(K) of the Act (as amended by section 3114 of the Affordable Care Act) requires that payment for services provided by a certified nurse midwife be paid at 100 percent of the PFS amount, this specialty will no longer be excluded from the ratesetting calculation. We proposed to crosswalk the PE\HR data from Obstetrics/gynecology to Certified Nurse Midwife. These proposed changes were reflected in the ''PE HR'' file available on the CMS Web site under the supporting data files for the CY 2012 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/.*

Comment: Several commenters supported the proposals to incorporate the data into ratesetting for CY 2012. Most of these commenters also supported the proposed proxy PE/HR value crosswalks. One commenter, however, objected to using the Psychiatry PE/HR crosswalk for Geriatric Psychiatry. The commenter noted that many of the specific geriatric issues such as mobility, hearing impairments, and cognitive impairments that increase the expenses for geriatrician's treating frail adults also apply to the practice expenses for geriatric psychiatrists. Therefore, the commenter argued that CMS should use a blend of information from Geriatric Medicine and Psychiatry as the PE/HR crosswalk.

Response: We appreciate the broad support for the proposal to incorporate utilization data from these specialties into ratesetting for CY 2012. We understand the commenters' concerns in terms of geriatric psychiatry and agree that in many ways the patient population for geriatric psychiatry may resemble the patient population for geriatric medicine. However, the primary drivers of the indirect practice expense per hour for these specialties are the administrative staff category and the office rent category. We disagree with the commenter that the administrative staff and office space requirements for geriatric psychiatrists more closely resemble the administrative staff and office space requirements for geriatrics than for psychiatry. In general, these categories are more likely to be driven by the types of services provided than the patient population served.

After consideration of the public comments we received, we are finalizing our CY 2012 proposals to update the PE/HR data as reflected in the ''PE HR'' file available on the CMS Web site under the supporting data files for the CY 2012 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*.

As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), CY 2012 is the third year of the 4-year transition to the PE RVUs calculated using the PPIS data.

Therefore, in general, the CY 2012 PE RVUs are a 25 percent/75 percent blend of the previous PE RVUs based on the SMS and supplemental survey data and the new PE RVUS developed using the PPIS data as described previously.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, equipment, and supplies) typically required to provide the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Section II.A.2.b. of this final rule with comment period describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocate the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the physician work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is described as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that perform the service to determine an initial indirect allocator. For example, if the direct portion of the PE RVUs for a given service were 2.00 and direct costs, on average, represented 25 percent of total costs for the specialties that performed the service, the initial indirect allocator would be 6.00 since 2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00.
- We then add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had work RVUs of 4.00 and the clinical labor portion of the direct PE RVUs was 1.50, we would add 6.00 plus 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- We next incorporate the specialty-specific indirect PE/HR data into the calculation. As a relatively extreme example for the sake of simplicity, assume in our previous example that, based on the survey data, the average indirect cost of the specialties performing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties performing the second service with an indirect allocator of 5.00. In this case, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

d. Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a hospital or facility setting, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. Because Medicare makes a separate payment to the facility for its costs of furnishing a service, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

e. Services With Technical Components (TCs) and Professional Components (PCs)

Diagnostic services are generally comprised of two components: a professional component (PC) and a technical component (TC), each of which may be performed independently or by different providers, or they may be performed together as a ''global'' service. When services have PC and TC components that can be billed separately, the payment for the global component equals the sum of the payment for the TC and PC. This is a result of using a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global components, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global components, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global under the bottom-up methodology.)

f. PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746).

(1) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data from the surveys.

(2) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Apply a scaling adjustment to the direct inputs.

Step 2: Calculate the current aggregate pool of direct PE costs. This is the product of the current aggregate PE (aggregate direct and indirect) RVUs, the CF, and the average direct PE percentage from the survey data.

Step 3: Calculate the aggregate pool of direct costs. This is the sum of the product of the direct costs for each service from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3 calculate a direct PE scaling adjustment so that the aggregate direct cost pool does not exceed the current aggregate direct cost pool and apply it to the direct costs from Step 1 for each service.

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs, as long as the same CF is used in Step 2 and Step 5. Different CFs will result in different direct PE scaling factors, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling factors offset one another.

(3) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results

of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global components.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs, the clinical PE RVUs, and the work RVUs. For most services the indirect allocator is: Indirect percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical PE RVUs.

(**Note:** For global services, the indirect allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes in the examples in Table 2, the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVUs, clinical PE RVUs, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the current aggregate pool of PE RVUs by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services performed by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (**Note:** For services with TCs and PCs, we calculate the indirect practice cost index across the global components, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global component.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(4) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 6 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment.

The final PE BN adjustment is calculated by comparing the results of Step 18 to the current pool of PE RVUs. This final BN adjustment is required primarily because certain specialties are excluded from the PE RVU calculation for ratesetting purposes, but all specialties are included for purposes of calculating the final BN adjustment. (See ''Specialties excluded from ratesetting calculation'' later in this section.)

(5) Setup File Information

- Specialties excluded from ratesetting calculation: For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain nonphysician practitioners paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1. We note that since specialty code 97 (physician assistant) is paid at a percentage of the PFS and therefore excluded from the ratesetting calculation, this specialty has been added to the table for CY 2012.

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TABLE 1: SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthestist
57	Individual certified prosthetist-orthotist
58	Individuals not included in 55, 56, or 57
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
95	Competitive Acquisition Program (CAP) Vendor
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
1	Supplier of oxygen and/or oxygen related equipment
2	Pedorthic personnel
3	Medical supply company with pedorthic personnel

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- Crosswalk certain low volume physician specialties: Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- Physical therapy utilization: Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- Identify professional and technical services not identified under the usual TC and 26 modifiers: Flag the services that are PC and TC services, but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- Payment modifiers: Payment modifiers are accounted for in the creation of the file. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier.
- Work RVUs: The setup file contains the work RVUs from this final rule with comment period.

(6) Equipment Cost Per Minute

The equipment cost per minute is calculated as:

*(1/(minutes per year * usage)) * price * ((interest rate/(1-(1/((1 + interest rate)− life of equipment)))) + maintenance)*

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.

usage = equipment utilization assumption; 0.75 for certain expensive diagnostic imaging equipment (see 74 FR 61753 through 61755 and section II.A.3. of the

CY 2011 PFS final rule with comment period) and 0.5 for others.
price = price of the particular piece of equipment.
interest rate = 0.11.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.

This interest rate was proposed and finalized during rulemaking for CY 1998 PFS (62 FR 33164). We solicit comment regarding reliable data on current prevailing loan rates for small businesses.

Comment: Several commenters, including the AMA RUC stated that CMS should establish a periodic review of the interest rate assumption for equipment costs using current interest rate data from the Small Business Association and the Federal Reserve and allow for public comment on periodic updates. The RUC also noted that current market volatility exacerbates the need to establish such a process. One commenter noted that exaggerated assumptions about equipment interest rates inflates services with high equipment cost inputs relative to services without high equipment cost inputs, such as most primary care services. Therefore, CMS should update the equipment interest rate assumption.

In addition to examining the interest rate assumption, the RUC requested that CMS review the assumptions regarding useful life of equipment and yearly maintenance costs associated with maintaining high cost equipment and allow for comment on the methodologies used in developing these assumptions.

Response: We appreciate the public comments we received in response to our request regarding reliable data on current prevailing loan rates for small businesses. We will examine the suggestions of the AMA RUC and the other commenters in order to inform any future rulemaking on this issue.

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TABLE 2: CALCULATION OF PE RVUS UNDER METHODOLOGY FOR SELECTED CODES

	Step	Source	Formula	99213 Office visit, est nonfacility	33533 CABG, arterial, single facility	71020 Chest x-ray nonfacility	71020-TC Chest xray nonfacility	71020-26 Chest xray nonfacility	93000 ECG, complete nonfacility	93005 ECG, tracing nonfacility	93010 ECG, report nonfacility
(1) Labor cost (Lab)	Step 1	AMA		13.32	77.52	5.74	5.74	0.00	6.12	6.12	0.00
(2) Supply cost (Sup)	Step 1	AMA		2.98	7.34	3.39	3.39	0.00	1.19	1.19	0.00
(3) Equipment cost (Eqp.)	Step 1	AMA		0.19	0.65	8.17	8.17	0.00	0.12	0.12	0.00
(4) Direct cost (Dir)	Step 1		=(1)+(2)+(3)	16.50	85.51	17.31	17.31	0.00	7.43	7.43	0.00
(5) Direct adjustment (Dir. Adj).	Steps 2-4	See footnote*		0.55	0.55	0.55	0.55	0.55	0.55	0.55	0.55
(6) Adjusted Labor	Steps 2-4	=Lab * Dir Adj	=(1)*(5)	7.38	42.98	3.18	3.18	0.00	3.39	3.39	0.00
(7) Adjusted Supplies	Steps 2-4	= Sup * Dir Adj	=(2)*(5)	1.65	4.07	1.88	1.88	0.00	0.66	0.66	0.00
(8) Adjusted Equipment	Steps 2-4	= Eqp * Dir Adj	=(3)*(5)	0.11	0.36	4.53	4.53	0.00	0.07	0.07	0.00
(9) Adjusted direct	Steps 2-4		=(6)+(7)+(8)	9.15	47.41	9.59	9.59	0.00	4.12	4.12	0.00
(10) Conversion Factor (CF)	Step 5	PFS		33.9764	33.9764	33.9764	33.9764	33.9764	33.9764	33.9764	33.9764
(11) Adj. labor cost converted	Step 5	=(Lab * Dir Adj)/CF	=(6)/(10)	0.22	1.26	0.09	0.09	0.00	0.10	0.10	0.00
(12) Adj. supply cost converted	Step 5	=(Sup * Dir Adj)/CF	=(7)/(10)	0.05	0.12	0.06	0.06	0.00	0.02	0.02	0.00
(13) Adj. equipment cost converted	Step 5	=(Eqp * Dir Adj)/CF	=(8)/(10)	0.00	0.01	0.13	0.13	0.00	0.00	0.00	0.00
(14) Adj. direct cost converted	Step 5		=(11)+(12)+(13)	0.27	1.40	0.28	0.28	0.00	0.12	0.12	0.00
(15) Work RVU	Setup File	PFS		0.97	33.75	0.22	0.00	0.22	0.17	0.00	0.17
(16) Dir_pct	Steps 6,7	Surveys		0.26	0.18	0.29	0.29	0.29	0.29	0.29	0.29
(17) Ind_pct	Steps 6,7	Surveys		0.74	0.82	0.71	0.71	0.71	0.71	0.71	0.71
(18) Ind. Alloc. Formula (1st part).	Step 8	See Step 8		((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)
(19) Ind. Alloc. (1st part).	Step 8		See (18)	0.79	6.51	0.69	0.69	0.00	0.30	0.30	0.00
(20) Ind. Alloc. Formulas (2nd part).	Step 8	See Step 8		(15)	(15)	(15+11)	(11)	(15)	(15+11)	(11)	(15)
(21) Ind. Alloc. (2nd part).	Step 8		See (20)	0.97	33.75	0.31	0.09	0.22	0.27	0.10	0.17
(22) Indirect Allocator (1st + 2nd)	Step 8		=(19)+(21)	1.76	40.26	1.01	0.79	0.22	0.57	0.40	0.17
(23) Indirect Adjustment (Ind. Adj.)	Steps 9-11	See footnote**		0.41	0.41	0.41	0.41	0.41	0.41	0.41	0.41
(24) Adjusted indirect allocator	Steps 9-11	=Ind Alloc * Ind Adj		0.71	16.38	0.41	0.32	0.09	0.23	0.16	0.07
(25) Ind. Practice Cost Index (IPCI)	Steps 12-16	See Steps 12 - 16		1.12	0.81	0.90	0.90	0.90	0.93	0.93	0.93
(26) Adjusted Indirect	Step 17	= Adj.Ind Alloc * PCI	=(24) * (25)	0.80	13.33	0.37	0.29	0.08	0.21	0.15	0.06
(29) PE RVU	Step 18	=(Adj Dir + Adj Ind) * budn	=((14)+(26)) * budn	1.07	14.72	0.65	0.57	0.08	0.34	0.27	0.06

Note: PE RVUs in table 2, row 29, may not match Addendum B due to rounding. * The direct adj = [current pe rvus * CF * avg dir pct]/[sum direct inputs] = [Step 2]/[Step 3]** The indirect adj = [current pe rvus * avg ind pct]/[sum of ind allocators] = [Step 9]/[Step 10]

Note: The use of any particular conversion factor (CF) in Table 2 to illustrate the PE calculation has no effect on the resulting RVUs.

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3. Changes to Direct PE Inputs

In this section, we discuss other specific CY 2012 proposals and changes related to direct PE inputs. The changes we proposed and are finalizing are included in the proposed CY 2012 direct PE database, which is available on the CMS Web site under the supporting data files for the CY 2012 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*.

a. Inverted Equipment Minutes

It came to our attention that the minutes allocated for two particular equipment items have been inverted. This inversion affected three codes: 37232 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)), 37233 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)), and 37234 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)). In each case, the number of minutes allocated to the ''printer, dye sublimation (photo, color)'' (ED031) should have been appropriately allocated to the ''stretcher'' (EF018). The number of minutes allocated to the stretcher should have been appropriately allocated to the printer. Therefore, we proposed input corrections to the times associated with the two equipment items in the three codes.

Comment: Several commenters agreed with these corrections as proposed.

Response: We appreciate the support for these proposed revisions, as well as the information provided that allowed us to make them.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal to modify the direct PE database by correcting the input errors associated with the two equipment items in the three codes. The CY 2012 direct PE database reflects these changes and is available on the CMS Web site under the supporting data files for the CY 2012 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*.

b. Labor and Supply Input Duplication

We recently identified a number of CPT codes with inadvertently duplicated labor and supply inputs in the PE database. We proposed to remove the duplicate labor and supply inputs in the CY 2012 database as detailed in Table 3.

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TABLE 3: LABOR AND SUPPLY INPUT DUPLICATION

CPT Code	Short Code Descriptor	CMS Labor/Supply Code	Description of Labor/Supply
12011	Repair superficial wound(s)	SA048	pack, minimum multi-specialty visit
15360	Apply cult derm sub t/a/l	SA054	pack, post-op incision care (suture)
19361	Breast reconstr w/lat flap	L037D	RN/LPN/MTA
21147	Reconstruct midface lefort	SA054	pack, post-op incision care (suture)
23515	Treat clavicle fracture	SA052	pack, post-op incision care (staple)
25415	Repair radius & ulna	SA052	pack, post-op incision care (staple)
	Repair radius & ulna	SA052	pack, post-op incision care (staple)
28005	Treat foot bone lesion	SA054	pack, post-op incision care (suture)
28456	Treat midfoot fracture	SA054	pack, post-op incision care (suture)
28485	Treat metatarsal fracture	SA054	pack, post-op incision care (suture)
32998	Perq rf ablate tx pul tumor	SG079	tape, surgical paper 1in (Micropore)
35501	Artery bypass graft	L037D	RN/LPN/MTA
	Artery bypass graft	SA048	pack, minimum multi-specialty visit
35509	Artery bypass graft	L037D	RN/LPN/MTA
	Artery bypass graft	SA048	pack, minimum multi-specialty visit
35601	Artery bypass graft	L037D	RN/LPN/MTA
	Artery bypass graft	SA048	pack, minimum multi-specialty visit
36147	Access av dial grft for eval	SB008	drape, sterile, c-arm, fluoro
	Access av dial grft for eval	SH026	Conray Inj (iothalamate 43%)
	Access av dial grft for eval	SK093	x-ray ID card (flashcard)
37231	Tib/per revasc stent & ather	SK034	film, x-ray 14in x 17in
45541	Correct rectal prolapse	SJ032	lubricating jelly (K-Y) (5gm uou)
45550	Repair rectum/remove sigmoid	SJ032	lubricating jelly (K-Y) (5gm uou)
46258	Remove in/ex hem grp w/fistu	SD003	Anoscope
	Remove in/ex hem grp w/fistu	SD003	Anoscope
	Remove in/ex hem grp w/fistu	SD003	Anoscope
46261	Remove in/ex hem grps & fiss	SD003	Anoscope
	Remove in/ex hem grps & fiss	SD003	Anoscope
	Remove in/ex hem grps & fiss	SD003	Anoscope
58563	Hysteroscopy ablation	SB027	gown, staff, impervious
64704	Revise hand/foot nerve	SA054	pack, post-op incision care (suture)
64726	Release foot/toe nerve	SA054	pack, post-op incision care (suture)
64782	Remove limb nerve lesion	SA054	pack, post-op incision care (suture)
65810	Drainage of eye	SA082	pack, ophthalmology visit (w-dilation)
67228	Treatment of retinal lesion	L038A	COMT/COT/RN/CST
	Treatment of retinal lesion	SA082	pack, ophthalmology visit (w-dilation)
	Treatment of retinal lesion	SH049	lidocaine 2% w-epi inj (Xylocaine w-epi)
76813	Ob us nuchal meas 1 gest	SK022	film, 8inx10in (ultrasound, MRI)
78730	Urinary bladder retention	SB044	underpad 2ft x 3ft (Chux)
88365	Insitu hybridization (fish)	SM016	eye shield, splash protection
91038	Esoph imped funct test > 1h	SJ016	denture cup
95875	Limb exercise test	SC051	syringe 10-12ml

Comment: Many commenters agreed with the proposal to remove the duplicate labor and supply inputs from the direct PE database. One commenter agreed with the proposal but also stated that the inputs for CPT code 76813 may not reflect the use of current technology.

Response: We appreciate the broad support for the proposal. We refer stakeholders who do not believe that the direct PE database reflects current use technology for particular codes to the public process for nominating potentially misvalued codes in section II.B. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal to remove the duplicate labor and supply inputs in the CY 2012 database as detailed in Table 3. The CY 2012 direct PE database reflects these changes and is available on the CMS Web site under the supporting data files for the CY 2012 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/.*

c. AMA RUC Recommendations for Moderate Sedation Direct PE Inputs

For services described by certain codes, the direct PE database includes nonfacility inputs that reflect the assumption that moderate sedation is inherent in the procedure. These codes

are listed in Table 4. The AMA RUC has recently provided CMS with a recommendation that standardizes the nonfacility direct PE inputs that account for moderate sedation as typically furnished as part of these services. Specifically, the RUC recommended that the direct PE inputs allocated for moderate sedation include the following:

- Clinical Labor Inputs: Registered Nurse (L051A) time that includes two minutes of time to initiate sedation, the number of minutes associated with the physician intra-service work time, and 15 minutes for every hour of patient recovery time for post-service patient monitoring. Supply Inputs: ''Pack, conscious sedation'' (SA044) that includes: an angiocatheter 14g–24g, bandage, strip 0.75in × 3in, catheter, suction, dressing, 4in × 4.75in (Tegaderm), electrode, ECG (single), electrode, ground, gas, oxygen, gauze, sterile 4in × 4in, gloves, sterile, gown, surgical, sterile, iv infusion set, kit, iv starter, oxygen mask (1) and tubing (7ft), pulse oximeter sensor probe wrap, stop cock, 3-way, swab-pad, alcohol, syringe 1ml, syringe-needle 3ml 22–26g, tape, surgical paper 1in (Micropore), tourniquet, and non-latex 1in × 18in.
- Equipment Inputs: ''Table, instrument, mobile'' (EF027), ''ECG, 3-channel (with SpO2, NIBP, temp, resp)'' (EQ011), ''IV infusion pump'' (EQ032), ''pulse oxymetry recording software (prolonged monitoring)'' (EQ212), and ''blood pressure monitor, ambulatory, w-battery charger'' (EQ269).

We have reviewed this recommendation and generally agree with these inputs. However, we note that the equipment item ''ECG, 3-channel (with SpO2, NIBP, temp, resp)'' (EQ011) incorporates the functionality of the equipment items ''pulse oxymetry recording software (prolonged monitoring)'' (EQ212), and ''blood pressure monitor, ambulatory, w-battery charger'' (EQ269). Therefore, we did not include these two items as standard nonfacility inputs for moderate sedation in our proposal to accept the AMA RUC recommendation with the refinement as stated.

TABLE 4: INHERENT MODERATE SEDATION CODES VALUED IN THE NONFACILITY SETTING

CPT Code	Short Descriptor
19298	Place breast rad tube/caths
20982	Ablate bone tumor(s) perq
22520	Percut vertebroplasty thor
22521	Percut vertebroplasty lumb
22526	Idet single level
22527	Idet 1 or more levels
31615	Visualization of windpipe
31620	Endobronchial us add-on
31622	Dx bronchoscope/wash
31623	Dx bronchoscope/brush
31624	Dx bronchoscope/lavage
31625	Bronchoscopy w/biopsy(s)
31626	Bronchoscopy w/markers
31627	Navigational bronchoscopy
31628	Bronchoscopy/lung bx each
31629	Bronchoscopy/needle bx each
31634	Bronch w/balloon occlusion
31635	Bronchoscopy w/fb removal
31645	Bronchoscopy clear airways
31646	Bronchoscopy reclear airway
31656	Bronchoscopy inj for x-ray
32201	Drain percut lung lesion
32550	Insert pleural cath
32553	Ins mark thor for rt perq
35471	Repair arterial blockage
35472	Repair arterial blockage
35475	Repair arterial blockage
35476	Repair venous blockage
36147	Access av dial grft for eval
36148	Access av dial grft for proc
36200	Place catheter in aorta
36245	Place catheter in artery
36481	Insertion of catheter vein
36555	Insert non-tunnel cv cath
36557	Insert tunneled cv cath
36558	Insert tunneled cv cath
36560	Insert tunneled cv cath
36561	Insert tunneled cv cath
36563	Insert tunneled cv cath
36565	Insert tunneled cv cath
36566	Insert tunneled cv cath

CPT Code	Short Descriptor
36568	Insert picc cath
36570	Insert picvad cath
36571	Insert picvad cath
36576	Repair tunneled cv cath
36578	Replace tunneled cv cath
36581	Replace tunneled cv cath
36582	Replace tunneled cv cath
36583	Replace tunneled cv cath
36585	Replace picvad cath
36590	Removal tunneled cv cath
36870	Percut thrombect av fistula
37183	Remove hepatic shunt (tips)
37184	Prim art mech thrombectomy
37185	Prim art m-thrombect add-on
37186	Sec art m-thrombect add-on
37187	Venous mech thrombectomy
37188	Venous m-thrombectomy add-on
37203	Transcatheter retrieval
37210	Embolization uterine fibroid
37220	Iliac revasc
37221	Iliac revasc w/stent
37222	Iliac revasc add-on
37223	Iliac revasc w/stent add-on
37224	Fem/popl revas w/tla
37225	Fem/popl revas w/ather
37226	Fem/popl revasc w/stent
37227	Fem/popl revasc stnt & ather
37228	Tib/per revasc w/tla
37229	Tib/per revasc w/ather
37230	Tib/per revasc w/stent
37231	Tib/per revasc stent & ather
37232	Tib/per revasc add-on
37233	Tibper revasc w/ather add-on
37234	Revsc opn/prq tib/pero stent
37235	Tib/per revasc stnt & ather
43200	Esophagus endoscopy
43201	Esoph scope w/submucous inj
43202	Esophagus endoscopy biopsy
43216	Esophagus endoscopy/lesion
43217	Esophagus endoscopy
43234	Upper gi endoscopy exam
43235	Uppr gi endoscopy diagnosis
43236	Uppr gi scope w/submuc inj
43239	Upper gi endoscopy biopsy

CPT Code	Short Descriptor
43453	Dilate esophagus
43456	Dilate esophagus
43458	Dilate esophagus
44385	Endoscopy of bowel pouch
44386	Endoscopy bowel pouch/biop
44388	Colonoscopy
44389	Colonoscopy with biopsy
44390	Colonoscopy for foreign body
44391	Colonoscopy for bleeding
44392	Colonoscopy & polypectomy
44393	Colonoscopy lesion removal
44394	Colonoscopy w/snare
44901	Drain app abscess percut
45303	Proctosigmoidoscopy dilate
45305	Proctosigmoidoscopy w/bx
45307	Proctosigmoidoscopy fb
45308	Proctosigmoidoscopy removal
45309	Proctosigmoidoscopy removal
45315	Proctosigmoidoscopy removal
45317	Proctosigmoidoscopy bleed
45320	Proctosigmoidoscopy ablate
45332	Sigmoidoscopy w/fb removal
45333	Sigmoidoscopy & polypectomy
45335	Sigmoidoscopy w/submuc inj
45338	Sigmoidoscopy w/tumr remove
45339	Sigmoidoscopy w/ablate tumr
45340	Sig w/balloon dilation
45378	Diagnostic colonoscopy
45379	Colonoscopy w/fb removal
45380	Colonoscopy and biopsy
45381	Colonoscopy submucous inj
45382	Colonoscopy/control bleeding
45383	Lesion removal colonoscopy
45384	Lesion remove colonoscopy
45385	Lesion removal colonoscopy
45386	Colonoscopy dilate stricture
47000	Needle biopsy of liver
47382	Percut ablate liver rf
47525	Change bile duct catheter
48511	Drain pancreatic pseudocyst
49021	Drain abdominal abscess
49041	Drain percut abdom abscess
49061	Drain percut retroper absc
49411	Ins mark abd/pel for rt perq

CPT Code	Short Descriptor
49418	Insert tun ip cath perc
49440	Place gastrostomy tube perc
49441	Place duod/jej tube perc
49442	Place cecostomy tube perc
49446	Change g-tube to g-j perc
50021	Renal abscess percut drain
50200	Renal biopsy perq
50382	Change ureter stent percut
50384	Remove ureter stent percut
50385	Change stent via transureth
50386	Remove stent via transureth
50387	Change ext/int ureter stent
50592	Perc rf ablate renal tumor
50593	Perc cryo ablate renal tum
57155	Insert uteri tandems/ovoids
58823	Drain pelvic abscess percut
66720	Destruction ciliary body
69300	Revise external ear
77371	Srs multisource
77600	Hyperthermia treatment
77605	Hyperthermia treatment
77610	Hyperthermia treatment
77615	Hyperthermia treatment
92960	Cardioversion electric ext
93312	Echo transesophageal
93314	Echo transesophageal
93451	Right heart cath
93452	Left hrt cath w/ventrclgrphy
93453	R&l hrt cath w/ventriclgrphy
93454	Coronary artery angio s&i
93455	Coronary art/grft angio s&i
93456	Rhrt coronary artery angio
93457	Rhrt art/grft angio
93458	Lhrt artery/ventricle angio
93459	Lhrt art/grft angio
93460	R&l hrt art/ventricle angio
93461	R&l hrt art/ventricle angio
93464	Exercise w/hemodynamic meas
93505	Biopsy of heart lining
93566	Inject r ventr/atrial angio
93568	Inject pulm art hrt cath
93642	Electrophysiology evaluation

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Comment: Several commenters, including the AMA RUC, agreed with CMS' proposal to accept the recommendations for moderate sedation direct PE inputs with the stated refinements. One commenter suggested that a particular code on the list should be removed since moderate sedation is not typically performed when that service is furnished.

Response: We appreciate the support for our proposal to accept the

recommendation as well as those in favor of our refinements. We acknowledge and appreciate the perspectives of the commenter who suggested that a particular code should not include moderate sedation. However, we note that we generally include nonfacility direct PE inputs for moderate sedation for all services valued in the nonfacility setting and reported using CPT codes that are identified by the CPT Editorial Panel as having moderate sedation as inherent to the procedure.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal to accept the AMA RUC recommendation with the refinement as stated. The CY 2012 direct PE database reflects these changes and is available on the CMS Web site under the supporting data files for the CY 2012 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/.*

d. Updates to Price and Useful Life for Existing Direct Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking beginning with the CY 2012 PFS final rule with comment period.

During 2010, we received a request to update the price of ''tray, bone marrow biopsy-aspiration'' (SA062) from $24.27 to $34.47. The request included multiple invoices that documented updated prices for the supply item. We also received a request to update the useful life of ''holter monitor'' (EQ127) from 7 years to 5 years, based on its entry in the AHA's publication, ''Estimated Useful Lives of Depreciable Hospital Assets,'' which we use as a standard reference. In each of these cases, we proposed to accept the updated inputs, as requested. The CY 2012 direct PE database reflects these proposed changes and is available on the CMS Web site under the supporting data files for the CY 2012 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/.*

Comment: Several commenters expressed support for the proposal to update the supply items as proposed. MedPAC expressed continued misgivings that this process for updating prices is flawed because it relies on voluntary requests from stakeholders who have a financial stake in the process. Therefore, MedPAC believes that stakeholders are unlikely to provide CMS with evidence that prices for supplies and equipment have declined because it would lead to lower RVUs for particular services. MedPAC also called for CMS to establish an objective process to regularly update the prices of medical supplies and equipment to reflect market prices, especially for expense items.

Response: We appreciate the general support for the proposal. We also appreciate MedPAC's comments and understand the commission's concerns. As we have previously stated, we continue to believe it is important to establish a periodic and transparent process to update the cost of high-cost items to reflect typical market prices in our ratesetting methodology, and we continue to study the best way to establish such a process. We remind stakeholders that we have previously stated our difficulty in obtaining accurate pricing information, and this transparent process offers the opportunity for the community to object to increases in price inputs for particular items by providing accurate information about lower prices available to the practitioner community. We remind stakeholders that PFS payment rates are developed within a budget neutral system, and any increases in price inputs for particular supply items result in corresponding decreases to the relative value of all other direct practice expense inputs. Had any interested stakeholder presented information that indicated that increasing the price input for the bone marrow biopsy-aspiration was inappropriate, we would have considered evidence of lower available prices prior to amending the price input in the CY 2012 direct PE database.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal to accept the updated inputs, as requested. The CY 2012 direct PE database reflects these changes and is available on the CMS Web site under the supporting data files for the CY 2012 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/.*

4. Development of Code-Specific PE RVUs

When creating G codes, we often develop work, PE, and malpractice RVUs by crosswalking the RVUs from similar (reference) codes. In most of these cases, the PE RVUs are directly crosswalked pending the availability of utilization data. Once that data is available, we crosswalk the direct PE inputs and develop PE RVUs using the regular practice expense methodology, including allocators that are derived from utilization data. For CY 2012, we are using this process to develop PE RVUs for the following services: G0245 (Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include: (1) The diagnosis of LOPS, (2) a patient history, (3) a physical examination that consists of at least the following elements: (a) Visual inspection of the forefoot, hindfoot and toe web spaces, (b) evaluation of a protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and recommendation of footwear and (4) patient education); G0246 (Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following: (1) A patient history, (2) a physical examination that includes: (a) Visual inspection of the forefoot, hindfoot and toe web spaces, (b) evaluation of protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and recommendation of footwear, and (3) patient education); G0247 (Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include, the local care of superficial wounds (for example, superficial to muscle and fascia) and at least the following if present: (1) Local care of superficial wounds, (2) debridement of corns and calluses, and (3) trimming and debridement of nails); G0341 (Percutaneous islet cell transplant, includes portal vein catheterization and infusion); G0342 (Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion); G0343 (Laparotomy for islet cell transplant, includes portal vein catheterization and infusion); and G0365 (Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow)). The values in Addendum B reflect the updated PE RVUs.

In addition, there is a series of G-codes describing surgical pathology services with PE RVUs historically valued outside of the regular PE methodology. These codes are: G0416 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1–20 specimens); G0417 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy

sampling, 21–40 specimens); G0418 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41–60 specimens); and G0419 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens.) The PE RVUs for these codes were established as described in the CY 2009 PFS final rule with comment period (73 FR 69751). In reviewing these values for CY 2012, we noted that because the PE RVUs established through rulemaking in CY 2009 were neither developed using the regular PE methodology nor directly crosswalked from other codes, the PE RVUs for these codes were not adjusted to account for the CY 2011 MEI rebasing and revising, which is discussed in the CY 2011 PFS final rule with comment period (75 FR 73262). While it was technically appropriate to insulate the PE RVUs from that adjustment in CY 2011, upon further review, we believe adjusting these PE RVUs would result in more accurate payment rates relative to the RVUs for other PFS services. Therefore, we proposed to adjust the PE RVUs for these codes by 1.182, the adjustment rate that accounted for the MEI rebasing and revising for CY 2011. The PE RVUs in Addendum B to the CY 2011 PFS proposed rule reflected the proposed updates.

Comment: In general, commenters were supportive of the proposal to develop PE RVUs for these services through the PE methodology. Several commenters, however, urged CMS to reconsider using the standard PE methodology to develop PE RVUs for this service since the resulting payment rate for G0365 would be significantly lower than the current rate.

Response: We appreciate the general support for proposal. We are also grateful to those commenters who alerted us to the significant change in PE RVUs for G0365. In developing the proposal, we did not expect the newly developed PE RVUs for G0365 to change significantly from those previously established outside the methodology. In re-examining the disparities between the CY 2011 PE RVUs and those that appeared in the proposed rule, we discovered that an inadvertent data entry error in the proposed direct PE database had led to the development and display of erroneous PE RVUs. Because the commenters' objections to the proposal in methodology resulted directly from concerns about the resulting PE RVUs, we believe that those concerns are addressed by the correction of direct PE database error and the development of PE RVUs for G0365 that are more similar to the current PE RVUs.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal to develop PE RVUs through the methodologies explained in the proposal. The final CY 2012 RVUs for these codes are displayed in Addendum B to this final rule with comment period.

5. Physician Time for Select Services

As we describe in section II.A.2.f. of this final rule with comment period, in creating the indirect practice cost index, we calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services performed by the specialty.

During a review of the physician time data for the CY 2012 PFS rulemaking, we noted an anomaly regarding the physician time allotted to a series of group service codes that are listed in Table 5. We believe that the time associated with these codes reflects the typical amount of time spent by the practitioner in furnishing the group service. However, because the services are billed per patient receiving the service, the time for these codes should be divided by the typical number of patients per session. In reviewing the data used in the valuation of work RVUs for these services, we noted that in one vignette for these services, the typical group session consisted of 6 patients. Therefore we proposed adjusted times for these services based on 6 patients. However, we sought comment on the typical number of patients seen per session for each of these services.

TABLE 5: GROUP EDUCATION AND THERAPY CODES WITH TIME CHANGES

CPT Code	Short Descriptor
90849	Multiple family group psytx
90853	Group psychotherapy
90857	Intac group psytx
92508	Speech/hearing therapy
96153	Intervene hlth/behave group
97150	Group therapeutic procedures
97804	Medical nutrition group
G0271	Group mnt 2 or more 30 mins
G0421	Ed svc ckd grp per session
G0109	Diab manage trn ind/group

Comment: Several commenters alerted CMS to inaccurate post-service times and rounding discrepancies in the physician time file that did not correspond with the intent of the proposal. Specifically, commenters urged CMS to recalculate the times for group education/therapy to ensure they reflect the intent of the proposal.

Response: We appreciate being informed of these inaccuracies and discrepancies. As the commenters noted, the physician time file as displayed in the supporting web files for the CY 2012 PFS proposed rule included inappropriate post-service times and rounding discrepancies for some of the codes addressed in the proposal. We have addressed these issues in the physician time file used in developing the PE RVUs for CY 2012.

Comment: Several commenters, including the AMA RUC, submitted useful information regarding the typical group size for particular services. In many cases, however, commenters expressed concerns about this proposal that stretched beyond the scope of the proposed rule, including concerns about detrimental effect on work RVUs for the services, inappropriate clinical comparisons of unrelated services by CMS, or Medicare or other payment policy changes regarding appropriate group sizes for billing or coverage purposes.

Response: We did not propose any changes to the work RVUs or other policies related to these services. Our proposal related to the physician time data as used in the practice expense methodology as we describe in section II.A.2.f. of this final rule with comment period. In creating the indirect practice cost index, we calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services performed by the specialty. The proposal addresses the times associated for these codes only insofar as they contribute to the aggregate pools of indirect PE at the specialty level. In formulating the proposal, we addressed these services together because we believe that these group services share particular coding, not clinical, characteristics that complicate the use of time data in the practice expense methodology. If appropriate, we would address any changes to the work RVUs or other polices in future rulemaking.

We appreciate all of the comments regarding this proposal. In the following paragraphs, we address how we will use this submitted information in order to set final time values for these codes—

- 90849 (Multiple-family group psychotherapy);
- 90853 (Group psychotherapy (other than of a multiple-family group); and
- 90857 (Interactive group psychotherapy).

Comment: The AMA RUC recommended that CMS postpone any changes to the physician times for these codes since these services are currently under revision by the CPT Editorial Panel and the AMA RUC intends to provide CMS with new recommendations in the near future.

Response: We appreciate that CPT and the AMA RUC are both examining these services, and we will consider any codes or recommendations regarding these services. Until then, we continue to believe that because these services are billed per patient, the physician time for the corresponding codes should be divided by the typical number of patients per session in order to arrive at more appropriate PE RVUs across the PFS. We note that the vignette for 90853 includes a typical group session of 6 patients. Therefore, pending new recommendations from the AMA RUC, we believe it would be appropriate to establish physician time for this code as 2 pre-service minutes, 14 intra-service minutes, and 8 post-service minutes with the understanding that the total resulting minutes is the product of these and the number of patients in the group.

We believe that the typical group session may be similar for 90857 based on similar code descriptors, work RVUs, and clinical vignettes. Therefore, pending new recommendations from the AMA RUC, we believe it would be appropriate to establish physician time for this code as 3 pre-service minutes, 9 intra-service minutes, and 10 post-service minutes with the understanding that the total resulting minutes is the product of these and the number of patients in the group.

For 90849, we believe that it would be most appropriate to wait for the new recommendations prior to adjusting the physician time because the typical group size and typical patient size is different, and we received no information regarding the typical group size.

- 92508 (Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals)

Comment: Several commenters pointed out that the CPT 92508 was recently reviewed by the HCPAC and that the recommended physician times already are considered the appropriate proration by the number of patients in the group.

Response: We agree with the commenter's assessment and therefore, believe it would be appropriate to discard our proposed physician time changes for CPT 92508 and maintain the current time of 2 minutes pre-time, 17 minutes intra-time and 3 minutes post-time for CY 2012.

- 96153 (Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients))

Comment: The AMA RUC reported that because the February 2001 HCPAC recommendation indicated that the typical number of people receiving this service per group was 6 individuals, CMS' proposal to divide the physician time by six is appropriate.

Response: We appreciate the information submitted by the AMA RUC and thank them for pointing out initially the inaccuracy in the post service minutes. Considering this information, we believe it is appropriate to amend the physician time for CPT code 96153 to 1 pre-service minute, 3 intra-service minutes, and 1 post-service minute with the understanding that the total resulting minutes is the product of these and the number of patients in the group.

- 97150 (Therapeutic procedure(s), group (2 or more individuals))

Comment: In its comment, the AMA RUC noted that this code is scheduled to be reviewed by the RUC early in 2012. Therefore, the AMA RUC recommends that CMS postpone any changes until receiving the new recommendation. Another commenter informed CMS that the typical group size is two for this procedure.

Response: We appreciate the AMA RUC's comments and we will consider any codes or recommendations regarding these services. Until then, we continue to believe that, because these services are billed per patient, the physician time for the corresponding codes should be divided by the typical number of patients per session in order to arrive at more appropriate PE RVUs across the PFS. We also appreciate the other commenter's information that two patients are the typical group size for this service. Therefore, pending the new recommendation from the AMA RUC, we believe it would be appropriate to establish physician time for this code as 1 pre-service minute, 12 intra-service minutes, and 2 post-service minutes with the understanding that the total resulting minutes is the product of these and the number of patients in the group.

- 97804 (Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes)

Comment: The AMA RUC suggested that CMS should rely on information provided by the American Dietetic Association for a specific typical number of individuals in a group for CPT code 97804. The American Dietetic Association commented that groups of four to six patients were typical when this service is furnished.

Response: We appreciate the information provided by the commenters. Considering this information, we believe it is appropriate to amend the physician time for CPT code 97804 to 2 pre-service minutes, 6 intra-service minutes, and 2 post-service minutes with the understanding that the total resulting minutes is the product of these and the number of patients in the group.

- G0109 (Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes)

Comment: A commenter submitted information supporting a typical group size of 6 patients for this service and urged CMS to use that number in determining the appropriate physician time associated with the code.

Response: We appreciate the commenter's response. Considering this information, we believe it is appropriate to amend the physician time for CPT code 97804 to 2 pre-service minutes, 5 intra-service minutes, and 2 post-service minutes with the understanding that the total resulting minutes is the product of these and the number of patients in the group.

- G0271 (Medical nutrition therapy, reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition, or treatment regimen (including additional hours needed for renal disease), group (2 or more individuals), each 30 minutes), and G0421 (Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour)

We received no comments regarding the typical group time for these services. However, given the similarities of these services to CPT code 97804 (Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes), we believe it would be appropriate to use the times for that code as a reasonable crosswalk and establish physician time for these codes as 2 pre-service minutes, 6 intra-service minutes, and 2 post-service minutes with the understanding that the total resulting minutes is the product of these and the number of patients in the group.

After consideration of the public comments and related information, we are finalizing our proposed updates to the physician time file, as amended for certain codes as explicitly addressed in this section. The final time values for these codes can be found in the final CY 2012 Physician Time file, which is available on the CMS Web site under the supporting data files for the CY 2012 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

As a result of our review, we also proposed to update our physician time file to reflect the physician time associated with certain G-codes that had previously been missing from the file.

We received no comments regarding our proposal to update the physician time file to reflect the physician time associated with the G-codes that were previously missing from the file. Therefore, we are finalizing our updates to the physician time file. The final time values can be found in the final CY 2012 Physician Time file, which is available on the CMS Web site under the supporting data files for the CY 2012 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

B. Potentially Misvalued Services Under the Physician Fee Schedule

1. Valuing Services Under the PFS

As discussed in section I. of this final rule with comment period, in order to value services under the PFS, section 1848(c) of the Act requires the Secretary to determine relative values for physicians' services based on three components: work, practice expense (PE), and malpractice. Section 1848(c)(1)(A) of the Act defines the work component to include ''the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service.'' Additionally, the statute provides that the work component shall include activities that occur before and after direct patient contact. Furthermore, the statute specifies that with respect to surgical procedures, the valuation of the work component for the code must reflect a ''global'' concept in which pre-operative and post-operative physicians' services related to the procedure are also included.

In addition, section 1848(c)(2)(C)(i) of the Act specifies that ''the Secretary shall determine a number of work relative value units (RVUs) for the service based on the relative resources incorporating physician time and intensity required in furnishing the service.'' As discussed in detail in sections I.A.2. and I.A.3. of this final rule with comment period, the statute also defines the PE and malpractice components and provides specific guidance in the calculation of the RVUs for each of these components. Section 1848(c)(1)(B) of the Act defines the PE component as ''the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses.''

Section 1848(c)(2)(C)(ii) of the Act specifies that the ''Secretary shall determine a number of practice expense relative value units for the services for years beginning with 1999 based on the relative practice expense resources involved in furnishing the service.'' Furthermore, section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. On March 23, 2010, the Affordable Care Act was enacted, further requiring the Secretary to periodically identify and review potentially misvalued codes, and make appropriate adjustments to the relative values of those services identified as being potentially misvalued. Section 3134(a) of the Affordable Care Act added a new section 1848(c)(2)(K) to the Act which requires the Secretary to periodically identify potentially misvalued services using certain criteria, and to review and make appropriate adjustments to the relative values for those services. Section 3134(a) of the Affordable Care Act also added a new section 1848(c)(2)(L) to the Act which requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, identified using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section I.A.1. of this final rule with comment period, we generally establish physician work RVUs for new and revised codes based on our review of recommendations received from the American Medical Association Specialty Society Relative Value Scale Update Committee (AMA RUC). We also receive recommendations from the AMA RUC regarding direct PE inputs for services, which we evaluate in order to develop the PE RVUs under the PFS. The AMA RUC also provides recommendations to us on the values for codes that have been identified as potentially misvalued. To respond to concerns expressed by MedPAC, the Congress, and other stakeholders regarding accurate valuation of services under the PFS, the AMA RUC created the Five-Year Review Identification Workgroup in 2006. In addition to providing recommendations to us for work RVUs and physician times, the AMA RUC's Practice Expense Subcommittee reviews direct PE inputs (clinical labor, medical supplies, and medical equipment) for individual services.

In accordance with section 1848(c) of the Act, we determine appropriate adjustments to the RVUs, taking into account the recommendations provided by the AMA RUC and MedPAC, explain the basis of these adjustments, and respond to public comments in the PFS proposed and final rules. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available, in addition to taking into account the results of consultations with organizations representing physicians.

2. Identifying, Reviewing, and Validating the RVUs of Potentially Misvalued Services Under the PFS

a. Background

In its March 2006 Report to the Congress, MedPAC noted that ''misvalued services can distort the price signals for physicians' services as well as for other health care services that physicians order, such as hospital services.'' In that same report MedPAC postulated that physicians' services under the PFS can become misvalued over time for a number of reasons: For example, MedPAC stated, ''when a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' That is, the amount of physician work needed to furnish an existing service may decrease when new technologies are incorporated. Services can also become overvalued when practice expenses decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently, reducing its cost per use. Likewise, services can become undervalued when physician work increases or practice expenses rise. In the ensuing years since MedPAC's 2006 report, additional groups of potentially misvalued services have been identified by the Congress, CMS, MedPAC, the AMA RUC, and other stakeholders.

In recent years CMS and the AMA RUC have taken increasingly significant steps to address potentially misvalued codes. As MedPAC noted in its March 2009 Report to the Congress, in the intervening years since MedPAC made the initial recommendations, ''CMS and the AMA RUC have taken several steps to improve the review process.'' Most recently, section 1848(c)(2)(K)(ii) of the Act (as added by section 3134(a) of the Affordable Care Act) directed the Secretary to specifically examine, as determined appropriate, potentially misvalued services in seven categories as follows:

- Codes and families of codes for which there has been the fastest growth.
- Codes and families of codes that have experienced substantial changes in practice expenses.
- Codes that are recently established for new technologies or services.
- Multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes which have not been subject to review since the implementation of the RBRVS (the so-called 'Harvard-valued codes').
- Other codes determined to be appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of the RVUs with the periodic review described in section 1848(c)(2)(B) of the Act. Finally, section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) which may include consolidation of individual services into bundled codes for payment under the physician fee schedule.

b. Progress in Identifying and Reviewing Potentially Misvalued Codes

Over the last several years, CMS, in conjunction with the AMA RUC, has identified and reviewed numerous potentially misvalued codes in all seven of the categories specified in section 1848(c)(2)(K)(ii) of the Act, and we plan to continue our work examining potentially misvalued codes in these areas over the upcoming years, consistent with the new legislative requirements on this issue. In the current process, we request the AMA RUC to review potentially misvalued codes that we identify and to make recommendations on revised work RVUs and/or direct PE inputs for those codes to us. The AMA RUC, through its own processes, also might identify and review potentially misvalued procedures. We then assess the recommended revised work RVUs and/or direct PE inputs and, in accordance with section 1848(c) of the Act, we determine if the recommendations constitute appropriate adjustments to the RVUs under the PFS.

Since CY 2009, as a part of the annual potentially misvalued code review, we have reviewed over 700 potentially misvalued codes to refine work RVUs and direct PE inputs in addition to continuing the comprehensive Five-Year Review process. We have adopted appropriate work RVUs and direct PE inputs for these services as a result of these reviews.

Our prior reviews of codes under the potentially misvalued codes initiative have included codes in all seven categories specified in section 1848(c)(2)(K)(ii) of the Act. That is, we have reviewed and assigned more appropriate values to certain—

- Codes and families of codes for which there has been the fastest growth;
- Codes and families of codes that have experienced substantial changes in practice expenses;
- Codes that were recently established for new technologies or services;
- Multiple codes that are frequently billed in conjunction with furnishing a single service;
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment;
- Codes which had not been subject to review since the implementation of the RBRVS ('Harvard valued'); and
- Codes potentially misvalued as determined by the Secretary.

In this last category, we have previously proposed policies in CYs 2009, 2010, and 2011, and requested that the AMA RUC review codes for which there have been shifts in the site-of-service (that is, codes that were originally valued as being furnished in the inpatient setting, but that are now predominantly furnished on an outpatient basis), as well as codes that qualify as ''23-hour stay'' outpatient services (these services typically have lengthy hospital outpatient recovery periods). We note that a more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2011 PFS final rule with comment period (75 FR 73215 through 73216).

In CY 2011, we identified additional codes under section 1848(c)(2)(K)(ii) of the Act that we believe are ripe for review and referred them to the AMA RUC (75 FR 73215 through 73216). Specifically, we identified potentially misvalued codes in the category of ''Other codes determined to be appropriate by the Secretary,'' referring lists of codes that have low work RVUs but that are high volume based on claims data, as well as targeted key

codes that the AMA RUC uses as reference services for valuing other services (termed ''multispecialty points of comparison'' services).

Since the publication of the CY 2011 PFS final rule with comment period, we released the Fourth Five-Year Review of Work (76 FR 32410), which discussed the identification and review of an additional 173 potentially misvalued codes. We initiated the Fourth Five-Year Review of work RVUs by soliciting public comments on potentially misvalued codes for all services included in the CY 2010 PFS final rule with comment period that was published in the **Federal Register** on November 25, 2009. In addition to the codes submitted by the commenters, we identified a number of potentially misvalued codes and requested the AMA RUC review and provide recommendations. Our identification of potentially misvalued codes for the Fourth Five-Year Review focused on two Affordable Care Act categories: site-of-service anomaly codes and Harvard valued codes. As discussed in the Fourth Five-Year Review of Work (76 FR 32410), we sent the AMA RUC an initial list of 219 codes for review. Consistent with our past practice, we requested the AMA RUC to review codes on a ''family'' basis rather than in isolation in order to ensure that appropriate relativity in the system was retained. Consequently, the AMA RUC included additional codes for review, resulting in a total of 290 codes for the Fourth Five-Year Review of Work. Of those 290 codes, 53 were subsequently sent by the AMA RUC to the CPT Editorial Panel to consider coding changes, 14 were not reviewed by the AMA RUC (and subsequently not reviewed by us) because the specialty society that had originally requested the review in its public comments on the CY 2010 PFS final rule with comment period elected to withdraw the codes, 36 were not reviewed by the AMA RUC because their values were set as interim final in the CY 2011 PFS final rule with comment period, and 14 were not reviewed by us because they were noncovered services under Medicare. Therefore, the AMA RUC reviewed 173 of the 290 codes initially identified for the Fourth Five-Year Review of Work, and provided the recommendations that were addressed in detail in the Fourth Five-Year Review of Work (76 FR 32410). In addition, under the Fourth Five-Year Review of Work, we reviewed recommendations for five additional potentially misvalued codes from the Health Care Professionals Advisory Committee (HCPAC), a deliberative body of nonphysician practitioners that also convenes during the AMA RUC meeting. The HCPAC represents physician assistants, chiropractors, nurses, occupational therapists, optometrists, physical therapists, podiatrists, psychologists, audiologists, speech pathologists, social workers, and registered dieticians.

In summary, since CY 2009, CMS and the AMA RUC have addressed a number of potentially misvalued codes. For CY 2009, the AMA RUC recommended revised work values and/or PE inputs for 204 misvalued services (73 FR 69883). For CY 2010, an additional 113 codes were identified as misvalued and the AMA RUC provided us new recommendations for revised work RVUs and/or PE inputs for these codes to us as discussed in the CY 2010 PFS final rule with comment period (74 FR 61778). For CY 2011, CMS reviewed and adopted more appropriate values for 209 codes under the annual review of potentially misvalued codes. For CY 2012, we recently released the Fourth Five-Year Review of Work, which discussed the review of 173 potentially misvalued codes and proposed appropriate adjustments to RVUs. In section II.B.5.of this final rule with comment period, we also provide a list of codes identified for future consideration as part of the potentially misvalued codes initiative, that is, in addition to the codes that are part of the Fourth Five-Year Review of Work, as discussed in that section, we are requesting the AMA RUC review these codes and submit recommendations to us.

c. Validating RVUs of Potentially Misvalued Codes

In addition to identifying and reviewing potentially misvalued codes, section 3134(a) of the Affordable Care Act added a new section 1848(c)(2)(L) of the Act, which specifies that the Secretary shall establish a formal process to validate RVUs under the PFS. The validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work. The Secretary is directed to validate a sampling of the work RVUs of codes identified through any of the seven categories of potentially misvalued codes specified by section 1848(c)(2)(K)(ii) of the Act. Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services.

In the CY 2011 PFS proposed rule (75 FR 40068), we solicited public comments on possible approaches and methodologies that we should consider for a validation process. We received a number of comments regarding possible approaches and methodologies for a validation process. As discussed in the CY 2011 PFS final rule with comment period (75 FR 73217), some commenters were skeptical that there could be viable alternative methods to the existing AMA RUC code review process for validating physician time and intensity that would preserve the appropriate relativity of specific physician's services under the current payment system. These commenters generally urged us to rely solely on the AMA RUC to provide valuations for services under the PFS.

While a number of commenters strongly opposed our plans to develop a formal validation process, many other commenters expressed support for the development and establishment of a system-wide validation process of the work RVUs under the PFS. As noted in the CY 2011 PFS final rule with comment period (75 FR 73217 through 73218), these commenters commended us for seeking new approaches to validation, as well as being open to suggestions from the public on this process. A number of commenters submitted technical advice and offered their time and expertise as resources for us to draw upon in any examination of possible approaches to developing a formal validation process.

However, in response to our solicitation of comments regarding time and motion studies, a number of commenters opposed the approach of using time and motion studies to validate estimates of physician time and intensity, stating that properly conducted time and motion studies are extraordinarily expensive and, given the thousands of codes paid under the PFS, it would be unlikely that all codes could be studied. As we stated in the CY 2011 PFS final rule with comment period (75 FR 73218), we understand that these studies would require significant resources and we remain open to suggestions for other approaches to developing a formal validation process. We noted that MedPAC suggested in its comment letter that we should consider ''collecting data on a recurring basis from a cohort of practices and other facilities where physicians and nonphysician clinical practitioners

work'' (75 FR 73218). As we stated previously, we intend to establish a more extensive validation process of RVUs in the future in accordance with the requirements of section 1848(c)(2)(L) of the Act.

While we received a modest number of comments specifically addressing technical and methodological aspects of developing a validation system, we believe it would be beneficial to provide an additional opportunity for stakeholders to submit comments on data sources and possible methodologies for developing a system-wide validation system. In the proposed rule, we solicited comments on data sources and studies which may be used to validate estimates of physician time and intensity that could be factored into the work RVUs, especially for services with rapid growth in Medicare expenditures, which is one of the Affordable Care Act categories that the statute specifically directs us to examine. We also solicited comments regarding MedPAC's suggestion of ''collecting data on a recurring basis from a cohort of practices and other facilities where physicians and nonphysician clinical practitioners work.'' We note that after our proposed rule was released, MedPAC further discussed its continuing concerns regarding accurate data. ''In our June 2011 Report to the Congress, we expressed deep concern in particular about the accuracy of the fee schedule's time estimates—estimates of the time that physicians and other health professionals spend furnishing services. These estimates are an important factor in determining the RVUs for practitioner work. However, research for CMS and for the Assistant Secretary for Planning and Evaluation has shown that the time estimates are likely too high for some services. In addition, anecdotal evidence and the experience of clinicians on the Commission raises questions about the time estimates'' (MedPAC Report to the Congress ''Medicare and the Health Care Delivery System, June 2011'').

We plan to discuss the validation process in more detail in a future PFS rule once we have considered the matter further in conjunction with the public comments received on the CY 2011 rulemaking, as well as comments received on this final rule with comment period. We note that any proposals we would make on the formal validation process would be subject to public comment, and we would consider those comments before finalizing the policies.

Comment: We received a number of comments and suggestions on developing a system-wide validation process, including stakeholders' reactions to MedPAC's suggestion of data collection from a cohort of physician practices.

Response: We thank the commenters for their suggestions on developing a system-wide validation system and, as we noted previously, we plan to discuss the development of the validation process in more detail in a future PFS rule.

3. Consolidating Reviews of Potentially Misvalued Codes

As previously discussed, we are statutorily required under section 1848(c)(2)(B) of the Act to review the RVUs of services paid under the PFS no less often than every 5 years. In the past, we have satisfied this requirement by conducting separate periodic reviews of work, PE, and malpractice RVUs for established services every 5-years in what is commonly known as CMS' Five-Year Reviews of Work, PE, and Malpractice RVUs. On May 24, 2011, we released the proposed notice regarding the Fourth Five-Year Review of Work RVUs. The most recent comprehensive Five-Year Review of PE RVUs occurred for CY 2010; the same year we began using the Physician Practice Information Survey (PPIS) data to update the PE RVUs. The last Five-Year Review of Malpractice RVUs also occurred for CY 2010. These Five-Year Reviews have historically included codes identified and nominated by the public for review, as well as those identified by CMS and the AMA RUC.

In addition to the Five-Year Reviews, beginning for CY 2009, CMS and the AMA RUC have identified and reviewed a number of potentially misvalued codes on an annual basis using various identification screens, such as codes with high growth rates, codes that are frequently billed together in one encounter, and codes that are valued as inpatient services but that are now predominately furnished as outpatient services. These annual reviews have not included codes identified by the public as potentially misvalued since, historically, the public has the opportunity to submit potentially misvalued codes during the Five-Year Review process.

With the enactment of the Affordable Care Act in 2010, which endorsed our initiative to identify and review potentially misvalued codes and emphasized the importance of our ongoing work in this area to improve accuracy and appropriateness of payments under the PFS, we believe that continuing the annual identification and review of potentially misvalued codes is necessary. Given that we are engaging in extensive reviews of work RVUs and direct PE inputs of potentially misvalued codes on an annual basis, we believe that separate and ''freestanding'' Five-Year Reviews of Work and PE may have become redundant with our annual efforts. Therefore, for CY 2012 and forward, we proposed to consolidate the formal Five-Year Review of Work and PE with the annual review of potentially misvalued codes. That is, we would begin meeting the statutory requirement to review work and PE RVUs for potentially misvalued codes at least once every 5-years through an annual process, rather than once every 5-years. Furthermore, to allow for public input and to preserve the public's ability to identify and nominate potentially misvalued codes for review, we proposed a process by which the public could submit codes for our potential review, along with supporting documentation, on an annual basis. Our review of these codes would be incorporated into our potentially misvalued codes initiative. This proposed public process is further discussed in section II.B.4. of this final rule with comment period. In the CY 2012 proposed rule, we solicited comments on our proposal to consolidate the formal Five-Year Reviews of Work and PE with the annual review of potentially misvalued codes.

Comment: Commenters overwhelmingly supported the proposal to consolidate review of potentially misvalued codes into one annual process. Commenters also agreed that the review should include both work and practice expense, and encouraged CMS to continue its efforts to ensure that professional liability valuations are as current as possible. However, some commenters were concerned that the number of codes that CMS and the public, through the proposed code nomination process, could potentially bring forward for review would create significant burden on specialty societies in terms of time, manpower, and financial resources on specialty societies. The commenters urged CMS to recognize that a reasonable timeline is required for specialty societies to conduct a credible evaluation of potentially misvalued services, especially as specialty societies already have a sizable number of pending requests for reviews of services previously identified under the potentially misvalued code initiative.

To alleviate concerns that the consolidation could result in requiring specialty societies to survey a large

volume of codes every year, commenters offered several suggestions for limiting the number of codes reviewed each year. Commenters requested that CMS consider establishing a timeframe under which codes could be resurveyed. That is, a number of commenters suggested that the physician work of a code should not be re-reviewed within a certain timeframe, such as a 3- or 5-year period after it was last reviewed. Commenters also asked that CMS consider a ''cap'' on the number of codes and/or code families that we would require any given specialty to review in a calendar year. Furthermore, some commenters were worried that in substituting an annual review process for one that previously occurred once every five years, the burden of reviewing codes identified as potentially misvalued would be distributed inequitably among the various specialties, leading to a perception of unfairness in the process which the commenters believed would undermine CMS' potentially misvalued codes initiative. These commenters urged CMS to establish a 3-year timetable for the review of potentially misvalued services where a comparable proportion of codes for each specialty each year would be specified in advance so that the specialty societies may be able to allocate resources more predictably and efficiently.

Commenters also expressed concern that CMS is proposing to review potentially misvalued codes on the same time frame as the review of new and revised codes where CMS has historically issued interim final values for these codes in the final rule with comment period. The commenters asserted they need to have the opportunity to review CMS' response to AMA RUC recommendations, comment on CMS' proposed values, and receive a response from CMS to these comments prior to January 1 of the year the revised RVUs will be used to pay physician claims. A commenter noted ''physicians should not be penalized by having to receive potentially incorrect reimbursement for a procedure for as much as 12 months because of the government's timing of its notice and comment processes.'' Other commenters, while supportive of CMS' proposal to consolidate reviews, stressed that the process should not be condensed so much that there is not time for thoughtful comment and consideration. Consequently, commenters urged CMS to work with the AMA RUC so that all recommendations for a given year are received by an earlier deadline, allowing for publication in that year's proposed rule and for comments to be addressed by CMS in that year's final rule before changes that affect payment are implemented.

Response: We appreciate the support commenters expressed for our proposed consolidated annual review of codes and thank the commenters for their comments and suggestions. We understand the commenters' concerns regarding the potential burden that some specialty societies may be expecting from this process. We agree with commenters that a reasonable timeline should be allowed for evaluation of services. Therefore, to address commenters' concern regarding the potential burden, we will be sensitive to the number of codes identified as potentially misvalued for any given specialty society, and we will prioritize codes for immediate review if the specialty society makes such a request to us. Since we cannot predict with certainty the number of codes that will be identified as potentially misvalued, nor the distribution of those codes among specialty societies for review, we do not believe we should predetermine ''caps'' or place time limitations on the review process that may unintentionally hinder the rapid progress of our potentially misvalued codes initiative. However, we may revisit the commenters' suggestions at a later date if the volume of codes to be reviewed becomes an issue.

To respond to the commenters who were worried that codes identified through the potentially misvalued codes process may not be equitably or ''fairly'' distributed among specialty societies and have suggested that CMS review a comparable proportion of codes for each specialty each year, we note that, based on our previous experience, the objective screens we have used to identify potentially misvalued codes do not produce lists of codes that are evenly distributed among the specialties that furnish them. Rather, the screens have tended to identify certain types of services more frequently than others (for example, due to rapidly changing technology) and therefore yield disproportionate numbers of potentially misvalued codes to be reviewed by the various specialty societies. However, we have received similar comments in previous rules regarding distribution among specialty societies. Consequently, in the CY 2012 proposed rule, we explicitly identified a list of potentially misvalued high expenditure codes that spans most specialties discussed in II.B.5.a. of this final rule with comment period.

Finally, to respond to the comments regarding the code review cycle, we note that the timing of CMS' current review process is constrained by the CPT Editorial Panel's scheduled release of new and revised codes by October 1 and the receipt of the complete AMA RUC's recommendations later in the year, which are at odds with the PFS rulemaking cycle. As we have indicated for many years in our PFS final rules with comment period, most recently in the CY 2011 rule (75 FR 73170), before adopting interim RVUs for new and revised codes, we have the opportunity to review and consider AMA RUC recommendations which are based on input from the medical community. If we did not adopt RVUs for new and revised codes in the initial year on an interim final basis, we would either have to delay using the codes for a year or permit each Medicare contractor to establish their own payment rate for the codes. We believe it would be contrary to the public interest to delay adopting values for new and revised codes for the initial year, especially since we have an opportunity to receive significant input from the medical community before adopting the values, and the alternatives could produce undesirable levels of uncertainty and inconsistency in payment for a year. We understand the preference of some commenters for the review of potentially misvalued codes to be conducted within a single rulemaking year in order to avoid payment under interim values for the coming year. However, we continue to believe that it is important to consolidate the work and PE reviews for all codes (new, revised, and potentially misvalued) into one cycle. As we have explained in several previous PFS final rules with comment period, most recently in the CY 2011 PFS final rule with comment period (75 FR 73170), we believe it is in the public interest to adopt interim final revised RVUs for codes that have been identified as misvalued. Similar to the new and revised codes, before making any changes to RVUs for potentially misvalued codes, we have an opportunity to review input from the medical community in the form of the AMA RUC recommendations for the codes. We believe a delay in implementing revised values for codes that have been identified as misvalued would perpetuate payment for the services at a rate that does not appropriately reflect the relative resources involved in furnishing the service and would continue unwarranted distortion in the payment for other services across the PFS.

We note that it is often difficult to draw definitive lines between the codes that are being reviewed as new, revised, or potentially misvalued. For example, CMS may identify a code as potentially misvalued in a given year and refer the family of codes to the AMA RUC for review. Subsequently, the AMA RUC may send the family of codes to the CPT Editorial Panel for revision because upon an initial review, the AMA RUC may have concluded that the family of services has evolved to the point that the code descriptors are no longer appropriate. The CPT Editorial Panel may revise the code(s) descriptors or may create entirely new codes to better define the service. In this final rule with comment period, we reviewed several new codes initially referred to the AMA RUC for review through our potentially misvalued codes initiative, and we believe that this trend likely will increase in the near future. Additionally, since CMS reviews and assigns interim values to new and revised codes in the PFS final rule with comment period for the coming year, consolidating the review of potentially misvalued codes with the new and revised codes is a more efficient and transparent process, and reduces the burden on both specialty societies and other stakeholders who would otherwise be called upon to consider, review and comment on the same family of codes in multiple rules. Moreover, consolidation of our review of new, revised, and potentially misvalued codes in one cycle allows for codes in a family to be reviewed together, resulting in more consistent valuation within code families and a better opportunity to maintain appropriate relativity within code families which, as we discuss in this section of this final rule with comment period, is a high priority.

Therefore, given the considerable overall support commenters expressed, we are finalizing our proposal without modification to consolidate periodic reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

We note that while we proposed to review the physician work RVUs and direct PE inputs of potentially misvalued codes on an annual basis, we did not propose at this time to review malpractice RVUs on an annual basis. As discussed in section II.C. of this final rule with comment period, in general, malpractice RVUs are based on malpractice insurance premium data on a specialty level. The last comprehensive review and update of the malpractice RVUs occurred for CY 2010 using data obtained from the PPIS data. Since it is not feasible to conduct such extensive physician surveys to obtain updated specialty level malpractice insurance premium data on an annual basis, we believe the comprehensive review of malpractice RVUs should continue to occur at 5-year intervals.

Furthermore, in identifying and reviewing potentially misvalued codes on an annual basis, we note that this new proposed process presents us with the opportunity to review simultaneously both the work RVUs and the direct PE inputs for each code. Heretofore, the work RVUs and direct PE inputs of potentially misvalued codes were commonly reviewed separately and at different times. For example, a code may have been identified as potentially misvalued based solely on its work RVUs so the AMA RUC would have reviewed the code and provided us with recommendations on the physician times and work RVUs. However, the direct PE inputs of the code would not necessarily have been reviewed concurrently and therefore, the AMA RUC would not necessarily have provided us with recommendations for any changes in the direct PE inputs of the code that would have been warranted to ensure that the PE RVUs of the code are determined more appropriately. Therefore, while this code may have been recently reviewed and revised under the potentially misvalued codes initiative for physician work, the PE component of the code could still be potentially misvalued. Going forward, we believe combining the reviews of both physician work and PE for each code under our potentially misvalued codes initiative will align the review of these codes and lead to more accurate and appropriate payments under the PFS.

Finally, it is important to note that the code-specific resource based relative value framework under the PFS system is one in which services are ranked relative to each other. That is, the work RVUs assigned to a code are based on the physician time and intensity expended on that particular service as compared to the physician time and intensity of the other services paid under the PFS. This concept of relativity to other services also applies to the PE RVUs, particularly when it comes to reviewing and assigning correct direct PE inputs that are relative to other similar services. Consequently, we are emphasizing the need to review both the work and PE components of codes that are identified as part of the potentially misvalued initiative to ensure that appropriate relativity is constructed and maintained in several key relationships:

- The work and PE RVUs of codes are ranked appropriately within the code family. That is, the RVUs of services within a family should be ranked progressively so that less intensive services and/or services that require less physician time and/or require fewer or less expensive direct PE inputs should be assigned lower work or PE RVUs relative to other codes within the family. For example, if a code for treatment of elbow fracture is under review under the potentially misvalued codes initiative, we would expect the work and PE RVUs for all the codes in the family also be reviewed in order to ensure that relativity is appropriately constructed and maintained within this family. Furthermore, as we noted in the CY 2010 PFS final rule with comment period (74 FR 61941), when we submit codes to the AMA RUC and request its review, in order to maintain relativity, we emphasized the importance of reviewing the base code of a family. The base code is the most important code to review because it is the basis for the valuation of other codes within the family and allows for all related codes to be reviewed at the same time (74 FR 61941).
- The work and PE RVUs of codes are appropriately relative based on a comparison of physician time and/or intensity and/or direct inputs to other services furnished by physicians in the same specialty. To continue the example discussed previously, if a code for treatment of elbow fracture is under review, we would expect this code to be compared to other codes, such as codes for treatment of humerus fracture, or other codes furnished by physicians in the same specialty, in order to ensure that the work and PE RVUs are appropriately relative within the specialty.
- The work and PE RVUs of codes are appropriately relative when compared to services across specialties. While it may be challenging to compare codes that describe completely unrelated services, since the entire PFS is a budget neutral system where payment differentials are dependent on the relative differences between services, it is essential that services across specialties are appropriately valued relative to each other. To illustrate the point, if a service furnished primarily by dermatology is analogous in physician time and intensity to another service furnished primarily by allergy/immunology, then we would expect the work RVUs for the two services to be

similar, even though the two services may be otherwise unrelated.

4. Public Nomination Process

Under the previous Five-Year Reviews, the public was provided with the opportunity to nominate potentially misvalued codes for review. To allow for public input and to preserve the public's ability to identify and nominate potentially misvalued codes for review under our annual potentially misvalued codes initiative, we proposed a process by which on an annual basis the public could submit codes, along with documentation supporting the need for review. We proposed that stakeholders may nominate potentially misvalued codes by submitting the code with supporting documentation during the 60-day public comment period following the release of the annual PFS final rule with comment period. We would evaluate the supporting documentation and decide whether the nominated code should be reviewed as potentially misvalued during the following year. If we were to receive an overwhelming number of nominated codes that qualified as potentially misvalued in any given year, we would prioritize the codes for review and could decide to hold our review of some of the potentially misvalued codes for a future year. We noted that we may identify additional potentially misvalued codes for review by the AMA RUC based on the seven statutory categories under section 1848(c)(2)(K)(ii) of the Act.

We encouraged stakeholders who believe they have identified a potentially misvalued code, supported by documentation, to nominate codes through the public process. We emphasized that in order to ensure that a nominated code will be fully considered to qualify as a potentially misvalued code to be reviewed under our annual process, accompanying documentation must be provided to show evidence of the code's inappropriate valuation, either in terms of inappropriate physician times, work RVUs, and/or direct PE inputs. The AMA RUC developed certain ''Guidelines for Compelling Evidence'' for the Third Five-Year Review which we believe could be applicable for members of the public as they gather supporting documentation for codes they wish to nominate for the annual review of potentially misvalued codes. The specific documentation that we would seek under this proposal includes the following:

- Documentation in the peer reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following:
  - ++ Technique.
  - ++ Knowledge and technology.
  - ++ Patient population.
  - ++ Site-of-service.
  - ++ Length of hospital stay.
  - ++ Physician time.
- An anomalous relationship between the code being proposed for review and other codes. For example, if code ''A'' describes a service that requires more work than codes ''B,'' ''C,'' and ''D,'' but is nevertheless valued lower. The commenter would need to assemble evidence on service time, technical skill, patient severity, complexity, length of stay and other factors for the code being considered and the codes to which it is compared. These reference services may be both inter- and intra-specialty.
- Evidence that technology has changed physician work, that is, diffusion of technology.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation;
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of physician time, work RVU, or direct PE inputs using other data sources (for example, Department of Veteran Affairs (VA) National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Physician Quality Reporting System (PQRS) databases).
- National surveys of physician time and intensity from professional and management societies and organizations, such as hospital associations.

We noted that when a code is nominated, and supporting documentation is provided, we would expect to receive a description of the reasons for the code's misvaluation with the submitted materials. That is, we would require a description and summary of the evidence is required that shows how the service may have changed since the original valuation or may have been inappropriately valued due to an incorrect assumption. We would also appreciate specific **Federal Register** citations, if they exist, where commenters believe the nominated codes were previously valued erroneously. We also proposed to consider only nominations of active codes that are covered by Medicare at the time of the nomination.

As proposed in the CY 2012 proposed rule, after we receive the nominated codes during the 60-day comment period following the release of the annual PFS final rule with comment period, we would review the supporting documentation and assess whether they appear to be potentially misvalued codes appropriate for review under the annual process. We proposed that, in the following PFS proposed rule, we would publish a list of the codes received under the public nomination process during the previous year and indicate whether the codes would be included in the current review of potentially misvalued codes. We would also indicate the publicly nominated codes that we would not be including in the current review (whether due to insufficient documentation or for other reasons). Under this proposed process, the first opportunity for the public to nominate codes would be during the public comment period for this CY 2012 PFS final rule with comment period. We would publish in the CY 2013 PFS proposed rule, the list of nominated codes, and indicate whether they will be reviewed as potentially misvalued codes. We would request that the AMA RUC review these potentially misvalued codes along with any other codes identified by CMS as potentially misvalued, and provide to us recommendations for appropriate physician times, work RVUs, and direct PE inputs. We requested public comments on this proposed code nomination process and indicated that we would consider any suggestions to modify and improve the proposed process.

Comment: The vast majority of commenters supported CMS' proposal to develop a public nomination process for potentially misvalued codes. The commenters noted that the proposed process would provide a way for the public to participate in the identification of potentially misvalued procedures. Commenters were enthusiastic that the proposal allows for stakeholders to propose a code for review on an immediate basis which is a significant improvement to the current process, noting that previously, only ''CMS and the RUC could bring a code forward for review whenever they have reason to believe it may be misvalued; however, physicians, other healthcare providers, specialty societies and other stakeholders are restricted to a five-year cycle.'' On the other hand, another commenter ''does not agree with the

once-a-year opportunity to nominate codes [and] * * * recommends that there should be greater opportunity for public comment.''

A number of commenters stated that they believe the supporting documentation criteria would ensure that all requests are considered fairly and urged CMS to conduct a rigorous review of public comments and supporting documentation when determining whether a publicly nominated code should be reviewed as a potentially misvalued code, especially when a code is nominated by only a few commenters or even a single commenter. Other commenters thought CMS should provide ''guidelines'' to justify bringing a code(s) forward for review in order to prevent a member of the public from asking that every single code paid under the Medicare PFS be reviewed. Some commenters noted that ''professional associations participating on the RUC frequently struggle with the concept and documentation of 'Compelling Evidence.' '' Consequently, the commenters believed that the public will likewise struggle with the concept of submitting evidence to substantiate potentially misvalued codes. Other commenters noted that the public nomination process proposed by CMS requires that commenters nominating codes include supportive evidence to show that the resource use related to the delivery of a service has changed in a way to suggest a code's RVUs may be misvalued, whereas CMS is not obligated to follow this same standard. The commenters suggested that CMS should be required to adhere to the supporting documentation that the public would need to provide when nominating a potentially misvalued code for review through the proposed public nomination process.

Several commenters believed that CMS should not restrict which codes could be nominated or referred. A number of commenters objected to CMS' proposal to consider only nominations of active codes that are covered by Medicare at the time of the nomination. The commenters believed this proposal was unfair to those specialties that do not serve a predominantly Medicare-aged population but who must also rely on the the resource based relative value scale. The commenters asserted that CMS has historically published the relative value recommendations from the AMA RUC for preventive services and other non-covered services. Commenters recommended that all valid CPT codes should remain open to comment and review. Commenters also believed as long as a stakeholder could provide adequate supporting documentation to support the nomination of the code, CMS should allow for the review of any code, including any codes that went through refinement in the past.

Commenters also expressed appreciation that CMS proposed to disclose in the PFS proposed rule the list of codes identified as potentially misvalued (including those that originated from the public nomination process) for future review because publishing the misvalued codes list provides some notice to affected parties who may wish to provide input during the review process. Some commenters suggested that following the nomination process, specialty societies should have another opportunity to review and comment on any relevant nominations before CMS decides to include the codes on the list of potentially misvalued codes in the proposed rule.

Response: We appreciate the enthusiasm expressed by commenters who welcome the opportunity to participate with us in the identification of potentially misvalued codes. We also acknowledge the commenters' concern that our requirements for accompanying documentation to show how the code is potentially misvalued may be viewed as burdensome and could pose a barrier to the public in nominating some codes. We provided guidelines in the proposed rule for such documentation in order to help the public to develop a strong case and assemble sufficient documentation when nominating a code. Although some commenters viewed the requirement to provide evidence of potential misvaluation as overly burdensome, it is important to demonstrate that a nominated code is not only potentially misvalued, but that improved accuracy in payment for the code would improve the overall accuracy of the physician fee schedule. As commenters have pointed out, reviewing potentially misvalued codes is resource intensive for the AMA RUC, specialty societies, CMS, and the public, and we must ensure that codes we refer as potentially misvalued warrant the requested review.

However, to respond to the commenters who suggested we should be required to follow the same process as the public for nominating potentially misvalued codes, we note that we have longstanding statutory authority to identify and review the RVUs of services no less often than every 5-years and that we frequently have exercised our discretion to prioritize codes for review.

We understand commenters' concerns about the burden that reviewing codes entails. We believe that by ranking codes in order of interest to CMS for review over a reasonable timeframe, we can help to reduce some of that burden. For this year, we have prioritized the review of codes to those that have some degree of significant financial impact on the PFS. Specifically, we have proposed a list of high expenditure codes for review in CY 2012. We also are limiting the review of RVUs to codes that are active, covered by Medicare, and for which the RVUs are used for payment purposes under the PFS so that resources are not expended on the review of codes with RVUs that have no financial impact on the PFS. We note that while we have published the AMA RUC relative value recommendations for non-covered services as a courtesy, these codes historically have not been reviewed by CMS and the RVUs are not valid for Medicare payment purposes. Therefore, while we will continue our historical practice of publishing the AMA RUC relative value recommendations for non-covered services, we will not be accepting for review either inactive or non-covered codes (for which the RVUs will have no financial impact on the PFS) through the public nomination process. We will consider any other active and Medicare covered services that are nominated by the public and supported by documentation of the nature described previously in this section.

Finally, we note that all timely comments received on the final rule with comment period can be accessed and reviewed by the public through *http://www.regulations.gov/* after the final rule's comment period closes. Therefore, anyone who wishes to look though the public comments can identify the codes that have been nominated by the public as potentially misvalued, as well as the accompanying supporting documentation. CMS will assess the list of publicly nominated codes, taking into consideration the documentation provided as well as the list of codes the agency has identified for review, and will identify and publish in the following year's proposed rule the list of nominated codes and codes selected for review. Accordingly, we are finalizing the proposed public nomination process without modification.

5. CY 2012 Identification and Review of Potentially Misvalued Services

a. Code Lists

While we anticipate receiving nominations from the public for potentially misvalued codes in conjunction with rulemaking, we believe it is imperative that we continue

the work of the review initiatives over the last several years and drive the agenda forward to identify, review, and adjust values for potentially misvalued codes for CY 2012.

In the CY 2011 PFS proposed rule (75 FR 40068 through 40069), we identified and referred to the AMA RUC a list of potentially misvalued codes in three areas:

- Codes on the AMA RUC's multi-specialty points of comparison (MPC) list (used as reference codes in the valuation of other codes),
- Services with low work RVUs that are billed in multiples (a statutory category); and
- Codes that have low work RVUs for which CMS claims data show high volume (that is, high utilization of these codes represents a significant dollar impact in the payment system).

Our understanding is that the AMA RUC is currently working towards reviewing these codes at our request. We intend to provide an update and discuss any RVU adjustments to codes that have been identified as potentially misvalued in the CY 2012 PFS final rule, as they move through the review process.

Meanwhile, for CY 2012, we are continuing with our work to identify and review additional services under the potentially misvalued codes initiative. Stakeholders have noted that many of the services previously identified under the potentially misvalued codes initiative were concentrated in certain specialties. To develop a robust and representative list of codes for review under the potentially misvalued codes initiative, we examined the highest PFS expenditure services by specialty (based on our most recently available claims data and using the specialty categories listed in the PFS specialty impact table, see Table 84 in section IX.B. of this final rule with comment period) and identified those that have not been reviewed since CY 2006 (which was the year we completed the Third Five-Year Review of Work and before we began our potentially misvalued codes initiative).

In our examination of the highest PFS expenditure codes for each specialty (we used the specialty categories listed in the PFS specialty impact table, see Table 84 in section IX.B. of this final rule with comment period), we noted that Evaluation and Management (E/M) services consistently appeared in the top 20 high PFS expenditure services. We noted as well that most of the E/M services have not been reviewed since the comprehensive review of services for the Third Five-Year Review of Work in CY 2006. Therefore, after an examination of the highest PFS expenditure codes for each specialty, we have developed two code lists of potentially misvalued codes which we proposed to refer to the AMA RUC for review.

First, we proposed to request that the AMA RUC conduct a comprehensive review of all E/M codes, including the codes listed in Table 6. As shown previously, E/M services are commonly among the highest PFS expenditure services. Additionally in recent years, there has been significant interest in delivery system reforms, such as patient-centered medical homes and making the primary care physician the focus of managing the patient's chronic conditions. The chronic conditions challenging the Medicare population include heart disease, diabetes, respiratory disease, breast cancer, allergy, Alzheimer's disease, and factors associated with obesity. Thus, as the focus of primary care has evolved from an episodic treatment-based orientation to a focus on comprehensive patient-centered care management in order to meet the challenges of preventing and managing chronic disease, we believed a more current review of E/M codes was warranted. We note that although physicians in primary care specialties bill a high percentage of their services using the E/M codes, physicians in non-primary care specialties also bill these codes for many of their services.

Since we believe the focus of primary care is evolving to meet the challenges of preventing and managing chronic disease, we noted in the proposed rule that we would like the AMA RUC to prioritize review of the E/M codes and provide us with recommendations on the physician times, work RVUs, and direct PE inputs of at least half of the E/M codes listed in Table 6 by July 2012 in order for us to include any revised valuations for these codes in the CY 2013 PFS final rule with comment period. We also noted that we would expect the AMA RUC to review the remaining E/M codes listed in Table 6 by July 2013 in order for us to complete the comprehensive re-evaluation of E/M services and include the revised valuations for these codes in the CY 2014 PFS final rule with comment period.

BILLING CODE 4120–01–P

TABLE 6: E/M CODES REFERRED FOR AMA RUC REVIEW

CPT Code	Short Descriptor
99201	Office/outpatient visit new
99202	Office/outpatient visit new
99203	Office/outpatient visit new
99204	Office/outpatient visit new
99205	Office/outpatient visit new
99211	Office/outpatient visit est
99212	Office/outpatient visit est
99213	Office/outpatient visit est
99214	Office/outpatient visit est
99215	Office/outpatient visit est
99217	Observation care discharge
99218	Initial observation caree
99219	Initial observation care
99220	Initial observation care
99221	Initial hospital care
99222	Initial hospital care
99223	Initial hospital care
99224	Subsequent observation care
99225	Subsequent observation care
99226	Subsequent observation care
99231	Subsequent hospital care
99232	Subsequent hospital care
99233	Subsequent hospital care
99234	Observ/hosp same date
99235	Observ/hosp same date
99236	Observ/hosp same date
99238	Hospital discharge day
99239	Hospital discharge day
99281	Emergency dept visit
99282	Emergency dept visit
99283	Emergency dept visit
99284	Emergency dept visit
99285	Emergency dept visit
99291	Critical care first hour
99292	Critical care addl 30 min
99304	Nursing facility care init
99305	Nursing facility care init
99306	Nursing facility care init
99307	Nursing fac care subseq
99308	Nursing fac care subseq
99309	Nursing fac care subseq
99310	Nursing fac care subseq
99315	Nursing fac discharge day
99316	Nursing fac discharge day
99318	Annual nursing fac assessmnt
99324	Domicil/r-home visit new pat

CPT Code	Short Descriptor
99325	Domicil/r-home visit new pat
99326	Domicil/r-home visit new pat
99327	Domicil/r-home visit new pat
99328	Domicil/r-home visit new pat
99334	Domicil/r-home visit est pat
99335	Domicil/r-home visit est pat
99336	Domicil/r-home visit est pat
99337	Domicil/r-home visit est pat
99341	Home visit new patient
99342	Home visit new patient
99343	Home visit new patient
99344	Home visit new patient
99345	Home visit new patient
99347	Home visit est patient
99348	Home visit est patient
99349	Home visit est patient
99350	Home visit est patient
99354	Prolonged service office
99355	Prolonged service office
99356	Prolonged service inpatient
99357	Prolonged service inpatient
99406	Behav chng smoking 3-10 min
99407	Behav chng smoking > 10 min
99460	Init nb em per day hosp
99461	Init nb em per day non-fac
99462	Sbsq nb em per day hosp
99463	Same day nb discharge
99464	Attendance at delivery
99465	Nb resuscitation
99466	Ped crit care transport
99467	Ped crit care transport addl
99468	Neonate crit care initial
99469	Neonate crit care subsq
99471	Ped critical care initial
99472	Ped critical care subsq
99475	Ped crit care age 2-5 init
99476	Ped crit care age 2-5 subsq
99477	Init day hosp neonate care
99478	Ic lbw inf < 1500 gm subsq
99479	Ic lbw inf 1500-2500 g subsq
99480	Ic inf pbw 2501-5000 g subsq
92002	Eye exam new patient
92004	Eye exam new patient
92012	Eye exam established pat
92014	Eye exam & treatment

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Comment: Many commenters did not believe that reviewing the work RVUs and direct PE inputs of all E/M services is warranted at this time. A significant number of commenters generally agreed that health care delivery has changed, that chronic disease management has led to increases in physician time and effort, and that primary care physicians provide valuable services to Medicare beneficiaries that are not captured appropriately in the E/M services. Some commenters did not believe that the resource-based relative value scale is the appropriate system to account for

changes in health care delivery models. A smaller number of commenters did not believe that physician work for E/M services had changed since the codes were last reviewed.

The majority of commenters requested that CMS withdraw its proposal to review all E/M codes because the current E/M codes, as written, do not fully encompass the work associated with patient-centered care management. The commenters noted that there are many codes that have been reviewed and valued by the AMA RUC for such services, including medical team conference, comprehensive preventive evaluation, physician supervision of a hospice patient, international normalized ratio management, smoking and alcohol counseling, case management, monthly medical home management, anticoagulation management, and phone or electronic evaluation. Some commenters noted that the AMA RUC has previously provided recommendations to value telephone and electronic evaluation services that complement coordinated care. While Medicare either does not pay separately for or does not cover many of these services, the commenters believed these services are part of a patient centered care management model and are necessary services for managing patients with chronic conditions. The commenters urged CMS to provide explicit payment for these coordination services rather than attempt to address the primary care issue through the comprehensive review of current E/M code values. For example, commenters suggested CMS ''work with the medical community to develop and implement the patient-centered medical home, reward prevention and wellness, eliminate fragmentation and duplication, and produce a cohesive system of care that prevents unnecessary complications from acute or chronic illness, hospitalizations, and other avoidable expenses.''

Some commenters asserted that the current E/M codes have code descriptors and documentation requirements that do not capture the work necessary for chronic disease management. Commenters noted that the current E/M codes were developed 20 years ago and describe care of patients with acute problems. In addition, the commenters believed the current E/M codes do not describe care to treat chronic medical problems of patients in skilled nursing facilities which were treated in the hospital a few years ago. Commenters asserted that physicians are now caring for an increasingly complex elderly population with multiple chronic problems who require services such as extensive care coordination that was not part of standard medical practice when many of the E/M codes were created. Thus, while the commenters agreed that care coordination would help better manage chronic diseases in the elderly, they believed this care would be better described by new codes, and not the current E/M codes. Accordingly, the commenters recommended that CMS undertake a comprehensive review of the existing E/M service codes in collaboration with the AMA RUC and the CPT Editorial Panel. That is, the commenters envisioned and supported an extensive review that considers revisions to these codes that will better recognize the work of primary care physicians and cognitive specialists who provide care for patients with acute and chronic conditions before focusing on the valuation of the codes.

Many commenters, representing different medical specialties, noted that CMS' focus on primary care as the locus for care coordination and chronic disease management is misplaced. Commenters asserted that patient care coordination, prevention, performance measurement and the adoption of health information technology affects the entire medical community. These commenters argued that that these trends and initiatives will pose challenges for specialty medicine as well. Specifically, a commenter stated, ''We believe that high quality provision of such services is not defined by the specialty of the provider and thus we cannot support policy options that focus on provider specialty rather than on the content and the quality of the service being provided.''

Other commenters noted that the E/M codes are used by many surgeons and other specialists because nearly every procedural CPT code involves one or more E/M service within the code's global period. Commenters suggested that CMS unbundle E/M services from surgical codes in order to ensure that surgical patients received the appropriate follow-up care and management of post-procedure activity to achieve desired outcomes. That is, CMS should apply zero-day global periods to surgical codes, such that post-operative hospital and office visits must meet the medical necessity and documentation requirements for evaluation and management coding in order to be paid separately.

Finally, some commenters noted that the previous comprehensive review of the evaluation and management codes in 2006 did not improve the emphasis on chronic care management, stating that ''the third 5-Year Review failed to achieve the goals of properly compensating primary physicians for chronic care management, so there is no expectation that another review within the existing system will result in a different outcome.'' A few commenters supported the proposal to review the E/M codes and they ''consider the review and re-evaluation of E&M codes as a critical immediate step to ensure patient access to care and to maintaining the viability of the [their] workforce.''

Response: We thank the commenters for their comments on our proposal to review E/M services and address the evolving challenges of chronic care management. We also appreciate commenters' support for recognizing the importance of primary care and care coordination, and appropriately valuing such care within Medicare's statutory structure for physician payment and quality reporting. We understand some commenters' concerns about the ability of the current E/M coding and documentation system to appropriately value primary care services and improved care coordination. We understand that many commenters would prefer that we consider paying separately for non-face-to-face care coordination activities, such as telephone calls and medical team conferences, rather than finalize the proposal to request that the AMA RUC review all 91 E/M codes at this time. We will continue to explore valuations of E/M services and other potential refinements to the PFS that would appropriately value these services. We are also examining many other programs that may contribute to more appropriate valuation of services and better health care outcomes.

We would like to assure the commenters that we, as well as the HHS' Assistant Secretary for Planning and Evaluation (ASPE), are actively researching our current coding and payment systems to appropriately value these services. As detailed in the proposed rule (75 FR 42917), we are considering several approaches to improve coordinated care and health care transitions to reduce readmissions or subsequent illnesses, improve beneficiary outcomes, and avoid additional financial burden on the health care system. We are committed to achieving better care for individuals, better health for populations, and reduced expenditure growth. Reforms such as Accountable Care Organizations and Medical Homes and reforms of our current fee-for-service payment system are designed to achieve these goals.

As an example, we recently launched the Partnership for Patients (in April 2011), a national public-private patient safety initiative for which more than 6,000 organizations—including physician and nurses' organizations, consumer groups, employers and over 3,000 hospitals—have pledged to help achieve the Partnership's goals of reducing hospital complications and improving care transitions. The Partnership for Patients includes the Community-Based Care Transitions Program, which provides funding to community-based organizations partnering with eligible hospitals to coordinate a continuum of post-acute care in order to test models for improving care transitions for high risk Medicare beneficiaries. Achieving the goals of the Partnership for Patients will take the combined effort of many key stakeholders across the health care system—physicians, nurses, hospitals, health plans, employers and unions, patients and their advocates, as well as the Federal and State governments. Many important stakeholders have already pledged to join this Partnership in a shared effort to save thousands of lives, stop millions of injuries and take important steps toward a more dependable and affordable health care system. We are currently working with these stakeholders to improve care processes and systems, enhance communication and coordination to reduce complication for patients, raise public awareness and develop information, tools and resources to help patients and families effectively engage with their providers to avoid preventable complications, and provide the incentives and support that will enable clinicians and hospitals to deliver high-quality health care to their patients, with minimal burdens. (For more information regarding the Partnership for Patients Initiative, we refer readers to *http://www.healthcare.gov/compare/partnership-for-patients/index.html*.)

Additionally, the Center for Medicare and Medicaid Innovation (Innovation Center) of CMS has undertaken several demonstrations to support care coordination and primary care. Most recently, on September 28, 2011, we released a request for applications for the Comprehensive Primary Care Initiative, a CMS-led multipayer initiative to provide enhanced support for comprehensive primary care. A primary care practice is a key point of contact for patients' health care needs. In recent years, new ways have emerged to strengthen primary care by improving care coordination, making it easier to work together, and helping clinicians spend more time with their patients. Under the Comprehensive Primary Care Initiative, we intend to pay primary care providers a monthly care management fee on behalf of Medicare fee-for-service beneficiaries and, in participating states, Medicaid fee-for-service beneficiaries for improved and comprehensive care management. Specifically, participating primary care practices will be given support to better coordinate primary care for their Medicare patients, including creating personalized care plans for patients with serious or chronic diseases follow personalized care plans, give patients 24-hour access to care and health information, more preventive care, and more patient centered care management. The work of the Comprehensive Primary Care Initiative could inform and help further develop innovative revisions to the PFS. (For more information regarding the Comprehensive Primary Care Initiative, we refer readers to *http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/cpci/*.)

Further, HHS' ASPE has convened a Technical Expert Panel (TEP) to conduct studies that could inform efforts to accurately align physician payments in Medicare, which may help expand the supply of primary care physicians and improve the value of care for beneficiaries. One of the major tasks being undertaken by this TEP is to develop new approaches to defining visits and paying for primary care services under the physician fee schedule. There are a number of services that are increasingly viewed as key to high-quality primary care but that do not require a face-to-face encounter with the patient. While the valuations of current E/M services include care coordination, communication and other management, this project will consider how visits are defined and will examine whether we need to adjust payments to appropriately pay for primary care activities. It makes sense to reassess how visits are defined because it is becoming increasingly more common for primary care physicians to be engaged in the management of multiple established chronic conditions rather than evaluation and treatment of acute, new problems. The complexity and time for the physician is more often associated with decision-making than with the history-taking and physicals. Further, the chronic care model involves much greater attention to teaching patient self-management skills, doing more proactive care coordination, and anticipation of health care needs. We believe the TEP findings could provide us with improved information for the valuation of primary care services, including care coordination, which may be more effective than simply reviewing the work RVUs and direct PE inputs of current E/M services. In addition to ASPE's efforts that are focused directly on physician payment, they also have a second project underway to research effective methods for increasing the supply of primary care providers and services. This project will analyze what is known about the relative effectiveness of various strategies to increase the supply of primary care providers and services in order to meet these future health system needs.

Accordingly, given the significant concern expressed by the majority of commenters over the possible inadequacies of the current E/M coding and documentation structure to address evolving chronic care management and support primary care and our ongoing research on how to best provide payment for primary care and patient-centered care management, we are not finalizing the proposal to review the list of 91 E/M codes at this time. Instead, we believe allowing time for consideration of the findings of the Comprehensive Primary Care Initiative, the ASPE research on balancing physician incentives and evaluating payment for primary care services, demonstrations that we have undertaken on care coordination, as well as other initiatives assessing how to value and encourage primary care will provide improved information for the valuation of chronic care management, primary care, and care transitions. We also will continue to consider the numerous policy alternatives that commenters offered, such as separate E/M codes for established visits for patients with chronic disease versus a post-surgical follow-up office visits. We intend to continue to work with stakeholders on how to value and pay for primary care and patient-centered care management, and we continue to welcome ideas from the medical community for how to improve care management through the provision of primary care services. Second, we also proposed providing a select list of high PFS expenditure procedural codes representing services furnished by an array of specialties, as listed in Table 7. These procedural codes have not been reviewed since CY 2006 (before we began our potentially misvalued codes initiatives in CY 2008) and, based on the most recently available data, have CY 2010 allowed charges of greater than $10 million at the specialty level (based on the

specialty categories listed in the PFS specialty impact table and CY 2010 Medicare claims data). A number of the codes in Table 7 would not otherwise be identified as potentially misvalued services using the screens we have used in recent years with the AMA RUC or based on one of the six specific statutory categories under section 1848(c)(2)(k)(ii) of the Act. However, we identified the potentially misvalued codes listed in Table 7 under the seventh statutory category, ''other codes determined to be appropriate by the Secretary.'' We selected these codes based on the fact that they have not been reviewed for at least 6 years, and in many cases the last review occurred more than 10 years ago. They represent high Medicare expenditures under the PFS; thus, we believe that a review to assess changes in physician work and update direct PE inputs is warranted. Furthermore, since these codes have significant impact on PFS payment on a specialty level, a review of the relativity of the codes to ensure that the work and PE RVUs are appropriately relative within the specialty and across specialties, as discussed previously, is essential. For these reasons, we have identified these codes as potentially misvalued and proposed to request the AMA RUC review the codes listed in Table 7 and provide us with recommendations on the physician times, work RVUs and direct PE inputs in a timely manner. That is, similar to our proposal for the AMA RUC to review E/M codes in a timely manner, we proposed to request that the AMA RUC review at least half of the procedural codes listed in Table 7 by July 2012 in order for us to include any revised valuations for these codes in the CY 2013 PFS final rule with comment period.

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TABLE 7: SELECT LIST OF PROCEDURAL CODES REFERRED FOR AMA RUC REVIEW

CPT Code	Short Descriptor
95117	Immunotherapy Injections
33533	Cabg, Arterial, Single
33405	Replacement Of Aortic Valve
33430	Replacement Of Mitral Valve
93015	Cardiovascular Stress Test
93880	Extracranial Study
93000	Electrocardiogram, Complete
17311	Mohs, 1 Stage, H/N/Hf/G
17312	Mohs Addl Stage
17004	Destroy Premlg Lesions 15+
45378	Diagnostic Colonoscopy
43235	Uppr Gi Endoscopy, Diagnosis
47562	Laparoscopic Cholecystectomy
47563	Laparo Cholecystectomy/Graph
49505	Prp I/Hern Init Reduc >5 Yr
96413	Chemo, Iv Infusion, 1 Hr
96367	Tx/Proph/Dg Addl Seq Iv Inf
96365	Ther/Proph/Diag Iv Inf, Init
62311	Inject Spine L/S (Cd)
35476	Repair Venous Blockage
36870	Percut Thrombect Av Fistula
35475	Repair Arterial Blockage
95903	Motor Nerve Conduction Test
95819	Eeg, Awake And Asleep
95861	Muscle Test, 2 Limbs
22612	Lumbar Spine Fusion
63047	Removal Of Spinal Lamina
22851	Apply Spine Prosth Device
76830	Transvaginal Us, Non-Ob
67028	Injection Eye Drug
92235	Eye Exam With Photos
66982	Cataract Surgery, Complex
27447	Total Knee Arthroplasty
27130	Total Hip Arthroplasty
27236	Treat Thigh Fracture
69210	Remove Impacted Ear Wax
31237	Nasal/Sinus Endoscopy, Surg
88342	Immunohistochemistry
88112	Cytopath, Cell Enhance Tech
88312	Special Stains Group 1
97140	Manual Therapy
90862	Medication Management
90801	Psy Dx Interview
90805	Psytx, Off, 20-30 Min W/E&M
94720	Monoxide Diffusing Capacity

CPT Code	Short Descriptor
94240	Residual Lung Capacity
77014	Ct Scan For Therapy Guide
77301	Radiotherapy Dose Plan, Imrt
77421	Stereoscopic X-Ray Guidance
70450	Ct Head/Brain W/O Dye
70553	Mri Brain W/O & W/Dye
72148	Mri Lumbar Spine W/O Dye
20610	Drain/Inject, Joint/Bursa
53850	Prostatic Microwave Thermotx
50590	Fragmenting Of Kidney Stone
76872	Us, Transrectal
35301	Rechanneling Of Artery
98941	Chiropractic Manipulation
98940	Chiropractic Manipulation
98942	Chiropractic Manipulation
90806	Psytx, Off, 45-50 Min
90818	Psytx, Hosp, 45-50 Min
90808	Psytx, Office, 75-80 Min
72141	Mri Neck Spine W/O Dye
73221	Mri Joint Upr Extrem W/O Dye
70551	Mri Brain W/O Dye
92083	Visual Field Examination(S)
97530	Therapeutic Activities
97112	Neuromuscular Reeducation
97001	Pt Evaluation

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Comment: Some commenters did not believe that high expenditure/high volume was an appropriate criterion for us to use to identify the codes for the potentially misvalued codes initiative, stating ''simply because a service is frequently performed, does not indicate that the service may be overvalued.'' Additionally, the commenters believed that selecting codes that have not been reviewed since CY 2006 was arbitrary and assumes that the delivery of these services and procedures has changed radically over the past 5-years. Other commenters believed CMS should provide justification for the revaluation by providing evidence of how the delivery of a service or procedure has changed within 5 years.

Some commenters agreed that high expenditure codes should be reviewed on a periodic basis; however, the commenters suggested that the periodic basis should be a reasonably long length of time and 5 (or 6) years is not a sufficiently long period of time absent other evidence of potential changes in the service under review. The commenters suggested that CMS could automatically review high expenditure procedures every 10 or 15 years. MedPAC, commenting on the CY 2012 PFS proposed rule, agreed that accurate payments for high expenditure services ''can improve the balance of payments between primary care and services such as imaging tests, and other procedures.''

Finally, we received a number of comments on specific codes where commenters provided arguments as to why CMS should remove these codes from the high expenditure code list. The commenters noted that specific codes had been considered by the AMA RUC in the past five years or that certain codes are currently scheduled to be considered by either the CPT Editorial Panel for new coding or the AMA RUC for revised valuations (for work RVUs and/or PE inputs) at an upcoming meeting.

Response: As we noted previously, it is a long-standing statutory requirement that we review RVUs no less often than every 5-years and, in conducting these reviews, we have historically exercised our discretion to prioritize which codes to review. In proposing to prioritize this list of high expenditure codes, we stated that the reason we identified these codes is because they have significant impact on PFS payment on a specialty level and have not been recently reviewed. We believe that the practice of a service can evolve over time, as can the technology used to conduct the service, and such efficiencies could easily have developed since our last comprehensive review of services in 2006 for the third 5-year review. As such, a review of the relativity of these codes, which are high expenditure and high volume, to ensure that the work and PE RVUs are appropriately valued to reflect changes in practice and technology and relative to other services within the specialty and across specialties is essential to the overall accuracy of the PFS.

Because of the concerns expressed by commenters about the burden associated with code reviews, we believe that it is appropriate to prioritize review of codes to a manageable subset that also have a high impact on the PFS and work with the specialty society to spread review of the remaining codes identified as potentially misvalued over a reasonable timeframe. In this spirit, we do not believe it would be appropriate to remove codes from the high expenditure list unless we find, as some commenters indicated, that we have reviewed both the work RVUs and direct PE inputs for the code during the

specified time period. Also, regarding the suggestion to schedule review of high expenditure codes every 10 to 15-years, not only do we believe more regular monitoring of codes with high impact on the PFS will produce a more accurate and equitable payment system, but we have a statutory obligation to review codes at least every 5-years (although we do not always conduct a review that involves the AMA RUC). As noted, changes in technology and practice evolve for many services more rapidly than every 10 to 15-years. We also believe that, with our decision not to review the 91 E/M codes at this time, we have relieved some of the burden on specialty societies, which should enable them to complete their reviews of these high expenditure/high volume codes.

Finally, in reviewing the code specific comments, we noticed that in many cases, the commenters believed that the code should be removed from this code list because the work RVU had been reviewed within 6-years, or the code was recently considered at an AMA RUC meeting. We note that while a number of codes have been considered at an AMA RUC meeting, until we receive recommendations and review the codes for both work and direct PE inputs, we will continue to include these codes on the high expenditure list. We think some of the commenters may have believed that since a code was discussed at an AMA RUC meeting and sent to the CPT editorial panel or the code is being surveyed and prepared for a presentation at the AMA RUC, the code should be removed from the potentially misvalued high expenditure code list. We are clarifying that even if a code is about to be reviewed by the specialty society or AMA RUC, or referred to the CPT Editorial Panel, we would continue to include the code on our list of codes for review under the potentially misvalued codes initiative. Similarly, if a code is being reviewed by the CPT editorial panel, we would consider any replacement codes to address the potential misvaluation associated with the previous codes.

Accordingly, we are finalizing the proposed high expenditure/high volume list without modification.

Specific Codes

On an ongoing basis, public stakeholders (including physician specialty societies, beneficiaries, and other members of the public) bring concerns to us regarding direct PE inputs and physician work. In the past, we would consider these concerns and address them through proposals in annual rulemaking, technical corrections, or by requesting that the AMA RUC consider the issue.

Since last year's rulemaking, the public has brought a series of issues to our attention that relate directly to direct PE inputs and physician work. We believe that some of these issues will serve as examples of codes that might be brought forward by the public as potentially misvalued in the proposed nomination process as discussed previously in section II.B.4. of this final rule with comment period.

(1) Codes Potentially Requiring Updates to Direct PE Inputs

Abdomen and Pelvis CT. For CY 2011, AMA CPT created a series of new codes that describe combined CTs of the abdomen and pelvis. Prior to 2011, these services would have been billed using multiple stand-alone codes for each body region. The new codes are: 74176 (Computed tomography, abdomen and pelvis; without contrast material); 74177 (Computed tomography, abdomen and pelvis; with contrast material); and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by with contrast material(s) and further sections in one or both body regions.)

As stated in the CY 2011 PFS final rule with comment period (75 FR 73350), we accepted the AMA RUC-recommended direct PE inputs for these codes, with refinements to the equipment minutes to assure that the time associated with the equipment items reflected the time during the intra-service period when a clinician is using the piece of equipment, plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. We believe that the direct PE inputs of the new codes reflect the typical resources required to furnish the services in question.

However, stakeholders have alerted us that the resulting PE RVUs for the new codes reflect an anomalous rank order in comparison to the previously existing stand-alone codes. Specifically, the PE RVUs for the codes that describe CT scans without contrast for either body region are greater than the PE RVUs for 74176, which describes a CT scan of both body regions. We believe that the anomalous rank order of the PE RVUs for this series of codes may be the result of outdated direct PE inputs for the previously existing stand-alone codes. The physician work for those codes was last reviewed by the AMA RUC during the Third Five-Year Review of Work for CY 2007. However, the direct PE inputs for the codes have not been reviewed since 2003. Therefore, we are requesting that the AMA RUC review both the direct PE inputs and work values of the following codes in accordance with the consolidated approach to reviewing potentially misvalued codes as outlined in section II.B.2.c. of this final rule with comment period:

- 72192 Computed tomography, pelvis; without contrast material.
- 72193 Computed tomography, pelvis; with contrast material(s).
- 72194 Computed tomography, pelvis; without contrast material, followed by contrast material(s) and further sections.
- 74150 Computed tomography, abdomen; without contrast material.
- 74160 Computed tomography, abdomen; with contrast material(s).
- 74170 Computed tomography, abdomen; without contrast material, followed by contrast material(s) and further sections.

Comment: Several commenters suggested that the rank order anomalies resulted from a series of issues unrelated to the direct PE inputs for the existing component codes. These commenters argued that the anomaly resulted from CMS' refinement of equipment minutes in the new codes, errors in CMS' direct PE database, and the longstanding CMS policy that new codes are not subject to practice expense transitions. Furthermore, the commenters asserted that the AMA RUC reviewed the component code direct PE inputs when developing the direct PE inputs for the combined codes. Therefore, the commenters asked that CMS withdraw its request that the AMA RUC review the direct PE inputs of the existing codes.

Response: We refer readers to section III.B.2 of this final rule with comment period. There, we address interim final direct PE inputs from CY 2011, including accurate allocation of equipment minutes and, specifically, the direct PE inputs for CPT codes 74176, 74177, and 74178. In that section we finalize the interim direct PE inputs as published in the CY 2011 PFS final rule, with a minor refinement to the clinical labor inputs. We note that the refined PE RVUs for the combined codes do not significantly alter payment.

While we acknowledge the occasional irregularities that result from the application of broad-based payment transitions, our longstanding policy in a PFS transition payment year is that if the CPT Editorial Panel creates a new code for that year, the new code would be paid at its fully implemented PFS amount and not at a transition rate for that year.

While the commenters suggested that the RUC reviewed the direct PE inputs of the component codes recently, we have received no recent recommendation from the RUC regarding the direct PE inputs for these codes. Had the RUC reviewed the direct PE inputs for the component codes and made recommendations either to maintain or amend the current direct PE inputs, we would have responded to those recommendations. After considering these comments and noting the technical refinements to the direct PE inputs of the combined codes, we continue to believe that the direct PE inputs of the component codes should be reviewed. Therefore, we are maintaining our request that the RUC review the component codes.

Tissue Pathology. A stakeholder informed us that the direct PE inputs associated with a particular tissue examination code are atypical. Specifically, the stakeholder suggested that the AMA RUC relied upon an atypical clinical vignette in identifying the direct PE inputs for the service associated with CPT code 88305 (Level IV—Surgical pathology, gross and microscopic examination). The stakeholder claims that in furnishing the typical service, the required material includes a single block of tissue and 1–3 slides. The stakeholder argues that the typical cost of the resources needed to provide the service is approximately $18, but the PE RVUs for 2011 result in a national payment rate of $69.65 for the technical component of the service. Because the direct PE inputs associated with this code have not been reviewed since 1999, we are asking that the AMA RUC review both the direct PE inputs and work values of this code as soon as possible in accordance with the consolidated approach to reviewing potentially misvalued codes as outlined in section II.B.2.c. of this final rule with comment period though the work for this code was reviewed in April 2010.

Comment: Several commenters disagreed with CMS' request to review the work RVU of this code because the most recent extensive review of the physician work was conducted by the RUC in April of 2010. The AMA RUC expressed concern that CMS would ask the RUC to review the code solely on the basis of the stakeholder's assertions about overpayment. The AMA RUC asked CMS to consider that the stakeholder's estimates of typical costs do not reflect the range of practice costs considered in the PE methodology, and that the stakeholder should be directed to consider direct practice expense costs instead of full practice expense payment rates.

Response: We understand the commenters' requests to review only the direct PE inputs for the code since the physician work for this code and for the code family were recently reviewed by the RUC and CMS. We maintain that conducting a combined review of both physician work and direct PE for each code reviewed under our potentially misvalued codes initiative will lead to a more comprehensive evaluation and to more accurate and appropriate payments under the PFS. However, we understand that the advantages of a simultaneous review of work and direct practice may be limited in the case of this code where the work was so recently reviewed. Therefore, we believe that a review of the direct PE inputs alone is appropriate.

We acknowledge the RUC's concern that the commenter may have been comparing his perception of direct practice expense costs with broader practice expense payments for this code. We acknowledge the practice expense portion of PFS payment is developed in consideration of both direct and indirect practice expense costs. We also concur with the RUC that interested stakeholders can review the publicly available direct PE inputs associated with each code. Those inputs are available in the direct PE database on the CMS Web site under the downloads section for the ''CY 2012 PFS final rule with comment period'' at: *http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage*.

However, we note that the stakeholder's assessment of the direct costs associated with the typical service reported using CPT code 88305 is significantly lower than the summed direct practice expense inputs currently associated with the code. Additionally, as we stated in the CY 2012 PFS proposed rule, we are asking the RUC to review the direct PE inputs of the code because they have not been reviewed since 1999. We also point out that if the stakeholder had not brought the concern to us, this code would have appeared on our list of PFS high expenditure procedural codes that had not been reviewed since CY 2006. After consideration of these comments, we are maintaining our request that the RUC review CPT code 88305, but in the case of this code, we are only asking for a review of direct PE inputs.

In Situ Hybridization Testing. We received comments from the Large Urology Group Practice Association (LUGPA) regarding two new cytopathology codes that describe in situ hybridization testing of urine specimens. Prior to CY 2011, in situ hybridization testing was coded and billed using CPT Codes 88365 (In situ hybridization (*e.g.,* FISH), each probe), 88367 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; using computer-assisted technology) and 88368 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual). The appropriate CPT code listed would be billed one time for each probe used in the performance of the test, regardless of the medium of the specimen (that is, blood, tissue, tumor, bone marrow or urine).

For CY 2011, the AMA's CPT Editorial Panel created two new cytopathology codes that describe in situ hybridization testing using urine samples: CPT code 88120 (Cytopathology, in situ hybridization (*e.g.,* FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; manual) and CPT code 88121 (Cytopathology, in situ hybridization (*e.g.,* FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; using computer-assisted technology).

Because the descriptors indicate that the new codes account for approximately four probes, whereas 88367 and 88368 describe each probe, there are more PE RVUs associated with the new codes than with the previously existing codes that are currently still used for any specimen except for urine. However, because the previously existing codes are billed per probe, the payment for a test using a different specimen type could vary depending upon the number of probes. For example, a practitioner furnishing a test involving a blood specimen and using three probes would bill CPT code 88368 (total RVUs: 6.28) three times with the result of 18.84 RVUs. A practitioner furnishing the same test but using a urine sample instead of a blood sample would receive payment based on the 13.47 RVUs associated with CPT code 88120.

We accepted the RUC-recommended work values and direct PE inputs, without refinement, for the two new cytopathology codes that describe in situ hybridization testing using urine samples. We reviewed the direct PE recommendations made by the AMA RUC and considered the inputs to be appropriate. However, we shared LUGPA's concerns regarding the potential payment discrepancies between the codes that describe the same test using different specimen media. Therefore, in the CY 2012 PFS proposed rule, we asked the AMA RUC to review the both the direct PE inputs and work values of the following codes

in accordance with the consolidated approach to reviewing potentially misvlaued codes as outlined in section II.B.2.c. of this final rule with comment period: CPT codes 88365 (In situ hybridization (*e.g.,* FISH), each probe); 88367 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; using computer-assisted technology); and 88368 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual).

Comment: Several commenters urged CMS to remove the in situ hybridization codes from its request for review since the RUC reviewed the work values for those codes when valuing the new codes.

Response: We believe that these codes exemplify the need to conduct simultaneous review of direct PE inputs and physician work and time. As we explained in the proposal, maintaining appropriate relativity among payment rates, and PE RVUs in particular, requires the assignment of correct direct PE inputs relative to similar services. We understand that the RUC recommended maintaining the work RVUs for the existing codes in the context of the recommendation regarding the new codes, but the recommendations did not address the direct PE inputs of the existing codes that now describe similar tests using specimen media other than urine.

Comment: LUGPA urged CMS to resolve the payment discrepancies by amending the direct PE inputs for 88120 and 88121 in order to equalize payment with the payment rates with 88367 and 88368. Additionally, the association suggested that CMS should equalize the work and malpractice RVUs for these codes with 88367 and 88368. The association also reasserted the claim that the information which CMS accepted in its totality from the RUC and the CPT Editorial Panel, with respect to both the existence of and values for the new codes, is erroneous and unsupportable.

Response: We do not agree with the commenter's assertion that the technical resources required in conducting the urinary tract specimen test with and without the use of computer-assisted technology are exactly the same. We believe that using computer–assisted technology inherently alters the kind and amount of direct practice expense resources typically used in furnishing services. Therefore, we believe it would be inappropriate to use the direct inputs for the manual code in the calculation of PE RVUs for the code that describes the service when furnished using computer-assisted technology.

However, we continue to share the commenter's concerns regarding the potential payment discrepancies between the codes that describe the same test using different specimen media. If the direct resources required for conducting the test using urine specimens are different from the direct resources required for conducting the test using other specimen media, we do not believe it would be appropriate to assume the typical direct practice expense inputs for the non-specific specimen media codes that were previously valued based upon all the specimen media including urine are still accurate now that services using urine will be reported using different codes.

Therefore, we maintain our request as stated in the in the CY 2012 PFS proposed rule (76 FR 42795 and 42796) that the AMA RUC review both the direct PE inputs and work values of the existing codes that describe the test using specimen media other than urine.

After consideration of these comments, and in anticipation of forthcoming review of codes 88365, 88367, and 88368, we are maintaining for CY 2012 the current direct PE inputs for CPT codes 88120 and 88121 on an interim basis subject to public comment.

Ultrasound Equipment. A stakeholder has raised concerns about potential inconsistencies with the inputs and the prices related to ultrasound equipment in the direct PE database. Upon reviewing inputs and prices for ultrasound equipment, we have noted that there are 17 different pieces of ultrasound and ultrasound-related equipment in the database that are associated with 110 CPT Codes. The price inputs for ultrasound equipment range from $1,304.33 to $466,492.00. Therefore, we are asking the AMA RUC to review the ultrasound equipment included in those codes as well as the way the equipment is described and priced in the direct PE database.

In the past, the AMA RUC has provided us with valuable recommendations regarding particular categories of equipment and supply items that are used as direct PE inputs for a range of codes. For example, in the 2011 PFS final rule (75 FR 73204), we made changes to a series of codes following the RUC's review of services that include the radiographic fluoroscopic room (CMS Equipment Code EL014) as a direct PE input. The RUC review revealed the use of the item to no longer be typical for certain services in which it had been specified within the direct cost inputs. These recommendations have often prompted our proposals that have served to maintain appropriate relativity within the PFS, and we hope that the RUC will continue to address issues relating to equipment and supply inputs that affect many codes. Furthermore, we believe that in these kinds of cases, it may be appropriate to make changes to the related direct PE inputs for a series of codes without reevaluating the physician work or other direct PE inputs for the individual codes. In other words, while we generally believe that both the work and the direct practice expense inputs should be reviewed whenever the RUC makes recommendations regarding either component of a code's value, we recognize the value of discrete RUC reviews of direct PE items that serve as inputs for a series of service codes.

Comment: Many commenters expressed agreement with CMS' interest in establishing consistency regarding direct PE inputs for ultrasound equipment. The RUC agreed to review the types of equipment and the assignment to individual codes but reiterated that the RUC does not make recommendations related to specific prices used in the practice expense RVU calculations. A few commenters urged CMS and the RUC to provide manufacturers and other stakeholders the opportunity to provide input and feedback to the AMA RUC regarding descriptive and other information related to this equipment during any review.

Response: We appreciate the support for this request and the efforts of the RUC in taking on this review. We remind commenters that because the AMA RUC is an independent committee, concerned stakeholders should communicate directly with the AMA RUC regarding its professional composition. We note that we alone are responsible for all decisions about the direct PE inputs for purposes of PFS payment so, while the AMA RUC provides us with recommendations based on its broad expertise, we ultimately remain responsible for determining the direct PE inputs for all PFS services. Additionally, we note that any changes to the equipment inputs related to ultrasound services will be made through rulemaking and be subject to public comment. Finally, we remind interested stakeholders that throughout the year we meet with parties who want to share their views on topics of interest to them. These discussions may provide us with information regarding changes in medical practice and afford opportunities for the public to bring to our attention issues they believe we should consider for future rulemaking.

(2) Codes Without Direct Practice

Expense Inputs in the Non-Facility Setting Certain stakeholders have requested that we create nonfacility PE values for a series of kyphoplasty services CPT codes:

- 22523 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (*e.g.,* kyphoplasty); thoracic),
- 22524 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (*e.g.,* kyphoplasty); lumbar).
- 22525 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (*e.g.,* kyphoplasty); each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)).

In the case of these codes, we are asking the RUC to make recommendations regarding the appropriateness of creating nonfacility direct PE inputs. If the RUC were to make direct PE recommendations, we would review those recommendations as part of the annual process.

Comment: Several commenters asserted that determining the appropriateness of creating nonfacility direct PE inputs for particular services is not the role of the RUC. In response to this request, the RUC provided CMS with recommended direct PE inputs for CY 2012, but asserted that the RUC does not believe that it is within the Committee's expertise to determine whether a service can be performed safely or effectively in the office setting.

Response: We appreciate the commenter's' perspectives and understand the RUC's position. Since the RUC submitted nonfacility direct PE input recommendations with its annual recommendations on new, revised, and potentially misvalued codes for CY 2012, we priced the services on an interim basis in the nonfacility setting for CY 2012. However, we note that the valuation of a service under the PFS in particular settings does not address whether those services are medically reasonable and necessary in the case of individual patients, including being furnished in a setting appropriate to the patient's medical needs and condition. We address the nonfacility direct PE input recommendations for these codes in section III.B.2. of this final rule with comment period.

(3) Codes Potentially Requiring Updates to Physician Work

Cholecystectomy. We received a comment regarding a potential relativity problem between two cholecystectomy (gall bladder removal) CPT codes. CPT code 47600 (Cholecystectomy;) has a work RVU of 17.48, and CPT code 47605 (Cholecystectomy; with cholangiography) has a work RVU of 15.98. Upon examination of the physician time and visits associated with these codes, we found that CPT code 47600 includes 115 minutes of intra-service time and a total time of 420 minutes, including 3 office visits, 3 subsequent hospital care days, and 1 hospital discharge management day. CPT code 47605 includes 90 minutes of intra-service time and a total time of 387 minutes, including 2 office visits, 3 subsequent hospital care days, and 1 hospital discharge management day. We believe that the difference in physician time and visits is the cause for the difference in work RVU for these codes. However, upon clinical review, it does not appear that these visits appropriately reflect the relativity of these two services, as CPT code 47600 should not have more time and visits associated with the service than CPT code 47605. Therefore, we are asking the AMA RUC to review these two cholecystectomy CPT codes, 47600 and 47605.

Comment: Commenters did not disagree with us that there is a work RVU rank order anomaly between codes 47600 and 47605 but they believed 47605 is undervalued. The commenters agreed that these services should be reviewed together.

Response: We look forward to receiving recommendations from the AMA RUC and reviewing these codes. We note again that it is essential to value codes in the context of the code family and to consider the relativity with other services of similar time and intensity outside of the code family.

We thank the public for bringing these issues to our attention and kindly request that the public continue to do so.

6. Expanding the Multiple Procedure Payment Reduction (MPPR) Policy

a. Background

Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished to the same patient by the same physician on the same day, largely based on the presence of efficiencies in the practice expense (PE) and pre- and post-surgical physician work. Effective January 1, 1995, the MPPR policy, with the same percentage reduction, was extended to nuclear medicine diagnostic procedures (CPT codes 78306, 78320, 78802, 78803, 78806, and 78807). In the CY 1995 PFS final rule with comment period (59 FR 63410), we indicated that we would consider applying the policy to other diagnostic tests in the future.

Consistent with recommendations of MedPAC in its March 2005 Report to the Congress on Medicare Payment Policy, under the CY 2006 PFS, the MPPR policy was extended to the technical component (TC) of certain diagnostic imaging procedures performed on contiguous areas of the body in a single session (70 FR 70261). The reduction recognizes that, for the second and subsequent imaging procedures, there are some efficiencies in clinical labor, supplies, and equipment time. In particular, certain clinical labor activities and supplies are not duplicated for subsequent procedures and, because equipment time and indirect costs are allocated based on clinical labor time, those would also be reduced accordingly.

The imaging MPPR policy originally applied to computed tomography (CT) and computed tomographic angiography (CTA), magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA), and ultrasound services within 11 families of codes based on imaging modality and body region. When we adopted the policy in CY 2007, we stated that we believed efficiencies were most likely to occur when imaging procedures are performed on contiguous body areas because the patient and equipment have already been prepared for the second and subsequent procedures, potentially yielding resource savings in areas such as clerical time, technical preparation, and supplies (70 FR 45850). The MPPR policy originally applied only to procedures furnished in a single session involving contiguous body areas within a family of codes, not across families. Additionally, while the MPPR policy applies to TC-only services and to the TC of global services, it does not apply to professional component (PC) services.

Under the current imaging MPPR policy, full payment is made for the TC of the highest paid procedure, and payment is reduced by 50 percent of the TC for each additional procedure when an MPPR scenario applies. We originally planned to phase in the imaging MPPR policy over a 2-year period, with a 25 percent reduction in CY 2006 and a 50 percent reduction in

CY 2007 (70 FR 70263). However, the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) amended the statute to place a cap on the PFS payment amount for most imaging procedures at the amount paid under the hospital outpatient prospective payment system (OPPS). In view of the new OPPS payment cap added by the DRA, we decided in the PFS final rule with comment period for 2006 that it would be prudent to retain the imaging MPPR at 25 percent while we continued to examine the appropriate payment levels (71 FR 69659). The DRA also exempted reduced expenditures attributable to the imaging MPPR policy from the PFS budget neutrality provision. Effective July 1, 2010, section 3135(b) of the Affordable Care Act amended the statute to increase the MPPR on the TC of imaging services under the policy established in the CY 2006 PFS final rule with comment period from 25 to 50 percent, and exempted the reduced expenditures attributable to this further change from the PFS budget neutrality provision.

In the July 2009 GAO report entitled, ''Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved when Services are Provided Together,'' the GAO recommended that we take further steps to ensure that fees for services paid under the PFS reflect efficiencies that occur when services are furnished by the same physician to the same beneficiary on the same day. The GAO recommended the following: (1) expanding the existing imaging MPPR policy for certain services to the PC to reflect efficiencies in physician work for certain imaging services; and (2) expanding the MPPR to reflect PE efficiencies that occur when certain nonsurgical, nonimaging services are furnished together. The GAO report also encouraged us to focus on service pairs that have the most impact on Medicare spending.

In its March 2010 report, MedPAC noted its concerns about mispricing of services under the PFS. MedPAC indicated that it would explore whether expanding the unit of payment through packaging or bundling would improve payment accuracy and encourage more efficient use of services.

In the CYs 2009 and 2010 PFS proposed rules (73 FR 38586 and 74 FR 33554, respectively), we stated that we planned to analyze nonsurgical services commonly furnished together (for example, 60 to 75 percent of the time) to assess whether an expansion of the MPPR policy could be warranted. MedPAC encouraged us to consider duplicative physician work, as well as PE, in any expansion of the MPPR policy.

Section 1848(c)(2)(K) of the Act (as added by section 3134(a) of the Affordable Care Act) specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service, and review and make appropriate adjustments to their relative values. As a first step in applying this provision, in the CY 2010 final rule with comment period, we implemented a limited expansion of the imaging MPPR policy to additional combinations of imaging services.

Effective January 1, 2011 the imaging MPPR applies regardless of code family; that is, the policy applies to multiple imaging services furnished within the same family of codes or across families. This policy is consistent with the standard PFS MPPR policy for surgical procedures that does not group procedures by body region. The current imaging MPPR policy applies to CT and CTA, MRI and MRA, and ultrasound procedure services furnished to the same patient in the same session, regardless of the imaging modality, and is not limited to contiguous body areas.

We note that section 1848(c)(2)(B)(v)(VI) of the Act (as added by section 3135(b) of the Affordable Care Act) specifies that reduced expenditures attributable to the increase in the imaging MPPR from 25 to 50 percent (effective for fee schedules established beginning with 2010 and for services furnished on or after July 1, 2010) are excluded from the PFS budget neutrality adjustment. That is, the reduced payments for code combinations within a family of codes (contiguous body areas) are excluded from budget neutrality. However, this exclusion only applies to reduced expenditures attributable to the increase in the MPPR percentage from 25 to 50 percent, and not to reduced expenditures attributable to our policy change regarding additional code combinations across code families (non-contiguous body areas) that are subject to budget neutrality under the PFS

The complete list of codes subject to the CY 2012 MPPR policy for diagnostic imaging services is included in Addendum F.

As a further step in applying the provisions of section 3134(a) of the Affordable Care Act, effective January 1, 2011, we implemented an MPPR for therapy services. The MPPR applies to separately payable ''always therapy'' services, that is, services that are only paid by Medicare when furnished under a therapy plan of care. Contractor-priced codes, bundled codes, and add-on codes are excluded because an MPPR would not be applicable for ''always therapy'' services furnished in combination with these codes. The complete list of codes subject to the MPPR policy for therapy services is included in Addendum H.

In the CY 2011 proposed rule (75 FR 44075), we proposed to apply a 50 percent payment reduction to the PE component of the second and subsequent therapy services for multiple ''always therapy'' services furnished to a single patient in a single day. However, in response to public comments, in the CY 2011 PFS final rule with comment period (75 FR 73232), we adopted a 25 percent payment reduction to the PE component of the second and subsequent therapy services for multiple ''always therapy'' services furnished to a single patient in a single day.

Subsequent to publication of the CY 2011 PFS final rule with comment period, section 3 of the Physician Payment and Therapy Relief Act of 2010 (Pub. L. 111–286) revised the payment reduction percentage from 25 percent to 20 percent for therapy services furnished in office settings. The payment reduction percentage remains at 25 percent for services furnished in institutional settings. Section 4 of the Physician Payment and Therapy Relief Act of 2010 exempted the reduced expenditures attributable to the therapy MPPR policy from the PFS budget neutrality provision. Under our current policy as amended by the Physician Payment and Therapy Relief Act, for institutional services, full payment is made for the service or unit with the highest PE and payment for the PE component for the second and subsequent procedures or additional units of the same service is reduced by 25 percent. For non-institutional services, full payment is made for the service or unit with the highest PE and payment for the PE component for the second and subsequent procedures or additional units of the same service is reduced by 20 percent.

The MPPR policy applies to multiple units of the same therapy service, as well as to multiple different services, when furnished to the same patient on the same day. It applies to services furnished by an individual or group practice or ''incident to'' a physician's service. The MPPR applies when multiple therapy services are billed on the same date of service for one patient by the same practitioner or facility under the same National Provider Identifier (NPI), regardless of whether the services are furnished in one therapy discipline or multiple

disciplines, including, physical therapy, occupational therapy, or speech-language pathology.

The MPPR policy applies in all settings where outpatient therapy services are paid under Part B. This includes both services paid under the PFS that are furnished in the office setting, as well as to institutional services paid at the PFS rates that are furnished by outpatient hospitals, home health agencies, comprehensive outpatient rehabilitation facilities (CORFs), and other entities that are paid under Medicare Part B for outpatient therapy services.

In its June 2011 Report to the Congress, MedPAC further discussed its concern about the significant growth in ancillary services, specifically services for which physicians can self-refer under the in office ancillary exceptions list for the Ethics in Patient Referrals Act (also known as the Stark Law) including imaging, other diagnostic tests, and therapeutic services such as physical therapy and radiation therapy. MedPAC argues, in its June 2011 Report, that inaccurate pricing has played a role in this growth, and that there are additional efficiencies to be achieved in pricing imaging services notwithstanding a series of payment adjustments for imaging services over the past several years. MedPAC specifically recommended a multiple procedure payment reduction to the professional component of diagnostic imaging services provided by the same practitioner in the same session.

b. CY 2012 Expansion of the MPPR Policy to the Professional Component of Advanced Imaging Services

Over the past few years, as part of the potentially misvalued service initiative, the AMA RUC has examined several services that are billed together 75 percent or more of the time as part of the potentially misvalued service initiative. In several cases, the AMA RUC-recommended work values for new codes that describe the combined services, and those recommended values reflected the expected efficiencies. For example, for CY 2011, the AMA RUC valued the work for a series of new codes that describe CT of the abdomen and pelvis, specifically CPT codes:

- 74176 (Computed tomography, abdomen and pelvis; without contrast material).
- 74177 (Computed tomography, abdomen and pelvis; with contrast material).
- 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by with contrast material(s) and further sections in one or both body regions).

We accepted the work values recommended by the AMA RUC for these codes in the CY 2011 PFS final rule with comment period (75 FR 73229). The recommended work values reflected an expected efficiency for the typical combined service that paralleled the reductions that would typically result from a MPPR adjustment. For example, in support of the recommended work value of 1.74 RVUs for 74176, the AMA RUC explained that the full value of 74150 (Computed tomography, abdomen; without contrast material) (Work RVU = 1.19) plus half the value of 72192 (Computed tomography, pelvis; without contrast material) (½ Work RVU = 0.55) equals 1.74 work RVUs. The AMA RUC stated that its recommended valuation was appropriate even though the combined current work RVUs for of 74150 and 72192 would result in a total work RVU of 2.28. Furthermore, the AMA RUC validated its estimation of work efficiency for the combined service by comparing the code favorably with the work value associated with 74182 (Magnetic resonance, for example, proton imaging, abdomen; with contrast material(s)) (Work RVU = 1.73), which has a similar intra-service time, 20 minutes. Thus, we believe our current and final MPPR formulations are consistent with the AMA RUC's work to review code pairs for unaccounted-for efficiencies and to appropriately value comprehensive codes for a bundle of component services.

We continue to believe that there may be additional imaging and other diagnostic services for which there are efficiencies in work when furnished together, resulting in potentially excessive payment for these services under current policy. MedPAC also made this same observation in their recent June 2011 Report to the Congress.

As noted, Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures and nuclear medicine diagnostic procedures furnished to the same patient by the same physician on the same day.

In continuing to apply the provisions of section 3134(a) of the Affordable Care Act, for CY 2012 we proposed to expand the MPPR to the PC of Advanced Imaging Services (CT, MRI, and Ultrasound), that is, the same list of codes to which the MPPR on the TC of advanced imaging already applies (see Addendum F). Thus, the MPPR would apply to the PC and the TC of the codes. Specifically, we proposed to expand the 50 percent payment reduction currently applied to the TC to apply also to the PC of the second and subsequent advanced imaging services furnished in the same session. Full payment would be made for the PC and TC of the highest paid procedure, and payment would be reduced by 50 percent for the PC and TC for each additional procedure furnished to the same patient in the same session. This proposal was based on the expected efficiencies in furnishing multiple services in the same session due to duplication of physician work—primarily in the pre- and post-service periods, with smaller efficiencies in the intra-service period.

The proposal is consistent with the statutory requirement for the Secretary to identify, review, and adjust the relative values of potentially misvalued services under the PFS as specified by section 3134(a) of the Affordable Care Act. The proposal is also consistent both with our longstanding policy on surgical and nuclear medicine diagnostic procedures, which apply a 50 percent reduction to second and subsequent procedures. Furthermore, it is responsive to continued concerns about significant growth in imaging spending, and to MedPAC (March 2010, June 2011) and GAO (July 2009) recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies.

Finally, as noted, the proposal is consistent with the AMA RUC's recent methodology and rationale in valuing the work for a combined CT of the pelvis (CPT codes 72192, 72193 and 72194), and abdomen (CPT codes 74150, 74160 and 74170) where the AMA RUC assumed the work efficiency for the second service was 50 percent. Savings resulting from this proposal would be redistributed to other PFS services as required by the general statutory PFS budget neutrality provision.

Comment: Overall, most commenters opposed the expansion of the imaging MPPR policy to the PC. While many commenters acknowledged that there may be minimal efficiencies in the PC of second and subsequent procedures, they stated a 50 percent reduction was excessive. Commenters who agreed that some efficiencies exist indicated that activities with potential for duplication included: Review of medical history and prior imaging studies; review of the final report; and discussion of findings with the referring physician.

In contrast, a few commenters, including MedPAC, supported the proposal. MedPAC indicated that the proposal is consistent with the recommendation from its June 2011

Report to the Congress; noted that recent recommendations from the AMA RUC offer additional support; and agreed with a proposal to align the MPPR policy for the technical and professional portions of an imaging service.

Commenters opposed to our proposal raised several issues about the basis for CMS' proposed 50 percent reduction to the professional component for second and subsequent imaging services Many commenters cited a recent article entitled, ''Professional Component Payment Reductions for Diagnostic Imaging Examinations When More Than One Service Is Rendered by the Same Provider in the Same Session: An Analysis of Relevant Payment Policy,'' published June 29, 2011, in the Journal of the American College of Radiology''. The article argues that efficiencies within the professional component of advanced diagnostic imaging services including radiography and fluoroscopy, ultrasound, nuclear medicine, CT, and MRI are minimal and vary greatly across modalities. The article was authored by a group of radiologists that also participate in AMA RUC activities. They reached their conclusion after a review of the work for codes in the AMA RUC Resource Based Relative Value Scale Data Manager database. The authors focused their review on pre-service and post-service activities and did not review intra-service activities. The authors point out that pre- and post-service time is not a significant portion of time for imaging studies, unlike surgical procedures. The maximum percentage of potentially duplicated pre-service and post-service activity that this team identified ranged from 19 percent for nuclear medicine to 24 percent for ultrasound. The authors found a maximum percentage work reduction by modality ranging from 4.32 percent for CT to 8.15 percent for ultrasound. This translates to a maximum reduction in the professional component of only 2.96 percent for CT to 5.45 percent for ultrasound.

Commenters point out that neither GAO nor MedPAC supported a specific percentage reduction, but recommended that CMS conduct a review and analysis to determine the extent of efficiencies associated with the PC of multiple imaging services, and suggested that such efficiencies may vary by modality. Commenters highlighted several perceived deficiencies in the GAO's technical methodology, including a failure to distinguish between pre- post- and intra- physician work intensity, failure to recognize the wide variability in pre- and post- service time allocation among varied imaging services which makes a blanket policy more imprecise, and failure to consider clinical practice. Commenters argued that CMS provided no analysis to support the proposed MPPR level of 50 percent and did not identify potential areas of duplication in the pre-, post- and intra-service periods.

Commenters expressed views regarding our reference to the AMA RUC valuation of the work for bundled codes for CT of the pelvis and abdomen. Many commenters did not believe it was appropriate to propose a 50 percent MPPR to the PC for all advanced imaging services based on the AMA RUC's 50 percent reduction in work RVUs when valuing the combined pelvis and abdomen CT codes. Commenters indicated that the bundled code pair is not representative of most code pairs in that it is a focused contiguous body area using the same modality with significant overlap in the regions evaluated. Commenters noted that the AMA RUC has not consistently found a 50 percent reduction in physician work when imaging services are performed together.

The AMA RUC also objected to CMS using its recommended work values for the CT of Abdomen/Pelvis to substantiate our proposal. The AMA RUC asserted that it developed the recommended physician work values by estimating the magnitude of the physician work of the surveyed codes relative to physician work values of MRI, MRA, and evaluation and management services. When valuing the code for CT of Abdomen/Pelvis, the AMA RUC did not believe that the recommended physician work RVUs should be lower than the total RVUs resulting from applying a 50 percent MPPR to the professional component of the second and subsequent imaging service in the CT Abdomen/Pelvis code pair. The AMA RUC pointed out that the committee arrived at the recommended values using magnitude estimation and did not sum values for the component codes as suggested by CMS in the proposed rule.

Some commenters acknowledged that there are some efficiencies in the combined CT of the abdomen and pelvis, noting that overlapping images on a CT of the abdomen and pelvis may require less scrutiny. Commenters also noted that the physician has to review the patient history and provide dictation only once for multiple scans. Other commenters rejected the idea that there are efficiencies in the CT of the abdomen and pelvis. Commenters indicated that the service included only about 75 images 5 years ago. Today, it includes approximately 375 images, with the addition of thinner slice images and multiplanar reformatting.

Many commenters maintained that the proposed 50 percent MPPR for the PC of advanced imaging services is based on erroneous assumptions and a misunderstanding of the practice of medicine. These commenters argued that, generally, patients who are having multiple imaging studies on the same day tend to be patients who are seriously ill or injured patients, including cancer, trauma and stroke patients who invariably have significantly more complex pathology, requiring more time, rather than less. In some cases, the image using an initial modality may be inconclusive, requiring use of another imaging modality. Commenters argued that there are no efficiencies in physician work for interpretation of multiple advanced imaging scans for trauma and cancer patients, where images are less likely to be of contiguous anatomic areas.

Commenters maintained that, on average, studies with comparisons take longer than those that do not have comparison studies. The radiologists must look at more films and, when abnormalities are present, must compare each finding to the previous exam. The more studies there are, the more time it takes to interpret each one. Commenters asserted that radiologists are morally and professionally obligated to spend an equal amount of time, effort, and skill on interpreting images, irrespective of whether previous examinations have been performed on the same patient on the same day.

Finally, several commenters argued that technological advances in imaging have increased the intra-service work requiring radiologists to review many more images and more complex images than when the services were originally valued. They argue that contrary to the CMS proposal, clinical practice has become more time consuming because of the need to review hundreds of images per study compared to earlier imaging methods which took far fewer images. In addition to axial images, there frequently are coronal, sagittal, and oblique sequences as well as maximal intensity 3D images with each study. Images of non-contiguous body areas, for example, a CT of the brain and abdomen, are unrelated and are often read by different specialists, each separately requiring dedicated time for interpretation. Further, the search patterns used to identify possible issues in the images are different; technical aspects of viewing non-contiguous images are different; and the mental process used to formulate differential diagnoses are often unrelated. In some cases, such as when it is necessary to re-review prior images, commenters stated

that more time may be required compared to the time required to review a single image.

Response: We appreciate the many comments submitted on this proposal. However, we continue to believe that some level of duplication exists in the PC service for second and subsequent advanced imaging services. While our initial proposal was developed with reference to existing MPPR policies and supported by the AMA RUC valuation of new bundled CT imaging codes, as commenters recommended, we have performed additional analysis for this final rule with comment period. Specifically, we have reviewed the vignettes in the AMA RUC database for 12 high volume code pairs where vignettes were available. The codes we reviewed appear in Table 8 and constituted about 30 percent of utilization for the advanced imaging codes performed on the same day in CY 2010 claims data. Although our analysis did not include code pairs with different modalities, we note that our claims data indicate that such code pairs represent only 3 percent of expenditures for advanced imaging codes. Therefore, we do not believe the typical multiple advanced imaging scenario involves more than one modality. We also note that our analysis did not include ultrasound code pairs as there are no vignettes or specific physician times for these services in the AMA RUC database. To identify potential duplication in the PC of the code combinations for which vignettes and physician times were available, we performed a clinical assessment to identify the level of duplication in the typical case and assigned a reduction percentage of either 0, 25, 50, 75 or 100 to each vignette component in the pre-, post-, and intra-service periods.

Our claims analysis revealed that the majority of multiple imaging studies were for contiguous anatomic areas including thorax and abdomen/pelvis, and head/brain and neck/spine, and utilized the same modality. This suggests that multiple studies are typically performed to view a single underlying pathology that spans either multiple regions or lies in the region of overlap where a single study might be suboptimal. If the reasons for the studies were relatively unrelated, the observed association between contiguous areas and same modality would not exist. Conversely, the observation of this firm association between multiple studies on the same day implies that there are some efficiencies in interpreting history; predicting pathology; selecting protocols; reviewing scout and technique scans; focusing on particular tissue types and imaging windows; reviewing overlapping fields; reporting preliminary if not final results; and follow-up discussions with patients, staff and physicians. In contrast to the analysis published by the ACR, we found—

- Significant duplication in the pre-service work, which consists of reviewing patient history and any prior imaging studies, and determining the protocol and communicating that protocol with technologists;
- Significant duplication in the post-service work, which almost always consists of reviewing and signing a final report and discussing findings with the referring physician; and
- Moderate efficiencies in intra-service work. Specifically, supervising contrast (where appropriate), interpreting the examination and comparing it to other studies, and dictating the report for the medical record.

In conclusion, our analysis showed that, after applying a reduction percentage to each vignette component for the second and subsequent scans, identified as the code(s) in the code pair with the lower professional component RVU, and adjusting for intensity differences between pre-service and post-service work and intra-service work, the total RVU reduction ranges from 27.3 to 43.1 percent for second and subsequent procedures in the 12 code pairs.

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TABLE 8: FREQUENTLY BILLED ADVANCED IMAGING COMBINATIONS

Code	Descriptor	Code	Descriptor	Code	Descriptor
71260	Ct thorax w/dye	74177	Ct abdomen and pelvis w/dye		
71250	Ct thorax w/o dye	74176	Ct abdomen and pelvis w/o dye		
70496	Ct angiography, head	70498	Ct angiography, neck		
70544	Mr angiography head w/o dye	70551	Mri brain w/o dye		
72191	Ct angiograph pelv w/o&w/dye	74175	Ct angio abdom w/o & w/dye		
71260	Ct thorax w/dye	74178	Ct abdomen and pelvis 1+ regions		
71260	Ct thorax w/dye	74160	Ct abdomen w/dye		
70544	Mr angiography head w/o dye	70547	Mr angiography neck w/o dye	70551	Mri brain w/o dye
71275	Ct angiography, chest	72191	Ct angiograph pelv w/o&w/dye	74175	Ct angio abdom w/o & w/dye
71250	Ct thorax w/o dye	74150	Ct abdomen w/o dye		
72197	Mri pelvis w/o & w/dye	74183	Mri abdomen w/o & w/dye		
70544	Mr angiography head w/o dye	70549	Mr angiograph neck w/o&w/dye		

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Based on our further analysis and in response to comments, we believe that a 25 percent reduction would more appropriately capture the range of physician work efficiencies for second and subsequent imaging services furnished by the same physician (including physicians in the same group practice) to the same patient in the same session on the same day.

Commenters expressed concerns that there is wide variation in the potential efficiencies among different code pairs that such variability precludes broad application of a single percentage reduction, and that establishing new combined codes is the only mechanism for capturing accurate payment, for multiple imaging services. In general, we believe that MPPR policies capture efficiencies when several services are furnished in the same session and that it is appropriate to apply a single percentage reduction to second and subsequent procedures to capture those efficiencies. Because of the myriad potential combinations of advanced imaging scans, establishing new combined codes for each combination of advanced imaging scans is unwieldy and impractical. An MPPR policy is not precise, but reflects efficiencies in the aggregate, such as common patient history, interpretation of multiple images involving the same patient and same anatomical structures, and, typically, same modality. Our analysis of the specific activities included in furnishing advanced imaging scans together supports a reduction between 27.3 and 43.1 percent. The implementation of a 25 percent reduction in the PC for second and subsequent imaging services furnished by the same physician in the same session is less than range of reductions we observed for second and subsequent scans in our analysis. Therefore, while we acknowledge that efficiencies may vary across code pairs, we believe that a 25 percent reduction in the PC is reasonable and supported by our analysis. We note that, as with many of our policies, we will continue to review this MPPR policy and refine it as needed in future years to ensure that we continue to provide accurate payments under the PFS.

We disagree with commenters' assertions that there are no efficiencies in physician work for the interpretation of multiple advanced imaging scans for trauma and cancer patients. As noted previously, our analysis indicates that the typical multiple imaging case involves contiguous body areas, and only a very small percentage involve more than one modality. We note that this analysis included all claims data, including trauma and cancer patient imaging studies. In addition, we used conservative estimates of the reduction percentages for the observed efficiencies for second and subsequent procedures in our analysis. Finally, we believe there are efficiencies in work for all multiple imaging studies, including the review of medical history and prior imaging studies; contrast administration; review of the final report; and discussion of findings with the referring physician, regardless of the type of injury or patient's diagnosis.

Concerning comparison studies, we note that when interpreting previous studies, the radiologist would interpret not just the prior image itself, but also the patient history or, at a minimum, the portfolio of similar available studies. While we understand that time spent reviewing prior studies adds work by requiring the radiologist to review such studies, we believe that the availability of prior studies may also reduce work by creating a baseline against which new images can be quickly compared.

Commenters were also concerned with technological advances that may exponentially multiply the number of images that are produced in a single imaging session. While we agree with commenters that technology has multiplied the number of images produced, we note that that same technology has vastly improved viewability. The use of shuttles to scan through a series of images along imaged axis, 3–D rendering to allow visualization, rotation and zoom, and modeling to enhance suspect findings and increase the utility of pattern recognition all exist to improve the efficiency of data extraction that at one time had to be visualized entirely in the mind of the radiologist from a series of side-by-side flat images. Therefore, we believe that, in the aggregate, technological advances in imaging have not significantly increased the work of interpretation. Efficiencies resulting from technological advances are even more evident in cases of multiple contiguous images, where rendering allows joystick maneuvering through a single continuous image that may be billed independently, but which may be acquired as a single activity. Finally, we note that other commenters, and the study cited by the American College of Radiology, have acknowledged some efficiencies do exist and are not currently recognized in the coding and payment structure of these codes.

Comment: The AMA RUC requested that CMS continue to support the activities of the joint CPT/RUC workgroup to identify services that can be bundled together into one comprehensive code and to make sure that this bundled code is valued appropriately. The AMA RUC noted that it utilizes Medicare claims data to ensure that it understands what services are reported in conjunction with the codes that are under their review, and to ensure that there is no duplication of pre-service and post-service work, or in practice costs. The AMA RUC maintains that any duplication in the PC that may exist when performing two or more imaging services has already been removed from the individual codes as it is assumed that there are a certain number of instances for which one service will be furnished and reported with another service. The AMA RUC maintains that further expansion of the MPPR to the PC would result in unwarranted and unfair reductions to the payment rate. The AMA RUC has found, through review of survey data, that when codes are commonly reported together (that is, more than 75 percent of the time), the duplication in physician work for the second or subsequent services is not consistently 50 percent, and may range from anywhere between 0 percent and 100 percent. The AMA RUC views its current project to address efficiencies on an individual basis with bundled codes to be a fair and consistent process. Commenters noted that thirteen new bundled CPT codes have been developed and valued by the AMA RUC so far, and more bundled codes are being developed for the 2013 and 2014 CPT cycles. Therefore, the AMA RUC believes its efforts should more than address the GAO recommendation to systematically review services commonly furnished together, and that CMS' implementation of the imaging MPPR policy for the professional component of advanced imaging services is not warranted at this time.

Response: The imaging MPPR is not intended to supersede the AMA RUC process of developing recommended values for services described by CPT codes. We appreciate the work by the AMA RUC and encourage them to continue examining code pairs for duplication based upon the typical case, and appropriately valuing new comprehensive codes for bundled services that are established by the CPT Editorial Panel. We view the AMA RUC process and the MPPR policy as complimentary and equally reasonable means to the appropriate valuation and payment for services under the PFS. Codes subject to the MPPR that are subsequently bundled would no longer be subject to the MPPR when billed alone in a single session. At the same

time, the adoption of the MPPR for the PC of advanced imaging services will address duplications in work to ensure that multiple imaging services are paid more appropriately. As noted previously, we believe that an MPPR policy addresses work efficiencies present when more than one advanced imaging service is performed in the same session, and that creating new comprehensive codes to capture the myriad of unique combinations of advanced imaging services that could be performed in the same session would be unwieldy and impractical. In addition, we believe that the expansion of the MPPR policy for advanced imaging services to the PC is consistent with both the GAO and MedPAC recommendations. We note that as more code combinations are bundled into a single complete service reported by one CPT code, the MPPR policy would no longer apply for the combined services. For example, the MPPR no longer applies when the single code is billed for a combined CT of the pelvis and abdomen performed in the same session.

Comment: In the proposed rule, we cited section 3134 of the Affordable Care Act, which requires the Secretary identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service, and to review and make appropriate adjustments to their relative values. A commenter believed that we inappropriately relied on this authority to justify the expansion of the MPPR to PC services. The commenter noted that we stated in the PFS final rule for 2011 that ''[b]ecause of the different pieces of equipment used for CT/CTA, MRI/MRA, and ultrasound procedures, it would be highly unlikely that a single practitioner would furnish more than one imaging procedure involving two different modalities to one patient in a single session where the proposed MPPR would apply.'' Therefore, the commenter concluded that we should not rely on the authority under section 3134 of the Affordable Care Act to adjust payment for ''codes that are frequently billed in conjunction with furnishing a single service'' as the basis to expand the MPPR policy to procedures that we conceded are rarely billed together.

Response: We believe that the application of the MPPR to the PC of second and subsequent advanced imaging services furnished in the same session to the same patient is fully consistent with section 1848(c(2)(K) of the Act (as added by section 3134 of the Affordable Care Act). Additionally, we believe the proposed MPPR is consistent with our authority under section 1848(c)(2)(B) of the Act which requires us to review the relative and make adjustments to values for physicians' services at least once every 5 years, and with our authority to establish ancillary policies under section 1848(c)(4) of the Act. As noted previously, we have had several MPPR policies in place for many years before the enactment of section 3134 of the Affordable Care Act.

As explained previously, section 1848(c)(2)(K)(i) of the Act requires the Secretary to identify services within several specific categories as being potentially misvalued, and to make appropriate adjustments to their relative values. One of the specific categories listed under section 1834(c)(2)(K)(ii) of the Act is ''multiple codes that are frequently billed in conjunction with furnishing a single service.''

Therefore, we do not agree with the commenters that the MPPR policy undermines the goals of the Affordable Care Act. It appears the commenter may have misunderstood the point of the quoted statement from the proposed rule that, ''[b]ecause of the different pieces of equipment used for CT/CTA, MRI/MRA, and ultrasound procedures, it would be highly unlikely that a single practitioner would furnish more than one imaging procedure involving two different modalities to one patient in a single session where the proposed MPPR would apply.'' The commenter is correct that we conceded, in the circumstance where two different modalities are used, it is unlikely that two advanced imaging codes would be billed by a single physician for a single patient in a single session. However, the point of this statement was to indicate that the proposed MPPR would not apply in the vast majority of these situations. Although there remains the remote possibility that the MPPR would apply in a scenario where the codes for multiple advanced imaging services are not ''frequently billed in conjunction with furnishing a single service,'' we believe this would be exceedingly rare. Moreover, we would expect there to be some level of efficiencies in work even in these cases. As we indicated in the CY 2011 PFS final rule with comment period (75 FR 73231), application of a general MPPR policy to numerous imaging service combinations may result in an overestimate of efficiencies in some cases and an underestimate in others. But this can be true for any service paid under the PFS, and we believe it is important to establish a general policy to pay appropriately for the typical service or services furnished. Given that, based on our review of CY 2010 claims data, 97 percent of second and subsequent advanced imaging services furnished to the same patient on the same day involved the use of the same imaging modality, and that some of the cases that did involve different modalities might have been furnished by different physicians in different group practices (in which case the MPPR would not apply), we do not believe it is necessary to adjust our MPPR policy to address an uncommon scenario. Therefore, we believe the MPPR policy is fully consistent with section 1848(c)(2)(K) of the statute, as added by section 3134(a) of the Affordable Care Act, and that the policy fulfills several of our key statutory obligations by more appropriately valuing combinations of imaging services furnished to patients and paid under the PFS.

Comment: Commenters indicated that contemporary radiology is not designed to distinguish between imaging procedures performed during the ''same'' or ''different'' sessions with any degree of reliability. There is no practical method to reliably and efficiently make this distinction. This challenge is made even more difficult when the issue of ''same'' versus ''different'' interpreting physician(s) is taken into account. The process will also be challenging to auditors who will likely suggest that the burden is on the practice to prove claims submitted with a -59 modifier actually occurred in a separate session. Commenters are concerned that it is unclear how this can be efficiently documented, and request that this be considered before any new policy is adopted.

Commenters noted that imaging tests utilizing different modalities are rarely performed in the same session. For example, a patient may undergo an ultrasound, which would be interpreted by the physician to determine whether the patient requires a CT for further diagnostic evaluation. The physician supervises and/or performs and interprets each test separately, at different times, and speaks to the patient about the results of each test on separate occasions during the patient's visit. Also, separate written reports are required for each test.

Commenters further noted that in multiple trauma cases, the same radiologist would not interpret the entire series of exams. In addition, there are cases when a radiologist determines upon review that X-rays were insufficient to determine the problem and, therefore, recommends another type of imaging study be performed. The same radiologist may review the results of this second imaging test for the same

patient later in the same day. In this case, the radiologist needs to complete an entire dictation to reflect the subsequent study and provide his professional interpretation. Commenters specifically asked whether the MPPR would apply when—

- A physician does not read both scans together, for example, in emergency situations even though both scans were performed in the same session;
- Two physicians with different specialties each read a separate scan of a patient, though both scans were taken during the same session; and
- Physicians are in the same group practice.

Response: The MPPR for the PC of advanced imaging services applies to procedures furnished to the same patient, in the same session, on the same day. For purposes of the MPPR on the PC, scans interpreted at widely different times (such as in the emergency situation noted) would constitute separate sessions, even though the scans themselves were conducted in the same session and the MPPR on the TC would apply. We further recognize that in some cases, imaging tests utilizing different modalities may be conducted in separate sessions for the TC service, such as when the patient must be moved to another floor of the hospital; however, the PC services in such cases may, or may not, be furnished in separate sessions. As with the MPPR for multiple surgery, the MPPR on the PC for advanced imaging services applies in the case of multiple procedures furnished by a single physician or by multiple physicians in the same group practice. As a general policy, however, when multiple scans are conducted on a patient in the same session, we would generally consider the interpretations of those scans to be furnished in the same session, including cases when furnished by different physicians in the same group practice. In cases where the physician demonstrates the medical necessity of furnishing interpretations in separate sessions, use of the -59 modifier would be appropriate. We recognize that it may not always be a simple matter to determine whether a service was furnished in the ''same'' session, particularly in the case of the PC. The physician will need to exercise judgment to determine when it is appropriate to use the -59 modifier indicating separate sessions. We do not expect use of the modifier to be a frequent occurrence.

Comment: Some commenters expressed concern that the proposal may create an incentive to bypass ultrasound and simply order an advanced imaging procedure because, as the lower cost modality, ultrasound payment would be reduced. Another commenter indicated that CMS was proposing to include ultrasound under the definition of advanced imaging services for application of the MPPR, noting that this conflicts with the statutory definition of advanced imaging services as MRI, CT, PET and nuclear cardiology.

Response: Clearly, we do not intend the MPPR to encourage radiologists to forego ultrasound imaging in favor of advanced imaging modalities. We trust that radiologists will continue to utilize the modality or modalities that is/are both medically necessary and most appropriate, rather than use payment considerations to dictate the modality.

We believe the term ''advanced imaging'' has confused commenters because this term has been used to define different sets of imaging services for different Medicare initiatives. We have not revised the definition of advanced imaging services that we have used for the imaging MPPR policy regarding the TC of the second and subsequent imaging services Since 2006, for payment under the PFS, the imaging MPPR for the TC has included CT, MRI and ultrasound. While ultrasound services are included in both the existing imaging MPPR for the TC and in the MPPR policy we are finalizing for the PC beginning in CY 2012, we do not consider ultrasound services to be advanced imaging procedures for purposes of accreditation. Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) required the Secretary to designate organizations to accredit suppliers, including but not limited to physicians, non-physician practitioners and Independent Diagnostic Testing Facilities that furnish the technical component (TC) of advanced diagnostic imaging services, which include MRI, CT, and nuclear medicine imaging such as positron emission tomography (PET). The MIPPA provision expressly excludes ultrasound, X-ray, and fluoroscopy from this requirement.

Comment: Commenters indicated that CMS' proposed MPPR policy for the PC would result in a payment reduction that would adversely affect both the quality of care and access to care; shift imaging to hospitals; jeopardize the integrated, community-based care model; is counter-productive to the concept of pay for quality performance; and will encourage partial studies to be done over several different visits, which is inefficient for everyone involved and detrimental to patient care. Several commenters did not condone such an unprofessional response, but were concerned that practitioners might begin to circumvent this payment policy.

Response: We have no reason to believe that appropriately valuing services for payment under the PFS by revising payment to reflect duplication in the PC of multiple imaging services would negatively impact quality of care; jeopardize the integrated, community-based care model; be counter-productive to the concept of pay for quality performance; or limit patients' access to medically reasonable and necessary imaging services. We have no evidence to suggest any of the adverse impacts identified by the commenters have resulted from the implementation of the MPPR on the TC of imaging in 2006. In fact, to the contrary, MedPAC's analysis in its June 2011 report indicates there has been continued high annual growth in the use of imaging.

With respect to the ordering and scheduling of imaging services for Medicare beneficiaries, we require that Medicare-covered services be appropriate to patient needs. We would not expect the adoption of an MPPR for the PC of imaging services to result in imaging services being furnished on separate days by one provider merely so that the practitioner or provider may garner increased payment. We agree with the commenters who noted that such an unprofessional response on the part of practitioners would be inefficient and inappropriate. We will continue to monitor access to care and patterns of delivery for imaging services, with particular attention focused on identifying any changes in the delivery of same day imaging services that may be clinically inappropriate.

Comment: Commenters maintained that utilization of advanced imaging has not declined since implementation of the MPPRs or the OPPS cap because the ordering physician has not been impacted by MPPR payment policy. Commenters indicated that in order to address issues of over-utilization of imaging services, it would be more appropriate for CMS to address self-referral issues rather than continue to affect the payment for physicians performing and interpreting imaging studies through an MPPR or payment cap methodology.

Response: We understand the commenters' concerns and will continue to explore ways to appropriately address overutilization. We note that in addition to the commmenters' reference to physician self-referral, in its June 2011 report, MedPAC noted that numerous factors

contribute to overutilization include mispricing of services under the PFS.

In summary, after consideration of the public comments received, we are adopting our CY 2012 proposal to apply an MPPR to the PC of advanced imaging services, with a modification to apply a 25 percent reduction for CY 2012 rather than the 50 percent reduction we had proposed. We continue to believe that efficiencies exist in the PC of multiple imaging services, and we will continue to monitor code combinations for possible future adjustments to the reduction percentage applied through this MPPR policy.

Specifically, beginning in CY 2012 we are adopting an MPPR that applies a 25 percent reduction to the PC of second and subsequent advanced imaging services furnished by the same physician to the same patient, in the same session, on the same day. We are proposing to add CPT 74174 (Computed tomographic angiography, abdomen and pelvis; with contrast material(s), including noncontrast images, if performed, and image postprocessing), which is a new code for CY 2012, to the imaging MPPR list. This code is being added on an interim final basis and is open to public comment on this final rule with comment period. We note that the MPPR will apply when the combined new procedure is furnished in conjunction with another procedure(s). The complete list of services subject to the MPPR for the PC of imaging services is the same as for the MPPR currently applied to the TC of imaging services, and is shown in Addendum F. The PFS budget neutrality provision is applicable to the new MPPR for the PC of advanced imaging services. Therefore, the estimated reduced expenditures for imaging services have been redistributed to increase payment for other PFS services. We refer readers to section IX.C. of this final rule with comment period for further discussion of the impact of this policy.

c. Further Expansion of MPPR Policies Under Consideration for Future Years

Currently, the MPPR policies focus only on a select number of codes. We will be aggressively looking for efficiencies in other sets of codes during the coming years and will consider implementing more expansive multiple procedure payment reduction policies in CY 2013 and beyond. In the proposed rule, we invited public comment on the following MPPR policies which are under consideration. Any proposals would be presented in future rulemaking and subject to further public comment:

- Apply the MPPR to the TC of All Imaging Services. This approach would apply a payment reduction to the TC of the second and subsequent imaging services performed in the same session. Such an approach could define imaging consistent with our existing definition of imaging for purposes of the statutory cap on payment at the OPPS rate (including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography). Add-on codes that are always furnished with another service and have been valued accordingly could be excluded.

Such an approach would be based on the expected efficiencies due to duplication of clinical labor activities, supplies, and equipment time. This approach would apply to approximately 530 HCPCS codes, including the 119 codes to which the current imaging MPPR applies. Savings would be redistributed to other PFS services as required by the statutory PFS budget neutrality provision.

- Apply the MPPR to the PC of All Imaging Services. This approach would apply a payment reduction to the PC of the second or subsequent imaging services furnished in the same encounter. Such an approach could define imaging consistent with our existing definition of imaging for the cap on payment at the OPPS rate. Add-on codes that are always furnished with another service and have been valued accordingly could be excluded.

This approach would be based on efficiencies due to duplication of physician work primarily in the pre- and post-service periods, with smaller efficiencies in the intra-service period. This approach would apply to approximately 530 HCPCS codes, including the 119 codes to which the current imaging MPPR applies. Savings would be redistributed to other PFS services as required by the statutory PFS budget neutrality provision.

- Apply the MPPR to the TC of All Diagnostic Tests. This approach would apply a payment reduction to the TC of the second and subsequent diagnostic tests (such as radiology, cardiology, audiology, etc.) furnished in the same encounter. Add-on codes that are always furnished with another service and have been valued accordingly could be excluded.

The approach would be based on the expected efficiencies due to duplication of clinical labor activities, supplies, and equipment time. The approach would apply to approximately 700 HCPCS codes, including the approximately 560 HCPCS codes subject to the OPPS cap. The savings would be redistributed to other PFS services as required by the statutory PFS budget neutrality provision.

We received several comments concerning the future expansion of the MPPR. We will take the comments under consideration as we develop future proposals. Any proposals would be presented in future rulemaking and subject to further public comment.

d. Procedures Subject to the OPPS Cap

We are proposing to add the new codes in Table 9 to the list of procedures subject to the OPPS cap, effective January 1, 2012. These procedures meet the definition of imaging under section 5102(b) of the DRA. These codes are being added on an interim final basis and are open to public comment in this final rule with comment period.

TABLE 9. - PROPOSED NEW CODES SUBJECT TO THE OPPS CAP

Code	Descriptor
74174	Ct angio abd & pelv w/o & w/dye
77424	Io rad tx delivery by x-ray
78226	Hepatobiliary system imaging
78227	Hepatobil syst image w/drug
78579	Lung ventilation imaging
78582	Lung ventilat & perfus imaging
78597	Lung perfusion differential
78598	Lung perf & ventilat diferentl

C. Overview of the Methodology for the Calculation of Malpractice RVUs

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: work, PE, and malpractice. From 1992 to 1999, malpractice RVUs were charge-based, using weighted specialty-specific malpractice expense percentages and 1991 average allowed charges. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU. Section 4505(f) of the BBA amended section 1848(c) of the Act which required us to implement resource-based malpractice RVUs for services furnished beginning in 2000. Therefore, initial implementation of resource-based malpractice RVUs occurred in 2000.

The statute also requires that we review, and if necessary adjust, RVUs no less often than every 5-years. The first review and update of resource-based malpractice RVUs was addressed in the CY 2005 PFS final rule with comment period (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). In the CY 2010 PFS final rule with comment period, we implemented the second review and update of malpractice RVUs. For a discussion of the second review and update of malpractice RVUs, see the CY 2010 PFS proposed rule (74 FR 33537) and final rule with comment period (74 FR 61758).

As explained in the CY 2011 PFS final rule with comment period, malpractice RVUs for new and revised codes effective before the next Five-Year Review of Malpractice (for example, effective CY 2011 through CY 2014, assuming that the next review of malpractice RVUs occurs for CY 2015) are determined either by a direct crosswalk to a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code (75 FR 73208). For the modified crosswalk approach, we adjust (or ''scale'') the malpractice RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work value (or, if greater, the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code is 10 percent higher than the work RVU for its source code, the malpractice RVU for the revised code would be increased by 10 percent over the source code RVU. This approach presumes the same risk factor for the new/revised code and source code but uses the work RVU for the new/revised code to adjust for risk-of-service.

D. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Social Security Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure resource cost differences among localities compared to the national average for each of the three fee schedule components (that is, physician work, practice expense (PE), and malpractice). While requiring that the PE and malpractice GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the physician work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier States beginning January 1, 2011.

Section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs which was set to expire at the end of 2009 until it was extended through December 31, 2010 by section 3102(a) of the Affordable Care Act. Because the work GPCI floor was set to expire at the end of 2010, the GPCIs published in Addendum E of the CY 2011 PFS final rule with comment period did not reflect the 1.0 physician work floor. However, section 1848(e)(1)(E) of the Act was amended on December 15, 2010, by section 103 of the Medicare and Medicaid Extenders Act (MMEA) of 2010 (P.L. 111–309) to extend the 1.0 work GPCI floor through December 31, 2011. Appropriate changes to the CY 2011 GPCIs were made to reflect the 1.0 physician work floor required by section 103 of the MMEA. Since the work GPCI floor provided in section 1848(e)(1)(E) of the Act is set to expire prior to the implementation of the CY 2012 PFS, the CY 2012 physician work GPCIs, and summarized geographic adjustment factors (GAFs), presented in this final rule with comment period do not reflect the 1.0 work GPCI floor. As required by section 1848(e)(1)(G) and section 1848(e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier States will be applicable in CY 2012. Moreover, the limited recognition of cost differences in employee compensation and office rent for the PE GPCIs, and the related hold harmless provision, required under section 1848(e)(1)(H) of the Act was only applicable for CY 2010 and CY 2011 (75 FR 73253) and, therefore, is no longer effective beginning in CY 2012.

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs not less often than every 3 years. This section also specifies that if more than 1 year has elapsed since the last GPCI revision, we must phase in the adjustment over 2 years, applying only one-half of any adjustment in the first year.

As noted in the CY 2011 PFS final rule with comment period (75 FR 73252 through 73262), for the sixth GPCI update, we updated the data used to

compute all three GPCI components. Specifically, we utilized the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) data to calculate the physician work GPCIs (75 FR 73252). In addition, we used the 2006 through 2008 BLS OES data to calculate the employee compensation sub-component of practice expense (75 FR 73255). Consistent with previous updates, we used the 2 bedroom residential apartment rent data from HUD (2010) at the 50th percentile as a proxy for the relative cost differences in physician office rents (75 FR 73256). Lastly, we calculated the malpractice GPCIs using malpractice premium data from 2006 through 2007 (75 FR 73256).

Since more than 1-year had elapsed since the fifth GPCI update, as required by law, the sixth GPCI update changes are being phased in over a 2-year period. The current CY 2011 GPCIs reflect the first year of the transition. The final CY 2012 GPCIs reflect the full implementation with modifications reflecting the revisions contained in this final rule with comment period.

The Affordable Care Act requires that we analyze the current methodology and data sources used to calculate the PE GPCI component. Specifically, section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the Affordable Care Act) requires the Secretary to ''analyze current methods of establishing practice expense adjustments under subparagraph (A)(i) and evaluate data that fairly and reliably establishes distinctions in the cost of operating a medical practice in different fee schedule areas.'' Section 1848(e)(1)(H)(iv) of the Act also requires that such analysis shall include an evaluation of the following:

- The feasibility of using actual data or reliable survey data developed by medical organizations on the costs of operating a medical practice, including office rents and non-physician staff wages, in different fee schedule areas.
- The office expense portion of the practice expense geographic adjustment; including the extent to which types of office expenses are determined in local markets instead of national markets.
- The weights assigned to each area of the categories within the practice expense geographic adjustment.

In addition, the weights for different categories of practice expense in the GPCIs have historically matched the weights developed by the CMS Office of the Actuary (OACT) for use in the Medicare Economic Index (MEI), the measure of inflation used as part of the basis for the annual update to the physician fee schedule payment rates. In response to comments received on the CY 2011 Physician Fee Schedule proposed rule, however, we delayed moving to the new MEI weights developed by OACT for CY 2011 pending further analysis.

Lastly, we asked the Institute of Medicine (IOM) to evaluate the accuracy of the geographic adjustment factors used for Medicare physician payment. IOM will prepare two reports for the Congress and the Secretary of the Department of Health and Human Services. The revised first report (Phase I), which includes supplemental recommendations to the initial IOM release of June1, 2011, was released on September 28, 2011, and includes an evaluation of the accuracy of geographic adjustment factors for the hospital wage index and the GPCIs, and the methodology and data used to calculate them. The second report, expected in spring 2012, will evaluate the effects of the adjustment factors on the distribution of the health care workforce, quality of care, population health, and the ability to provide efficient, high value care. Given the timing of the release of IOM's revised report, we are unable to address the full scope of the IOM recommendations in this final rule with comment period. These reports can be accessed on the IOM's Web site at: *http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx*.

The recommendations that relate to or would have an effect on the GPCIs included in IOM's revised Phase I report are summarized as follows:

- Recommendation 2–1: The same labor market definition should be used for both the hospital wage index and the physician geographic adjustment factor. Metropolitan statistical areas and Statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets.
- Recommendation 2–2: The data used to construct the hospital wage index and the physician geographic adjustment factor should come from all health care employers.
- Recommendation 5–1: The GPCI cost share weights for adjusting fee-for-service payments to practitioners should continue to be national, including the three GPCIs (work, practice expense, and liability insurance) and the categories within the practice expense (office rent and personnel).
- Recommendation 5–2: Proxies should continue to be used to measure geographic variation in the physician work adjustment, but CMS should determine whether the seven proxies currently in use should be modified.
- Recommendation 5–3: CMS should consider an alternative method for setting the percentage of the work adjustment based on a systematic empirical process.
- Recommendation 5–4: The practice expense GPCI should be contructed with the full range of occupations employed in physicians' offices, each with a fixed national weight based on the hours of each occupation employed in physicians' offices nationwide.
- Recommendation 5–5: CMS and the Bureau of Labor Statistics should develop an agreement allowing the Bureau of Labor Statistics to analyze confidential data for the Centers for Medicare and Medicaid Services.
- Recommendation 5–6: A new source of information should be developed to determine the variation in the price of commercial office rent per square foot.
- Recommendation 5–7: Nonclinical labor-related expenses currently included under practice expense office expenses should be geographically adjusted as part of the wage component of the practice expense.

2. GPCI Revisions for CY 2012

The revised GPCI values we proposed were developed by a CMS contractor. As mentioned previously, there are three GPCI components (physician work, PE, and malpractice), and all GPCIs are developed through comparison to a national average for each component. Additionally, each of the three GPCIs relies on its own data source(s) and methodology for calculating its value. As discussed in more detail later in this section, we proposed to revise the PE GPCIs for CY 2012, as well as the cost share weights which correspond to all three GPCIs.

a. Physician Work GPCIs

The physician work GPCIs are designed to capture the relative cost of physician labor by Medicare PFS locality. Previously, the physician work GPCIs were developed using the median hourly earnings from the 2000 Census of workers in seven professional specialty occupation categories which we used as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories because Medicare payments are a key determinant of physicians' earnings. That is, including physicians' wages in the physician work GPCIs would, in effect, have made the indices dependent upon Medicare payments. As required by law, the physician work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

The physician work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. For the sixth GPCI update in CY 2011, we used the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) data as a replacement for the 2000 Census data. We did not propose to revise the physician work GPCI data source for CY 2012. However, we note that the work GPCIs will be revised to account for the expiration of the statutory work floor. The 1.5 work floor for Alaska is permanent and will be applicable in CY 2012. In addition, we proposed to revise the physician work cost share weight from 52.466 to 48.266 in line with the 2011 MEI weights, which are based on 2006 data (referred to hereinafter as the 2006-based MEI).

b. Practice Expense GPCIs

(1) Affordable Care Act Analysis and Revisions for PE GPCIs

(A) General Analysis for the CY 2012 PE GPCIs

As previously mentioned, section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the Affordable Care Act) requires the Secretary to ''analyze current methods of practice expense adjustments under subparagraph (A)(i) and evaluate data that fairly and reliably establishes distinctions in the cost of operating a medical practice in the different fee schedule areas.''

Moreover, section 1848 (e)(1)(H)(v) of the Act requires the Secretary to make appropriate adjustments to the PE GPCIs as a result of the required analysis, no later than January 1, 2012. We proposed to make four revisions to the PE data sources and cost share weights discussed herein effective January 1, 2012. Specifically, we proposed to: (1) Revise the occupations used to calculate the employee wage component of PE using BLS wage data specific to the office of physicians' industry; (2) utilize two bedroom rental data from the 2006–2008 American Community Survey as the proxy for physician office rent; (3) create a purchased service index that accounts for regional variation in labor input costs for contracted services from industries comprising the ''all other services'' category within the MEI office expense and the stand alone ''other professional expenses'' category of the MEI; and (4) use the 2006-based MEI (most recent MEI weights finalized in the CY 2011 final rule with comment period) to determine the GPCI cost share weights. These proposals were based on analyses we conducted to address commenter concerns in the CY 2011 final rule with comment period and a continuation of our PE evaluation as required by the Affordable Care Act. The main comments were related to: (1) the occupational groups used to calculate the employee wage component of PE, and (2) concerns by commenters stating that regional variation in purchased services such as legal and accounting were not sufficiently included in the GPCI methodology.

We began analyzing the current methods and data sources used in the establishment of the PE GPCIs during the CY 2011 rulemaking process (75 FR 40084). With respect to our CY 2011 analysis, we began with a review of the Government Accountability Office's (GAO) March 2005 Report entitled, ''Medicare Physician Fees: Geographic Adjustment Indices Are Valid in Design, but Data and Methods Need Refinement'' (GAO–05–119). While we have raised concerns in the past about some of the GAO's GPCI recommendations, we noted that with respect to the PE GPCIs, the GAO did not indicate any significant issues with the methods underlying the PE GPCIs. Rather, the report focused on some of the data sources used in the method. For example, the GAO stated that the wage data used for the PE GPCIs are not current. Similarly, commenters on previous PE GPCI updates predominantly focused on either the data sources used in the method or raised issues such as incentivizing the provision of care in different geographic areas. However, the latter issue (incentivizing the provision of care) is outside the scope of the statutory requirement that the PE GPCIs reflect the relative costs of the mix of goods and services comprising practice expenses in the different fee schedule areas relative to the national average.

To further analyze the PE office expense in accordance with section 1848(e)(1)(H)(iv) of the Act, we examined the following issues: the appropriateness of expanding the number of occupations included in the employee wage index; the appropriateness of replacing rental data from the Department of Housing and Urban Development (HUD) with data from the 2006–2008 American Community Survey (ACS) two bedroom rental data as a proxy for the office rent subcomponent of PE; and the appropriateness of adjusting the ''all other services'' and ''other professional expenses'' MEI categories for geographic variation in labor-related costs. We also examined available ACS occupational group data for potential use in determining geographic variation in the employee wage component of PE.

An additional component of the analysis under section 1848(e)(1)(H)(iv) of the Act is to evaluate the weights assigned to each of the categories within the practice expense geographic adjustment. As discussed in the CY 2011 final rule with comment period (75 FR 73256), in response to concerns raised by commenters and to allow us time to conduct additional analysis, we did not revise the GPCI cost share weights to reflect the weights used in the revised and rebased 2006 MEI that we adopted beginning in CY 2011. In response to those commenters who raised many points regarding the appropriateness of assigning labor-related costs in the medical equipment and supplies and miscellaneous component which do not reflect locality cost differentials, we agreed to address the GPCI cost share weights again in the CY 2012 PFS proposal. These issues are discussed in greater detail in section II.D.2.b.(1).(E). of this final rule with comment period that discusses our determination of the cost share weights.

We also stated in the CY 2011 final rule with comment period that we would review the findings of the Secretary's Medicare Geographic Payment Summit and the MEI technical advisory panel during future rulemaking (75 FR 73256). The Secretary convened the National Summit on Health Care Quality and Value on October 4, 2010. This Summit was attended by a number of policy experts that engaged in detailed discussions regarding geographic adjustment factors and geographic variation in payment and the promotion of high quality care. This National Summit was useful by informing us on issues that we are studying further through two Institute of Medicine studies. In accordance with section 3102(b) of the Affordable Care Act, we are also continuing to consider these issues in the course of this notice and comment rulemaking for the CY 2012 PFS, which includes revisions to the GPCI, and through preparation of a report to the Congress that we will be submitting later this year in accordance with section 3137(b) of the Affordable Care Act on a plan for reforming the hospital wage index. In addition, we announced the establishment of the MEI Technical Advisory Panel and request for nominations of members on October 7, 2011 (76 FR 62415 through 62416). We note that the panel will conclude by September 28, 2012 and we look forward to examining the recommendations of this panel once it has issued its report.

(B) Analysis of ACS Rental Data

In the CY 2011 final rule with comment period, we finalized our policy to use the 2010 Fair Market Rent (FMR) data produced by HUD at the 50th percentile as the proxy for relative cost differences in physician office rents. However, as part of our analysis required by section 1848(e)(1)(H)(iv) of the Act, we have now examined the suitability of utilizing 3-year (2006–2008) ACS rental data to serve as a proxy for physician office rents. We believe that the ACS rental data provide a sufficient degree of reliability and are an appropriate source on which to base our PE GPCI office rent proxy. We also believe that the ACS data provide a higher degree of accuracy than the HUD data since the ACS data are updated annually and not based on data collected by the 2000 Census long form. Moreover, it is our understanding that the Census ''long form,'' which is utilized to collect the necessary base year rents for the HUD Fair Market Rent (FMR) data, will no longer be available in future years. Therefore, we proposed to use the available 2006 through 2008 ACS rental data for two bedroom residential units as the proxy for physician office rent. We also sought comment regarding the potential use of 5-year ACS rental data as a proxy for physician office rent in future rulemaking.

We believe the ACS data will more accurately reflect geographic variation in the office rent component. As in past GPCI updates, we proposed to apply a nationally uniform weight to the office rent component. We proposed to use the 2006-based MEI weight for fixed capital and utilities as the weight for the office rent category in the PE GPCI, and to use the ACS residential rent data to develop the practice expense GPCI value.

(C) Employee Wage Analysis

Accurately evaluating the relative price that physicians pay for labor inputs requires both a mechanism for selecting the occupations to include in the employee wage index and identifying an accurate measure of the wages for each occupation. We received comments during the CY 2011 rulemaking cycle noting that the current employee wage methodology may omit key occupational categories for which cost varies significantly across regions. Commenters suggested including occupations such as accounting, legal, and information technology in the employee wage component of the PE GPCI. To address these concerns, we proposed to revise the employee wage index framework within the practice expense (PE) GPCI. Under this new methodology, we would only select occupational categories relevant to a physician's practice. We would use a comprehensive set of wage data from the Bureau of Labor Statistics Occupational Employment Statistics (BLS OES) specific to the offices of physicians industry. Utilizing wage and national cost share weight data from the BLS OES would not only provide a more systematic approach to determining which occupations should be included in the non-physician employee wage category of the PE GPCI, but would also enable us to determine how much weight each occupation should receive within the index.

Due to its reliability, public availability, level of detail, and national scope, we proposed to use BLS OES data to estimate both occupation cost shares and hourly wages for purposes of determining the non-physician employee wage component of the PE GPCI. The OES panel data are collected from approximately 200,000 establishments, and provide employment and wage estimates for about 800 occupations. At the national level, OES provides estimates for over 450 industry classifications (using the 3, 4, and 5 digit North American Industry Classification System (NAICS)), including the Offices of Physicians industry (NAICS 621100). As described in the census, the Offices of Physicians industry comprises establishments of health practitioners having the degree of M.D. (Doctor of Medicine) or D.O. (Doctor of Osteopathy) primarily engaged in the independent practice of general or specialized medicine (except psychiatry or psychoanalysis) or surgery. These practitioners operate private or group practices in their own offices (such as centers, clinics) or in the facilities of others (such as hospitals or Health Maintenance Organization (HMO) medical centers). The OES data provide significant detail on occupational categories and offer national level cost share estimates for the offices of physicians industry.

In the BLS OES data methodology, we weighted each occupation based on its share of total labor cost within the offices of physician industry. Specifically, each occupation's weight is proportional to the product of its occupation's employment share and average hourly wage. In this calculation, we used each occupation's employment level rather than hours worked, because the BLS OES does not contain industry-specific information describing the number of hours worked in each occupation (see: *http://www.bls.gov/oes/current/naics4_621100.htm*). Our proposed methodology accounted for 90 percent of the total wage share in the office of physicians industry. Additionally, our proposed strategy produced 33 individual occupations that accounted for many of the occupations commenters had stated were historically excluded from the employee wage calculation (for example, accounting, auditors, and medical transcriptionists).

We also evaluated available ACS occupational data as a potential data source for the non-physician employee wage PE GPCI subcomponent. Based on the occupations currently used to calculate employee wages, the BLS OES captures occupations with greater relevancy to physician office practices and is a more appropriate data source than the currently available ACS data. In addition, since our publication of the CY 2012 proposed rule, we have conducted an analysis of ACS wage data including an expanded mix of occupations. A review of this analysis can be found in our contractors ''Revisions to the Sixth Update of the Geographic Practice Cost Index: Final Report'' located on the physician fee schedule CY 2012 final rule with comment period Web site at: *http://www.cms.gov/PhysicianFeeSched/*. After careful analysis, we still believe that the BLS OES data provide for the most accurate and comprehensive measurement of physician non-physician employee wages.

(D) Purchased Services Analysis

For CY 2012, we proposed to geographically adjust the labor-related industries within the ''all other services'' and ''other professional expenses'' categories of the MEI. In response to commenters who stated that these purchased services were labor-related and should be adjusted geographically, we agreed to examine this issue further in the CY 2011 final rule with comment period and refrained from making any changes. Based on our subsequent examination of this issue, we believe it would be appropriate to geographically adjust for the labor-related component of purchased services within the ''All Other Services'' and ''Other Professional Expenses'' categories using BLS wage data. In total, there are 63 industries, or cost categories, accounted for within the ''all other services'' and ''other professional services'' categories of the 2006-based MEI. For purposes of the hospital wage index at 74 FR 43845, we defined a cost category as labor-related if the cost category is defined as being both labor intensive and its costs vary with, or are influenced by the local labor market.

The total purchased services component accounts for 8.095 percent of total practice cost. However, only 5.011 percentage points (of the total 8.095 percentage points assigned to purchased services) are defined as labor-related and thus adjusted for locality cost differences. These 5.011 percentage points represent cost categories that we believe are labor intensive and have costs that vary with, or are influenced by, the local labor market. The labor-related cost categories include but are not limited to building services (such as janitorial and landscaping), security services, and advertising services. The remaining weight assigned to the non labor-related industries (3.084 percentage points) represent industries that do not meet the criteria of being labor intensive or having their costs vary with the local labor market.

In order to calculate the labor-related and non labor- related shares, we would use a similar methodology that is employed in estimating the labor-related share of various CMS market baskets. A more detailed explanation of this methodology can be found under the supporting documents section of the CY 2012 PFS final rule with comment period Web page at *http://www.cms.gov/PhysicianFeeSched/*.

We believe our analysis, during 2010 and this year, of the current methods of establishing PE GPCIs and our evaluation of data that fairly and reliably establish distinctions in the cost of operating a medical practice in the different fee schedule areas meet the statutory requirements of section 1848(e)(1)(H)(iv) of the Act. A more detailed discussion of our analysis of current methods of establishing PE GPCIs and evaluation of data sources is included in our contractor's draft report entitled, ''Proposed Revisions to the Sixth Update of the Geographic Practice Cost Index.'' Our contractor's final report and associated analysis of the GPCI revisions, including the PE GPCIs, will be made publicly available on the CMS Web site. The final report may be accessed from the PFS Web site at: *http://www.cms.gov/PhysicianFeeSched/* under the ''Downloads'' section of the CY 2012 PFS final rule with comment period Web page.

Additionally, see section IX.F. of this final rule with comment period for Table 86, which reflects the GAF impacts resulting from these proposals. As the table demonstrates, the primary driver of the CY 2012 impact is the expiration of the work GPCI floor which had produced non budget-neutral increases to the CY 2011 GPCIs for lower cost areas as authorized under the Affordable Care Act the Medicare and Medicaid Extenders Act (MMEA).

(E) Determining the PE GPCI Cost Share Weights

To determine the cost share weights for the CY 2012 GPCIs, we proposed to use the weights established in the 2006-based MEI. The MEI was rebased and revised in the CY 2011 final rule with comment period to reflect the weighted-average annual price change for various inputs needed to provide physicians' services. As discussed in detail in that section (75 FR 73262 through 73277), the proposed expense categories in the MEI, along with their respective weights, were primarily derived from data collected in the 2006 AMA PPIS for self-employed physicians and selected self-employed non-medical doctor specialties. Since we have historically updated the GPCI cost share weights consistent with the most recent update to the MEI, and because we have addressed commenter concerns regarding the inclusion of the weight assigned to utilities with office rent and geographically adjusted for the labor intensive industries within the ''all other services'' and ''other professional expenses'' MEI categories, we believe it is appropriate to adopt the 2006-based MEI cost share weights.

(i) Practice Expense

For the cost share weight for the CY 2012 PE GPCIs, we used the 2006-based MEI weight for the PE category of 51.734 percent minus the professional liability insurance category weight of 4.295 percent. Therefore, we proposed a cost share weight for the PE GPCIs of 47.439 percent.

(ii) Employee Compensation

For the employee compensation portion of the PE GPCIs, we proposed to use the non-physician employee compensation category weight of 19.153 percent reflected in the 2006-based MEI.

(iii) Office Rent

We proposed that the weight for the office rent component be revised from 12.209 percent to 10.223 percent. The 12.209 percent office rent GPCI weight was set equal to the 2000-based MEI cost weight for office expenses, which was calculated using the American Medical Association's (AMA) Socioeconomic Monitoring Survey (SMS). The 12.209 percent reflected the expenses for rent, depreciation on medical buildings, mortgage interest, telephone, and utilities. We proposed to set the GPCI office rent equal to 10.223 percent reflecting the 2006-based MEI cost weights (75 FR 73263) for fixed capital (reflecting the expenses for rent, depreciation on medical buildings and mortgage interest) and utilities. We are no longer including telephone costs in the GPCI office rent cost weight because we believe these expenses do not vary by geographic area.

Consistent with the revised and rebased 2006-based MEI which was adopted in the CY 2011 final rule with comment period (75 FR 73263), we disaggregated the broader office expenses component for the PE GPCI into 10 new cost categories. In this disaggregation, the fixed capital component is the office expense category applicable to the office rent component of the PE GPCI. As discussed in the section dealing with office rent, we proposed to use 2006–2008 ACS rental data as the proxy for physician office rent. These data represent a gross rent amount and includes data on utilities expenditures. Since it is not possible to separate the utilities component of rent for all ACS survey respondents, it was necessary to combine these two components to calculate office rent and by extension, we proposed combining those two cost categories when assigning a weight to the office rent component.

(iv) Purchased Services

As discussed in the previous paragraphs, a new purchased services index was created to geographically adjust the labor-related components of the ''All Other Services'' and ''Other Professional Expenses'' categories of the 2006-based MEI office market basket. In order to calculate the purchased services index, we proposed to merge the corresponding weights of these two categories to form a combined purchased services weight of 8.095 percent. However, we proposed to only adjust for locality cost differences of the labor-related share of the industries comprising the ''All Other Services'' and ''Other Professional Expenses'' categories. We have determined that only 5.011 percentage points of the 8.095 percentage points would be adjusted for locality cost differences (5.011 adjusted purchased service + 3.084 non-adjusted purchased services = 8.095 total cost share weight).

(v) Equipment, Supplies, and Other Miscellaneous Expenses

To calculate the proposed medical equipment, supplies, and other miscellaneous expenses component, we removed professional liability (4.295 percentage points), non-physician employee compensation (19.153 percentage points), fixed capital/utilities (10.223 percentage points), and

purchased services (8.095 percentage points) from the PE category weight (51.734 percent). Therefore, we proposed a cost share weight for the medical equipment, supplies, and other miscellaneous expenses component of 9.968 percent. Consistent with previous methodology, this component of the PE GPCI is not adjusted for geographical variation.

(vi) Physician Work and Malpractice GPCIs

Furthermore, we proposed to use the physician compensation cost category weight of 48.266 percent as the work GPCI cost share weight; and we proposed to use the professional liability insurance weight of 4.295 percent for the malpractice GPCI cost share weight. We believe our analysis and evaluation of the weights assigned to each of the categories within the PE GPCIs satisfies the statutory requirements of section 1848(e)(1)(H)(iv) of the Act.

The cost share weights for the CY 2012 GPCIs are displayed in Table 10. For a detailed discussion regarding the GPCI cost share weights and how the weights account for local and national adjustments, see our contractor's ''Proposed Revisions to the Sixth Update of the Geographic Practice Cost Index'' draft report at (*http://www.cms.gov/PhysicianFeeSched/*). In addition, information regarding the CY 2011 update to the MEI can be reviewed beginning on 75 FR 73262.

Table 10: COST SHARE WEIGHTS FOR CY 2012 GPCIs

Expense Category	Current CY 2011 Cost Share Weights %	CY 2012 Cost Share Weights %
Physician Work	52.466	48.266
Practice Expense	43.669	47.439
Employee Compensation	18.654	19.153
Office Rent	12.209	10.223[1]
Purchased Services	N/A	8.095[2]
Equipment, Supplies, and Other	12.806	9.968
Malpractice Insurance	3.865	4.295

[1] ACS rental data is a measurement of gross rent and includes utilities. In order to accurately capture the utility measurement present in the ACS two bedroom gross rent data, the cost share weight for utilities is combined with the fixed capital portion to form the office rent index.

[2] The cost share weight for purchased services contains both an adjusted and non-adjusted portion. (5.011 percentage points geographically adjusted purchased services + 3.084 percentage points non-adjusted purchased services).

(F) PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier States effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in States determined to be frontier States. There are no changes to those States identified as ''Frontier States'' for the CY 2012 final rule with comment period. The qualifying States are reflected in Table 11. In accordance with statute, we will apply a 1.0 GPCI floor for these States in CY 2012.

TABLE 11: FRONTIER STATES UNDER SECTION 1848(E)(1)(I) OF THE ACT (As added by section 10324(c) of the Affordable Care Act)

State	Total Counties	Frontier Counties	Percent Frontier Counties (relative to counties in the State)
Montana	56	45	80%
Wyoming	23	17	74%
North Dakota	53	36	68%
Nevada	17	11	65%
South Dakota	66	34	52%

(2) Summary of CY 2012 PE GPCI Proposal

The PE GPCIs include four components: employee compensation, office rent, purchased services, and medical equipment, supplies and miscellaneous expenses. Our proposals relating to each of these components are as follows:

• Employee Compensation: We proposed to geographically adjust the employee compensation using the 2006 through 2008 BLS OES data specific to the offices of physicians industry along with nationwide wage data to determine the employee compensation component of the PE GPCIs. The employee compensation component accounts for 19.153 percent of total practice costs or 40.4 percent of the total PE GPCIs.

• Office Rents: We proposed to geographically adjust office rent using the 2006 through 2008 ACS residential rental data for two bedroom units as a proxy for the relative cost differences in physician office rents. In addition, we proposed to consolidate the utilities into the office rent weight to account for the utility data present in ACS gross rent data. The office rent component accounts for 10.223 percent of total practice cost or 21.5 percent of the PE GPCIs.

• Purchased Services: We proposed to geographically adjust the labor-related component of purchased services within the ''All Other Services'' and ''Other Professional Expenses ''categories using BLS wage data. The methodology employed to estimate purchased services expenses is based on the same data used to estimate the employee wage index. Specifically, the purchased services framework relies on BLS OES wage data to estimate the price of labor in industries that physician offices frequently rely upon for contracted services. As previously mentioned, the labor-related share adjustment for each industry was derived using a similar methodology as is employed for estimating the labor-related shares of CMS market baskets. Furthermore, the weight assigned to each industry within the purchased services index was based on the 2006-based MEI. A more detailed discussion regarding CMS market baskets, as well as the corresponding definitions of a ''labor-related share'' and a ''non-labor-related share'' can be viewed at (74 FR 43845). The total purchased services component accounts for 8.095 percent of total practice cost or 17.1 percent of the PE GPCI. However, the proportion of purchased services that is geographically adjusted for locality cost difference is 5.011 percentage points of the 8.095 percentage points or 10.6 percent of the PE GPCI.

• Medical Equipment, Supplies, and other Miscellaneous Expenses: We continue to believe that items such as medical equipment and supplies have a national market and that input prices do not vary appreciably among geographic areas. As discussed in previous GPCI updates in the CY 2008 and CY 2011 PFS proposed rules, specifically the fifth GPCI update (72 FR 38138) and sixth GPCI update (75 FR 73256), respectively, some price differences may exist, but we believe these differences are more likely to be based on volume discounts rather than on geographic market differences. For example, large physicians' practices may utilize more medical equipment and supplies and therefore may or may not receive volume discounts on some of these items. To the extent that such discounting may exist, it is a function of purchasing volume and not geographic location. The medical equipment, supplies, and miscellaneous expenses component was factored into the PE GPCIs with a component index of 1.000. The medical equipment, supplies, and other miscellaneous expense component account for 9.968 percent of total practice cost or 21.0 percent of the PE GPCI.

c. Malpractice GPCIs

The malpractice GPCIs are calculated based on insurer rate filings of premium data for $1 million to $3 million mature ''claims-made'' policies (policies for claims made rather than services furnished during the policy term). We chose claims-made policies because they are the most commonly used malpractice insurance policies in the United States. We used claims-made policy rates rather than occurrence policies because a claims-made policy covers physicians for the policy amount in effect when the claim is made, regardless of the date of event in question; whereas an occurrence policy covers a physician for the policy amount in effect at the time of the event in question, even if the policy is expired. Based on the data we analyzed, we proposed to revise the cost share weight for the malpractice GPCI from 3.865 percent to 4.295 percent.

d. Public Comments and CMS Responses Regarding the CY 2012 Proposed Revisions to the 6th GPCI Update

We received many public comments regarding the CY 2012 proposed GPCIs. Summaries of the comments and our responses follow.

Employee Compensation

Comment: Most commenters agreed with CMS' proposal to expand the occupations used to calculate the non-physician employee wage portion of the PE GPCI since the updated occupations better reflect the occupations found in physician practices. Many commenters indicated that BLS was the most appropriate data source since it represents the most current data available. Several commenters agreed with IOM's recommendation to include the full range of occupations employed in physicians' offices (100 percent of total non-physician wage share) from the BLS data, rather than the occupations representing 90 percent of the total non-physician wage share that we proposed. A few commenters did not support the use of BLS data since they do not include data describing the number of hours worked. A few commenters who provide radiation oncology services recommended adding the salaries of medical physicists to the non-physician employee compensation calculation based on wage data from the American Association of Physicists in Medicine or the American Academy of Pain Medicine. Some commenters indicated the occupational weights utilized by CMS are not representative of their actual practices or the Medical Group Management Association (MGMA) data.

Response: We agree with the commenters who indicated that the BLS is the most current and appropriate data source and disagree with the commenters who did not support the use of BLS data since it does not include data describing the number of hours worked. We believe that the BLS data provide the necessary detail on occupational categories and offer national level cost share estimates for the offices of physicians industry. In addition, as IOM noted in its report: ''The committee finds that independent, health-care specific data from the BLS provide the most conceptually appropriate measure of differences in wages for health professional labor and clinical and administrative office staff.'' (Geographic Adjustment in Medicare Payment: Phase I: Improving Accuracy, pp. 5–34, available at *http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.*)

We also agree with commenters who stated that the updated occupations better reflect the occupations found in physician practices and those who indicated we should expand the occupations to include the full range of

occupations employed in physician offices as recommended by IOM. As IOM noted in its report, ''the expansion of occupations will be a better reflection of the current workforce and a broader range of health professions, which will help to improve the accuracy of the adjustment. In addition, the expansion will anticipate further changes in the workforce brought by changes in labor market, including the increased demand for expertise in the adoption and use of health information technology'' (pp. 5–34). As such, we are modifying our proposal and including all (100%) of non-physician occupations in the offices of physicians industry in our employee compensation PE calculation. Our modification to include the full range of non-physician occupations in response to these comments will increase the number of occupations captured in our employee wage calculation from 33 to 155.

We disagree with commenters who provide radiation oncology services and suggested that we should include medical physicists wage data from the American Association of Physicists in Medicine or the American Academy of Pain Medicine. The use of a consistent and contemporaneous source for the employment and wage data included in the calculation is preferable to a mix of supplemental data sources. Also, while BLS does not collect employment and wage data for medical physicists or health physicists specifically, it does collect employment and wage data for physicists as a whole (SOC code 19–2012 specifically includes physicists, see *http://www.bls.gov/opub/ooq/2011/summer/art02.pdf,* pg. 20). These data will be included in our calculation now that we are incorporating the full range of occupations employed in physician offices.

With respect to the commenters who indicated the occupational weights utilized by CMS are not representative of their actual practices or the MGMA data, we understand that national occupational weights may not match individual practices or subsets of practices. However, we agree with IOM's preference for ''a consistent set of national weights applied to wage data from the full range of health sector occupations so that hourly wage comparisons can be made'' (pp. 5–34).

Office Rent

Comment: Some commenters agreed with our proposal to use the ACS data instead of the HUD FMR data. Additionally, some commenters stated that the 3-year ACS was preferable to the 5-year ACS rental data, because it is more recent and thus more likely to reflect current value differences in the rapidly changing marketplace. However, most commenters reiterated their longstanding opposition to the use of residential rent as a proxy for physician office space and indicated that a better solution would be for the government to develop actual data on the cost of renting medical office space consistent with the IOM recommendation. Some commenters recommended a survey of physicians to acquire data on medical office rent. Others recommended a continued use of HUD data for CY 2012 until the ACS is more robust. Several commenters recommended that CMS use data from the MGMA survey to develop a medical office rent index. Commenters also raised issues with the relative relationship between selected individual counties in the ACS data or between the ACS data and CMS' assigned weights, questioning the validity of the methodology. These comments noted that the rent index in Santa Clara increased 7 percent yet remained unchanged in surrounding counties; the rent index in Ft. Lauderdale, Florida, and Teton County, Wyoming, are higher than rent index for Manhattan, New York; and Polk County, Iowa, and San Francisco County, California, have inconsistencies between the ACS-reported median and CMS' assigned weights.

Response: We appreciate all the comments received on our proposal to utilize the 3-year (2006–2008) ACS 2 bedroom rental data as our proxy for physician office rent. We agree with the commenters who stated that the ACS data is preferable to the current HUD FMR data. We also agree with commenters that a commercial data source for office rent that provided for adequate data representation of urban and rural areas would be preferable to a residential rent proxy. As we have previously discussed in the CY 2005, CY 2008, and CY 2011 (69 FR 66262, 72 FR 73257, and 75 FR 73257 respectively) final rules, we recognize that apartment rents may not be a perfect proxy for physician office rent. We have conducted an exhaustive search for a reliable commercial rental data source and have not found any reliable data that meets our accuracy standards. We describe in detail our search for a current, reliable, and publicly available commercial rent data source in our ''Final Report on the Sixth Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule'' viewable at *http://www.cms.gov/PhysicianFeeSched/downloads/GPCI_Report.pdf.* In addition, the IOM in their report titled ''Geographic Adjustment in Medicare Payment Phase 1: Improving Accuracy'' (pp 5–35) was unable to identify a source for commercial rent data.

With regards to surveying physicians directly to gather data to compute office rent, we note that development and implementation of a survey could take several years. Moreover, we have historically not sought direct survey data from physicians related to the GPCI to avoid issues of circularity and self-reporting bias. Also, in the CY 2011 final rule with comment period (75 FR 73259) we asked for specific public comments regarding the benefits of utilizing physician cost reports to potentially achieve greater precision in measuring the relative cost difference among Medicare localities. We also asked for comments related to the administrative burden of requiring physicians to routinely complete these cost reports and whether this should be mandatory for physicians practices. We did not receive any feedback specifically related to this comment solicitation during the open public comment period for the CY 2011 final rule with comment period.

With regard to comments requesting that CMS use data from the MGMA survey to develop the office rent index, as we stated in the CY 2011 final rule with comment period (75 FR 73257), we have concerns with both the sample size and representativeness of the MGMA data. For example, the responses represent only about 2,250 (or approximately 1 percent of physician practices nationwide) and have disproportionate sample sizes for each State, suggesting very uneven response rates geographically. In addition, we also have concerns that the MGMA data have the potential for response bias. The MGMA's substantial reliance on its membership base suggests a nonrandom selection into the respondent group. Some evidence for such issues in the MGMA data arises from the very different sample sizes by State. For example, in the MGMA data, 10 States have fewer than 10 observations each, and California, New York, and New Jersey have fewer than 10 observations per locality. Therefore, we continue to believe the MGMA survey data would not be a sufficient rental data source for all PFS localities.

With regards to comments that rents in Santa Clara increased 7 percent yet remained unchanged in the surrounding counties (San Francisco, San Mateo and Santa Cruz), we contacted the Census Bureau and verified that the data were correct. We also checked with the Census Bureau regarding commenter observations that the rent index value

for two bedroom rental units is higher in Ft. Lauderdale, Florida, and Teton County, Wyoming, than in Manhattan. Census verified that these data were correct.

With regards to comments on rents in Polk County, Iowa, compared to San Francisco County, California, Polk County has the second highest office rent index of any county in Iowa (at 0.848). In order to accurately compare the specific relationship between these two counties office rent indices, the Polk County specific office rent index of (.848) should be applied. However, the commenters applied the Iowa ''Statewide'' locality level index of (.696) to Polk County in their calculations. Because Iowa is a Statewide locality, the higher office rent index for Polk County is reduced when combined with lower cost counties in our GPCI methodology.

As we have stated previously, we did not receive a special tabulation from Census in time to analyze 5-year ACS rental data as a potential data source for physician office rent for the CY 2012 rulemaking cycle. We have now received the 5-year ACS special tabulation from Census and will examine its suitability as a potential proxy for physician office rent. We will also continue our evaluation of ACS rental data during the upcoming year, and may propose further modifications to our office rent methodology in the CY 2013 PFS proposed rule.

We also note that HUD has proposed a new FMR methodology for 2012 that abandons the use of Census long-form data, which are no longer being collected, and instead relies exclusively on ACS data. We will be examining this new proposed methodology to potentially inform future rulemaking.

Purchased Services

Comment: Commenters generally agreed with our proposal to create a purchased service index to capture labor-related categories that reside within the ''All Other Services'' and ''Other Professional Expenses'' MEI categories. In addition, several commenters noted that the purchased services index accurately reflects variable professional and non-professional labor costs. However, some commenters disagreed with the proposal to create a purchased service index. The reasons cited included that there is no statutory requirement to add the purchased services proxy to the PE GPCI; the proposed methodology does not adequately capture geographic variation in purchased services; (for example there is no basis to support the assertion that the cost of capital is equal across the country) and, the purchased service index must be reflective of actual physician practice cost expenses and should be based on physician survey data. Lastly, some commenters recommend that CMS consult with physicians' organizations and others to test its categorizations, methodologies, and assumptions.

Response: We agree with commenters who stated that the purchased services index adds an additional level of precision to our PE GPCI calculations. Even though physician practices often purchase accounting, legal, advertising, consulting, landscaping, and other services from a variety of outside contractors, we have not previously included regional variation in the cost of purchased services within the current employee wage index. Specifically, the current methodology only measures regional variation in wages for workers that physician practices employ directly. For these reasons, we worked with our contractor to develop our proposed ''purchased services index'' to account for the regional labor cost variation within contracted services. This index captures labor-related categories residing within the ''all other services'' and ''other professional expenses'' MEI categories, and addresses the concerns of commenters, who in the CY 2011 final rule with comment period (75 FR 73258), thought that these services needed to be geographically adjusted.

We disagree with commenters who think there is insufficient statutory basis for a purchased services index. The incorporation of a purchased services index improves the accuracy of the GPCI consistent with the statute. It will allow for the GPCI to account for geographic variation in the price of a wider range of inputs.

We also disagree with commenters who asserted that the proposed methodology does not adequately capture geographic variation in purchased services, including the cost of capital, and asserted that our data sources were inadequate. To adjust for regional variation in the labor inputs of purchased services requires four key elements. These elements include: Wage data by occupation, industry employment levels, labor-related classifications by industry, and the share of physician practice expense. We are using a combination of BLS OES data and MEI weight data for these elements. The BLS OES data is the best currently available data source for this purpose and is used in many aspects of the GPCI calculation. The MEI weights represent our actuaries' best estimate for the weights for these categories. For a fuller discussion of the derivation of the MEI weights, see the CY 2011 final rule with comment period (75 FR 73262). With respect to capital, it is important to note that the proposed purchased services index does not assume that the cost of capital for physician practices is constant across the nation; instead, it assumes that the cost of capital for contracted firms is constant across the nation. Within the purchased services index, we assume a constant cost of capital for the purchased service firm primarily because we do not believe a reliable data source to measure capital costs for each purchased service industry currently exists.

With respect to commenters who recommended that we consult with physician organizations and others to test our categorizations, methodologies, and assumptions, we have been and will continue to be transparent with respect to our calculation of the purchased services index. We solicited comments on our proposed approach and have given consideration to all comments received.

Updated Cost Share Weights

Comment: Commenters expressed both support and concern with our proposal to update the cost share weights to reflect the 2006-based MEI weights finalized in the CY 2011 final rule with comment period. Several commenters noted that it was appropriate for CMS to update the cost share weights based on the more recent AMA physician survey data reflected in the current MEI weights, but not currently reflected in the GPCI cost share weights. Other commenters stated that the cost share weights should not be adjusted until CMS convenes the MEI technical advisory panel. A few commenters indicated that CMS should not update the cost share weights but should instead explore the use of alternative data sources, such as MGMA or physician surveys, for the weights.

Response: We agree with commenters who supported updating the GPCI cost share weights based on the MEI weights, which reflect the most recent AMA survey data. We have historically updated the GPCI cost share weights consistent with previous adjustments to the MEI. Due partly to concerns commenters raised during last year's rulemaking (see 75 FR 73256) on specific aspects of the GPCI methodology, we delayed updating the GPCI cost weights to reflect the updated MEI weights. Our CY 2012 changes to the GPCI methodology have addressed these comments where appropriate.

We disagree with commenters who indicated that the cost share weights

should not be adjusted until CMS convenes the MEI technical advisory panel. The current MEI cost share weights are based on the most recent AMA survey data. The current GPCI cost share weights are based on the old MEI weights reflecting older AMA survey data. It would not be appropriate to continue to delay the adoption of the current MEI weights reflective of more recent AMA survey data in favor of continuing to use the old MEI weights reflective of older AMA survey data. For additional discussion of the derivation of the MEI weights, please see (75 FR 73262). We will study the findings and recommendations of the MEI technical advisory panel once the panel has had an opportunity to meet and issue its findings. For similar reasons, we also disagree with commenters who indicated that CMS should not update the cost share weights but should instead explore the use of alternative data sources, such as MGMA or physician surveys, for the weights. In addition, as discussed earlier, we have concerns with both the sample size and representativeness of the MGMA data.

Impacts

Comment: Many commenters requested that CMS should provide an impact table that separately shows the impact of each of our proposals.

Response: We will provide separate impact tables in our ''Revisions to the Sixth Update of the Geographic Practice Cost Index: Final Report'' that will individually show the GAF impacts of: Revising the GPCI cost share weights to be consistent with the revised and rebased 2006-based MEI; expanding the occupations used in the calculation of non-physician employee wage to reflect the full range of occupations in the offices of physicians' industry; implementing a purchased service index to account for labor-related services in the ''all other services'' and ''other professional services'' MEI categories; and utilizing the 2006–2008 ACS for two bedroom units as the proxy for physician office rent. This final report is viewable at the following Web address: *http://www.cms.gov/PhysicianFeeSched/*.

Delay Implementation of GPCI Revisions Until IOM Studies Are Completed

Comment: Many commenters urged us not to move forward with proposed changes to the PE GPCI until CMS and various stakeholders have had an opportunity to assess the full impacts and recommendations of the IOM reports on Medicare geographic adjustments.

Response: As previously mentioned, section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the Affordable Care Act) requires the Secretary to ''analyze current methods of establishing practice expense adjustments under subparagraph (A)(i) and evaluate data that fairly and reliably establishes distinctions in the cost of operating a medical practice in the different fee schedule areas.''

Moreover, section 1848(e)(1)(H)(v) of the Act requires the Secretary to make appropriate adjustments to the PE GPCIs as a result of the required analysis no later than January 1, 2012. As a result of our analysis, we proposed the four changes to the PE GPCI calculation as discussed previously in this section. While we fully intend to continue our review of the recently released revised IOM Phase I report on the Medicare GPCIs, it is important and consistent with the statute to proceed with appropriate improvements to the GPCI methodology in conjunction with our review of IOM's reports and IOM's continuing work in this area. We may propose further improvements and modifications to the GPCIs methodology in future rulemaking once we have had an opportunity to assess IOM's recommendations in their entirety.

Budget Neutrality

Comment: Some commenters stated that the modifications proposed in the revised Sixth GPCI Update were not budget neutral. These commenters provided tables illustrating the impacts on the single view chest x-ray service.

Response: We disagree that the modifications in the revised Sixth GPCI were not budget neutral. Our actuaries have determined that the CY 2012 GPCIs are budget neutral in the aggregate prior to the application of any statutory GPCI provisions (section 1848(e)(1)(G) and section 1848(e)(1)(I) of the Act) that are exempt by law from budget neutrality. The GPCIs are not necessarily budget neutral on an individual service by service basis.

Other Issues

We received other public comments on matters that were not related to our proposed CY 2012 changes to the GPCIs. We thank the commenters for sharing their views and suggestions. Because we did not make proposals regarding these matters, we do not generally summarize or respond to such comments in this final rule with comment period. For example, we received numerous comments related to the physician work GPCI and the aforementioned expiration of the 1.000 work floor. Since we only proposed to update the cost share weights attributed to physician work, and noted that the statutorily required 1.0 physician work floor would be expiring at the end of CY 2011 in the CY 2012 proposed rule, we will not be responding to comments related to our methodologies or calculations of physician work in this final rule with comment period. For an in-depth discussion of our most recent physician work GPCI update, see the CY 2011 final rule with comment period (75 FR 73252 and 75 FR 73256 through 73260). We look forward to reviewing and evaluating the IOM's recommendations related to physician work included in its revised Phase I report. After we have reviewed the IOM's recommendations in their entirety, we may propose modifications to the physician work GPCI in future rulemaking.

We also received several comments regarding the calculations and methodology used to calculate the MEI, although we did not propose any changes in the methodology used to calculate the MEI. Many commenters reiterated concerns regarding the assignment of MEI weights to the 10 office expense subcategories as outlined in the 2011 Medicare physician payment schedule final rule with comment period. According to some commenters, it is not clear that the AMA PPIS survey expense categories match up with the industry-level data from the Bureau of Economic Analysis in a way that makes this assignment of subcategory weights possible. These commenters further state that the MEI technical advisory panel should revisit this issue, and consider whether other sources of data are available to split office rent from other types of office expenses, and to validate the office rent share as a percent of total expense.

While this issue is outside the scope of this final rule with comment, we note that the costs reported in the 2006 AMA PPIS survey questions for office expenses were crosswalked as closely as possible to the 2002 BEA I/O benchmark categories. The weights for Office Expenses found in the MEI were appropriately based on information reported by self-employed physicians and selected self-employed non-medical doctor specialties found in the 2006 American Medical Association Physician Practice Information Survey (PPIS). The PPIS was developed by medical associations and captures the costs of operating a medical practice, including office rents and non-physician wages. The survey results were further disaggregated using data from the Bureau of Economic Analysis' Benchmark Input/Output tables for Offices of Physicians, Dentists, and

Other Health Professionals. These resulting cost shares, along with the methods that were utilized in developing them, were proposed (75 FR 40087 through 40092) and finalized (75 FR 73262 through 73276) during the calendar year 2011, Physician Fee Schedule rule, rulemaking process. As stated in the CY 2011 final rule, (75 FR 73270 through 73276), the MEI technical advisory panel, will be asked to fully evaluate the index. In particular, the panel will be evaluating all technical aspects of the MEI including the cost categories, their associated weights and price proxies, and the productivity adjustment.

e. Summary of CY 2012 Final GPCIs

After consideration of the public comments received on the GPCIs, we are finalizing the revisions to the 6th GPCI update using the most current data, with modifications. We are also finalizing the proposal to change the GPCI cost share weights for CY 2012. As a result, the cost share weight for the physician work GPCI (as a percentage of the total) will be 48.266 percent, and the cost share weight for the PE GPCI will be 47.439 percent with a change in the employee compensation component from 18.654 to 19.153 percentage points. The cost share weight for the office rent component of the PE GPCI will be 10.223 percentage points (fixed capital with utilities), and the medical equipment, supplies, and other miscellaneous expenses component will be 9.968 percentage points. Moreover, the cost share weight for the malpractice GPCI will be 4.295 percent. In addition, we are finalizing the weight for purchased services at 8.095 percentage points (5.011 percentage points will be adjusted for geographic cost differences). Additionally, we will review the complete findings and recommendations from the Institute of Medicine's studies on geographic adjustment factors for physician payment and the MEI technical advisory panel once that information becomes fully available to CMS. We will once again consider the GPCIs for CY 2013 rulemaking in the context of our annual PFS rulemaking beginning in CY 2012 based on the information available at that time. We are finalizing the use of 2006 through 2008 ACS two bedroom rental data as a proxy for the relative cost difference in physicians' offices. Moreover, we will examine 5-year ACS rental data to determine its appropriateness as a potential data source for physician office rent. We will also examine HUDs CY 2012 proposed methodology, which utilizes ACS data exclusively, for potential use in future rulemaking. We are also finalizing our proposal to create a purchased services index to account for labor-related services with the ''all other services'' and ''other professional expenses'' MEI components. In response to public commenters who recommended we utilize BLS data to capture the ''full range'' of occupations included in the offices of physician industry to calculate employee wage, we are modifying our original proposal and expanding the number of occupations utilized in our calculation of non-physician employee wages to reflect 100 percent of the total wage share of non-physician occupations in the offices of physicians' industry.

As we indicated previously in this section, section 103 of the Medicare and Medicaid Extenders Act (MMEA) of 2010 (Pub. L. 111–309) extended the 1.0 work GPCI floor only through December 31, 2011. Therefore, the CY 2012 physician work GPCIs and summarized GAFs do not reflect the 1.0 work floor. Moreover, the limited recognition of cost differences in employee compensation and office rent for the PE GPCIs, and the related hold harmless provision, required under section 1848 (e)(1)(H) of the Act was only applicable for CY 2010 and CY 2011 (75 FR 73253) and, therefore under current law, is no longer effective beginning in CY 2012. However, the permanent 1.5 work GPCI floor for Alaska (as established by section 134(b) of the MIPPA) will remain in effect for CY 2012. We are finalizing the CY 2012 GPCIs shown in Addendum E. The GPCIs have been budget neutralized to ensure that nationwide, total RVUs are not impacted by changes in locality GPCIs. The 1.0 PE GPCI floor for frontier States was applied to the budget neutralized GPCIs. The frontier States are the following: Montana; Wyoming; North Dakota; Nevada; and South Dakota. The CY 2012 updated GAFs and GPCIs may be found in Addenda D and E of this final rule with comment period.

3. Payment Localities

The current PFS locality structure was developed and implemented in 1997. There are currently 89 total PFS localities; 34 localities are Statewide areas (that is, only one locality for the entire State). There are 52 localities in the other 16 States, with 10 States having 2 localities, 2 States having 3 localities, 1 State having 4 localities, and 3 States having 5 or more localities. The District of Columbia, Maryland, Virginia suburbs, Puerto Rico, and the Virgin Islands are additional localities that make up the remaining 3 of the total of 89 localities. The development of the current locality structure is described in detail in the CY 1997 PFS proposed rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494).

As we have previously noted in the CYs 2008 and 2009 proposed rules (72 FR 38139 and 73 FR 38513), any changes to the locality configuration must be made in a budget neutral manner within a State and can lead to significant redistributions in payments. For many years, we have not considered making changes to localities without the support of a State medical association in order to demonstrate consensus for the change among the professionals whose payments would be affected (since such changes would be redistributive, with some increasing and some decreasing). However, we have recognized that, over time, changes in demographics or local economic conditions may lead us to conduct a more comprehensive examination of existing payment localities.

For the past several years, we have been involved in discussions with physician groups and their representatives about recent shifts in relative demographics and economic conditions. We explained in the CY 2008 PFS final rule with comment period that we intended to conduct a thorough analysis of potential approaches to reconfiguring localities and would address this issue again in future rulemaking. For more information, we refer readers to the CY 2008 PFS proposed rule (72 FR 38139) and subsequent final rule with comment period (72 FR 66245).

As a follow-up to the CY 2008 PFS final rule with comment period, we acquired a contractor to conduct a preliminary study of several options for revising the payment localities on a nationwide basis. The final report entitled, ''Review of Alternative GPCI Payment Locality Structures—Final Report,'' is accessible from the CMS PFS Web page *http://www.cms.hhs.gov/PhysicianFeeSched/10_Interim_Study.asp#TopOfPage* under the heading ''Review of Alternative GPCI Payment Locality Structures—Final Report.'' The report may also be accessed directly from the following link: *http://www.cms.gov/PhysicianFeeSched/downloads/Alt_GPCI_Payment_Locality_Structures_Review.pdf.*

We did not make any proposals regarding the PFS locality configurations for CY 2012. However, we did receive some comments regarding IOM's recommendation to modify Medicare PFS localities to reflect metropolitan statistical areas (MSA)-based definitions. We will

address any changes to Medicare PFS localities in future rulemaking.

4. Report From the Institute of Medicine

At our request, the Institute of Medicine is conducting a study of the geographic adjustment factors in Medicare payment. It is a comprehensive empirical study of the geographic adjustment factors established under sections 1848(e) (GPCI) and 1886(d)(3)(E) of the Act (hospital wage index). These adjustments are designed to ensure Medicare payment fees and rates reflect differences in input costs across geographic areas. The factors IOM is evaluating include the—

- Accuracy of the adjustment factors;
- Methodology used to determine the adjustment factors, and
- Sources of data and the degree to which such data are representative.

Within the context of the U.S. health care marketplace, the IOM is also evaluating and considering the—

- Effect of the adjustment factors on the level and distribution of the health care workforce and resources, including—

++ Recruitment and retention taking into account mobility between urban and rural areas;

++ Ability of hospitals and other facilities to maintain an adequate and skilled workforce; and

++ Patient access to providers and needed medical technologies;

- Effect of adjustment factors on population health and quality of care; and
- Effect of the adjustment factors on the ability of providers to furnish efficient, high value care.

The revised first report ''Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy'' that was released September 28, 2011 and is available on the IOM Web site *http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx*. It evaluates the accuracy of geographic adjustment factors and the methodology and data used to calculate them, and contains supplemental GPCI recommendations that were not contained in IOM's initial June 1st report. In its final report, scheduled to be released in the spring of 2012, the IOM will consider the role effect of Medicare payments in on matters such as the distribution of the health care workforce, population health, and the ability of providers to produce high-value, high-quality health care.

The recommendations included in IOM's revised Phase I report that relate to or would have an effect on the GPCIs are summarized as follows:

- Recommendation 2–1: The same labor market definition should be used for both the hospital wage index and the physician geographic adjustment factor. Metropolitan statistical areas and Statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets.
- Recommendation 2–2: The data used to construct the hospital wage index and the physician geographic adjustment factor should come from all health care employers.
- Recommendation 5–1: The GPCI cost share weights for adjusting fee-for-service payments to practitioners should continue to be national, including the three GPCIs (work, practice expense, and liability insurance) and the categories within the practice expense (office rent and personnel).
- Recommendation 5–2: Proxies should continue to be used to measure geographic variation in the physician work adjustment, but CMS should determine whether the seven proxies currently in use should be modified.
- Recommendation 5–3: CMS should consider an alternative method for setting the percentage of the work adjustment based on a systematic empirical process.
- Recommendation 5–4: The practice expense GPCI should be constructed with the full range of occupations employed in physicians' offices, each with a fixed national weight based on the hours of each occupation employed in physicians' offices nationwide.
- Recommendation 5–5: CMS and the Bureau of Labor Statistics should develop an agreement allowing the Bureau of Labor Statistics to analyze confidential data for the Centers for Medicare and Medicaid Services.
- Recommendation 5–6: A new source of information should be developed to determine the variation in the price of commercial office rent per square foot.
- Recommendation 5–7: Nonclinical labor-related expenses currently included under practice expense office expenses should be geographically adjusted as part of the wage component of the practice expense.

We note that the GPCI revisions we are finalizing in this final rule with comment period address three of the IOM recommendations referenced above. Specifically, our final GPCIs utilize the full range of non-physician occupations in the non-physician employee wage calculation consistent with IOM recommendation 5–4. Additionally, we created a new purchased service index to account for non-clinical labor-related expenses similar to IOM recommendation 5–7. Lastly, we have consistently used national cost share weights (MEI) to determine the appropriate weight attributed to each GPCI component, which is supported by recommendation 5–1. We may propose further improvements to the GPCI methodology in future rulemaking to address the remaining IOM recommendations once we have had an opportunity to assess IOM's recommendations in their entirety.

E. Medicare Telehealth Services for the Physician Fee Schedule

1. Billing and Payment for Telehealth Services

a. History

Prior to January 1, 1999, Medicare coverage for services delivered via a telecommunications system was limited to services that did not require a face-to-face encounter under the traditional model of medical care. Examples of these services included interpretation of an x-ray, or electrocardiogram, or electroencephalogram tracing, and cardiac pacemaker analysis.

Section 4206 of the BBA provided for coverage of, and payment for, consultation services delivered via a telecommunications system to Medicare beneficiaries residing in rural health professional shortage areas (HPSAs) as defined by the Public Health Service Act. Additionally, the BBA required that a Medicare practitioner (telepresenter) be with the patient at the time of a teleconsultation. Further, the BBA specified that payment for a teleconsultation had to be shared between the consulting practitioner and the referring practitioner and could not exceed the fee schedule payment which would have been made to the consultant for the service provided. The BBA prohibited payment for any telephone line charges or facility fees associated with the teleconsultation. We implemented this provision in the CY 1999 PFS final rule with comment period (63 FR 58814).

Effective October 1, 2001, section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554) (BIPA) added a new section, 1834(m), to the Act which significantly expanded Medicare telehealth services. Section 1834(m)(4)(F)(i) of the Act defines *Medicare telehealth* services to include consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when delivered via a telecommunications system. We first implemented this

provision in the CY 2002 PFS final rule with comment period (66 FR 55246). Section 1834(m)(4)(F)(ii) of the Act required the Secretary to establish a process that provides for annual updates to the list of Medicare telehealth services. We established this process in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified in regulations at § 410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under § 410.78(a)(3), an interactive telecommunications system is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real time interactive communication between the patient and the practitioner at the distant site. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system. An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act does allow the use of asynchronous ''store-and-forward'' technology in delivering these services when the originating site is a Federal telemedicine demonstration program in Alaska or Hawaii. As specified in regulations at § 410.78(a)(1), store and forward means the asynchronous transmission of medical information from an originating site to be reviewed at a later time by the practitioner at the distant site.

Medicare telehealth services may be provided to an eligible telehealth individual notwithstanding the fact that the individual practitioner providing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual means an individual enrolled under Part B who receives a telehealth service furnished at an originating site. As specified in BIPA, originating sites are limited under section 1834(m)(3)(C) of the Act to specified medical facilities located in specific geographic areas. The initial list of telehealth originating sites included the office of a practitioner, a critical access hospital (CAH), a rural health clinic (RHC), a Federally qualified health center (FQHC) and a hospital (as defined in Section 1861(e) of the Act). More recently, section 149 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) expanded the list of telehealth originating sites to include hospital-based renal dialysis centers, skilled nursing facilities (SNFs), and community mental health centers (CMHCs). In order to serve as a telehealth originating site, these sites must be located in an area designated as a rural health professional shortage area (HPSA), in a county that is not in a metropolitan statistical area (MSA), or must be an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000. Finally, section 1834(m) of the Act does not require the eligible telehealth individual to be presented by a practitioner at the originating site.

b. Current Telehealth Billing and Payment Policies

As noted previously, Medicare telehealth services can only be furnished to an eligible telehealth beneficiary in an originating site. An originating site is defined as one of the specified sites where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system. In general, originating sites must be located in a rural HPSA or in a county outside of an MSA. The originating sites authorized by the statute are as follows:

- Offices of a physician or practitioner.
- Hospitals.
- CAHs.
- RHCs.
- FQHCs.
- Hospital-Based Or Critical Access Hospital-Based Renal Dialysis Centers (including Satellites).
- SNFs.
- CMHCs.

Currently approved Medicare telehealth services include the following:

- Initial inpatient consultations.
- Follow-up inpatient consultations.
- Office or other outpatient visits.
- Individual psychotherapy.
- Pharmacologic management.
- Psychiatric diagnostic interview examination.
- End-stage renal disease (ESRD) related services.
- Individual and group medical nutrition therapy (MNT).
- Neurobehavioral status exam.
- Individual and group health and behavior assessment and intervention (HBAI).
- Subsequent hospital care.
- Subsequent nursing facility care.
- Individual and group kidney disease education (KDE).
- Individual and group diabetes self-management training services (DSMT).

In general, the practitioner at the distant site may be any of the following, provided that the practitioner is licensed under State law to furnish the service being furnished via a telecommunications system:

- Physician.
- Physician assistant (PA).
- Nurse practitioner (NP).
- Clinical nurse specialist (CNS);
- Nurse-midwife.
- Clinical psychologist.
- Clinical social worker.
- Registered dietitian or nutrition professional.

Practitioners furnishing Medicare telehealth services are located at a distant site, and they submit claims for telehealth services to the Medicare contractors that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system. Distant site practitioners must submit the appropriate HCPCS procedure code for a covered professional telehealth service, appended with the -GT (Via interactive audio and video telecommunications system) or -GQ (Via asynchronous telecommunications system) modifier. By reporting the -GT or -GQ modifier with a covered telehealth procedure code, the distant site practitioner certifies that the beneficiary was present at a telehealth originating site when the telehealth service was furnished. The usual Medicare deductible and coinsurance policies apply to the telehealth services reported by distant site practitioners.

Section 1834(m)(2)(B) of the Act provides for payment of a facility fee to the originating site. To be paid the originating site facility fee, the provider or supplier where the eligible telehealth individual is located must submit a claim with HCPCS code Q3014 (Telehealth originating site facility fee), and the provider or supplier is paid according to the applicable payment methodology for that facility or location. The usual Medicare deductible and coinsurance policies apply to HCPCS code Q3014. By submitting HCPCS code Q3014, the originating site certifies that it is located in either a rural HPSA or non-MSA county or is an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000 as specified in section 1834(m)(4)(C)(i)(III) of the Act.

As previously described, certain professional services that are commonly

furnished remotely using telecommunications technology, but that do not require the patient to be present in-person with the practitioner when they are furnished, are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in-person at the medical facility furnishing care to the patient. Such services typically involve circumstances where a practitioner is able to visualize some aspect of the patient's condition without the patient being present and without the interposition of a third person's judgment. Visualization by the practitioner can be possible by means of x-rays, electrocardiogram or electroencephalogram tracings, tissue samples, etc. For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted via telephone (that is, electronically, rather than by means of a verbal description) is a covered physician's service. These remote services are not Medicare telehealth services as defined under section 1834(m) of the Act. Rather, these remote services that utilize telecommunications technology are considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology; they are paid under the same conditions as in-person physicians' services (with no requirements regarding permissible originating sites), and should be reported in the same way (that is, without the -GT or -GQ modifier appended).

2. Requests for Adding Services to the List of Medicare Telehealth Services

As noted previously, in the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. We assign any request to make additions to the list of Medicare telehealth services to one of the following categories:

- Category 1: Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter. We also look for similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment.
- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the use of a telecommunications system to deliver the service produces similar diagnostic findings or therapeutic interventions as compared with the in-person delivery of the same service. Requestors should submit evidence showing that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to in-person delivery of the requested service.

Since establishing the process to add or remove services from the list of approved telehealth services, we have added the following to the list of Medicare telehealth services: individual and group HBAI services; psychiatric diagnostic interview examination; ESRD services with 2 to 3 visits per month and 4 or more visits per month (although we require at least 1 visit a month to be furnished in-person by a physician, CNS, NP, or PA in order to examine the vascular access site); individual and group MNT; neurobehavioral status exam; initial and follow-up inpatient telehealth consultations for beneficiaries in hospitals and skilled nursing facilities (SNFs); subsequent hospital care (with the limitation of one telehealth visit every 3 days); subsequent nursing facility care (with the limitation of one telehealth visit every 30 days); individual and group KDE; and individual and group DSMT services (with a minimum of 1 hour of in-person instruction to ensure effective injection training).

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, requests submitted before the end of CY 2011 will be considered for the CY 2013 proposed rule. Each request for adding a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requestors should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at *http://www.cms.gov/telehealth/.*

3. Submitted Requests for Addition to the List of Telehealth Services for CY 2012

We received requests in CY 2010 to add the following services as Medicare telehealth services effective for CY 2012: (1) Smoking cessation services; (2) critical care services; (3) domiciliary or rest home evaluation and management services; (4) genetic counseling services; (5) online evaluation and management services; (6) data collection services; and (7) audiology services. The following presents a discussion of these requests, including our proposals for additions to the CY 2012 telehealth list.

a. Smoking Cessation Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add smoking cessation services, reported by CPT codes 99406 (Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes) and 99407 (Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes) to the list of approved telehealth services for CY 2012 on a category 1 basis.

Smoking Cessation services are defined as face-to-face behavior change interventions. We believe the interaction between a practitioner and a beneficiary receiving smoking cessation services is similar to the education, assessment, and counseling elements of individual KDE reported by HCPCS code G0420 (Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per 1 hour), and individual MNT services, reported by HCPCS code G0270 (Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in the same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face-to-face with the patient, each 15 minutes); CPT code 97802 (Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes); and CPT code 97803 (Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes), all services that are currently on the telehealth list.

Therefore, we proposed to add CPT codes 99406 and 99407 to the list of telehealth services for CY 2012 on a category 1 basis. Additionally, we proposed to add HCPCS codes G0436 (Smoking and tobacco cessation

counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes) and G0437 (Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes) to the list of telehealth services for CY 2012 since these related services are similar to the codes for which we received formal public requests.

Consistent with this proposal, we also proposed to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include these smoking cessation services as Medicare telehealth services.

Comment: All commenters expressed support for CMS' proposal to add smoking cessation services to the list of Medicare telehealth services for CY 2012. One commenter stated that the proposal would contribute to ensuring that all Medicare beneficiaries—regardless of where they reside—have access to these services that are a valuable step toward reducing tobacco use among the Medicare population. Another commenter stated that the proposal would go far in helping many rural Americans gain access to these services that they would otherwise not have.

Response: We agree with the commenters that adding smoking cessation services to the list of Medicare telehealth services will help to provide greater access to the services for beneficiaries in rural or other isolated areas.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal to add CPT codes 99406 and 99407 to the list of telehealth services for CY 2012 on a category 1 basis. Additionally, we are finalizing our proposal to add HCPCS codes G0436 (Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes) and G0437 (Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes) to the list of telehealth services for CY 2012 and to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include smoking cessation services as Medicare telehealth services.

b. Critical Care Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add critical care service CPT codes 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and 99292 (Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes) to the list of approved telehealth services. We previously received this request for the CY 2009 and CY 2010 PFS rulemaking cycles (73 FR 38517, 73 FR 69744 and 69745, 74 FR 33548, and 74 FR 61764) and did not add the codes on a category 1 basis due to the acute nature of the typical patient. We continue to believe that patients requiring critical care services are more acutely ill than those patients typically receiving any service currently on the list of telehealth services. Therefore, we cannot consider critical care services on a category 1 basis.

In the CY 2009 PFS proposed rule (73 FR 38517), we explained that we had no evidence suggesting that the use of telehealth could be a reasonable surrogate for the in-person delivery of critical care services; therefore, we would not add the services on a category 2 basis. Requestors submitted new studies for CY 2012, but none demonstrated that comparable outcomes to a face-to-face encounter can be achieved using telehealth to deliver these services. The studies we received primarily addressed other issues relating to telehealth services. Some studies addressed the cost benefits and cost savings of telehealth services. Others focused on the positive outcomes of telehealth treatment when compared with no treatment at all. One submitted study addressed the equivalency of patient outcomes for telehealth services delivered to patients in emergency rooms, but the study's authors specifically restricted their population to patients whose complaints were not considered to be genuine emergencies. Given that limitation, it seems unlikely that any of these patients would have required critical care services as defined by CPT codes 99291 and 99292.

We note that consultations are included on the list of Medicare telehealth services and may be billed by practitioners furnishing services to critically ill patients These services are described by the following HCPCS codes: G0425 (Initial inpatient telehealth consultation, typically 30 minutes communicating with the patient via telehealth), G0426 (Initial inpatient telehealth consultation, typically 50 minutes communicating with the patient via telehealth), G0427 (Initial inpatient telehealth consultation, typically 70 minutes or more communicating with the patient via telehealth), G0406 (Follow-up inpatient telehealth consultation, limited, physicians typically spend 15 minutes communicating with the patient via telehealth), G0407 (Follow-up inpatient telehealth consultation, intermediate, physicians typically spend 25 minutes communicating with the patient via telehealth), and G0408 (Follow-up inpatient telehealth consultation, complex, physicians typically spend 35 minutes or more communicating with the patient via telehealth). Critical care services, as reported by the applicable CPT codes and described in the introductory language in the CPT book, consist of direct delivery by a physician of medical care for a critically ill or injured patient, including high complexity decision-making to assess, manipulate, and support vital system functions. Critical care requires interpretation of multiple physiologic parameters and/or application of advanced technologies, including temporary pacing, ventilation management, and vascular access services. The payment rates under the PFS reflect this full scope of physician work. To add the critical services to the telehealth list would require the physician to be able to deliver this full scope of services via telehealth. Based on the code descriptions, we have previously believed that it is not possible to deliver the full range of critical care services without a physical physician presence with the patient.

We note that there are existing Category III CPT codes (temporary codes for emerging services that allow data collection) for remote real-time interactive video-conferenced critical care services that, consistent with our treatment of other Category III CPT codes, are not nationally priced under the PFS. The fact that the CPT Editorial Panel created these additional Category III CPT codes suggests to us that these video-conferenced critical care services are not the same as the in-person critical care services requested for addition to the telehealth list.

Because we did not find evidence that use of a telecommunications system to deliver critical care services produces similar diagnostic or therapeutic outcomes as compared with the face-to-face deliver of the services, we did not propose to add critical care services (as described by CPT codes 99291 and 99292) to the list of approved telehealth services. We reiterated that our decision not to propose to add critical care services to the list of approved telehealth services does not preclude physicians from furnishing telehealth consultations to critically ill patients using the consultation codes that are on the list of Medicare telehealth services.

Comment: One commenter supported CMS's decision not to add critical care services because the use of a telecommunications system to deliver critical services is unlikely to produce

''similar diagnostic findings or therapeutic interventions as compared with the in-person delivery of the same service.''

Response: We appreciate this support for our proposal. As we stated in the CY 2012 PFS proposed rule (76 FR 42843), none of the submitted requests to add these services included evidence that demonstrated delivery via telehealth resulted in comparable outcomes to in-person care.

Comment: One commenter disagreed with CMS' decision not to add critical care services to the list of Medicare Telehealth Services. The commenter argued that because the patient who requires critical care is more acutely ill than patients receiving any of the services currently on the list of approved codes, these services should be added to the list. This commenter also suggested that the proposal to allow consulting physicians to use the inpatient telehealth g-codes to report care of critically ill patients through telehealth was inappropriate because not all critically ill patients are inpatients.

Response: We appreciate and share the commenter's concern for beneficiary access to care. However, we reiterate that no evidence that we received meets the criteria to add these services to the list of Medicare telehealth services. Regarding the appropriateness of the telehealth consultation g-codes in the emergency department setting, we refer the commenter to section II.E.5. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our decision not to add critical care services to the list of Medicare telehealth services for CY 2012.

c. Domiciliary or Rest Home Evaluation and Management Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add the following domiciliary or rest home evaluation and management CPT codes to the telehealth list for CY 2012:

- 99334 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; a problem focused examination; or straightforward medical decision making. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Physicians typically spend 15 minutes with the patient and/or family or caregiver).
- 99335 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Physicians typically spend 25 minutes with the patient and/or family or caregiver).
- 99336 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; a detailed examination; medical decision making of moderate complexity. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Physicians typically spend 40 minutes with the patient and/or family or caregiver).
- 99337 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; a comprehensive examination; medical decision making of moderate to high complexity. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Physicians typically spend 60 minutes with the patient and/or family or caregiver).

A domiciliary or rest home is not permitted under current statute to serve as an originating site for Medicare telehealth services. Therefore, we did not propose to add domiciliary or rest home evaluation and management services to the list of Medicare telehealth services for CY 2012.

Comment: One commenter disagreed with our proposal not to add domiciliary or rest home evaluation and management services because neither domiciliaries nor rest homes are permitted under current statue to serve as an originating site for Medicare Telehealth services. The commenter argued that because CMS added new ESRD-related G-codes to the list of approved Medicare Telehealth services in 2005 despite the fact that dialysis centers were not then permitted under statute to serve as originating sites, CMS' current reasoning is invalid.

Comment: We acknowledge that we previously added certain ESRD services to the list of Medicare telehealth services when dialysis centers were not permitted under statute to serve as telehealth originating sites. However, the services in question can also be furnished in sites that were eligible originating sites when the codes were added to the list. At this time, we do not believe that domiciliary or rest home evaluation and management services can be furnished outside of domiciliaries or rest homes.

After consideration of the public comments we received, we are finalizing our decision not to add domiciliary or rest home evaluation and management services to the list of Medicare telehealth services for CY2012.

d. Genetic Counseling Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add CPT code 96040 (Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family) to the telehealth list for CY 2012. We note that CPT guidance regarding reporting genetic counseling and education furnished by a physician to an individual directs physicians to evaluation and management (E/M) CPT codes and that services described by CPT code 96040 are provided by trained genetic counselors. Physicians and nonphysician practitioners who may independently bill Medicare for their service and who are counseling individuals would generally report office or other outpatient evaluation and management (E/M) CPT codes for office visits that involve significant counseling, including genetic counseling, and these office visit CPT codes are already on the list of telehealth services. CPT code 96040 would only be reported by genetic counselors for genetic counseling services. These practitioners cannot bill Medicare directly for their professional services and they are also not on the list of practitioners who can furnish telehealth services (specified in section 1834(m)(4)(E) of the Act). As such, we do not believe that it would be necessary or appropriate to add CPT code 96040 to the list of Medicare

telehealth services. Therefore, we did not propose to add genetic counseling services to the list of Medicare telehealth services for CY 2012.

Comment: One commenter expressed concerns about beneficiary access concerns to genetic counseling but acknowledged the statutory constraints faced by CMS.

Response: We appreciate the commenter's concerns and their agreement with our conclusions regarding our statutory limitations.

After consideration of the public comments we received, we are finalizing our decision not to add genetic counseling services to the list of Medicare telehealth services for CY 2012.

e. Online Evaluation and Management Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add CPT code 99444 (Online evaluation and management service provided by a physician to an established patient, guardian, or health care provider not originating from a related E/M service provided within the previous 7 days, using the Internet or similar electronic communications network) to the list of Medicare telehealth services.

As we explained in the CY 2008 PFS final rule with comment period (72 FR 66371), we assigned a status indicator of ''N'' (Non-covered service) to these services because: (1) These services are non-face-to-face; and (2) the code descriptor includes language that recognizes the provision of services to parties other than the beneficiary and for whom Medicare does not provide coverage (for example, a guardian).

According to section 1834(m)(2)(A) of the Act, Medicare is required to pay for telehealth services at an amount equal to the amount that a practitioner would have been paid had such service been furnished without the use of a telecommunications system. As such, we do not believe it would be appropriate to make payment for services furnished via telehealth when those services would not otherwise be covered under Medicare. Because CPT code 99444 is currently noncovered, we did not propose to add online evaluation and management services to the list of Medicare Telehealth Services for CY 2012.

Comment: One commenter argued that adding online evaluation and management and other services to the list of Medicare telehealth services would support chronic care management and care coordination. The same commenter also asserted that adding these services would be administratively easy for CMS to implement.

Response: While we appreciate the potential value of maximizing the use of communication technology in care coordination and chronic care management, we cannot consider adding services that are not otherwise payable under the physician fee schedule to the Medicare telehealth benefit, as defined in 1834 (m) of the Act. Our decision not to add online evaluation and management or any other requested services to the list of Medicare telehealth services does not result from concern about administrative burden.

After consideration of the public comments we received, we are finalizing our decision not to add online evaluation and management services to the list of Medicare telehealth services for CY 2012.

f. Data Collection Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add CPT codes 99090 (Analysis of clinical data stored in computers (*e.g.,* ECGs, blood pressures, hematologic data)) and 99091 (Collection and interpretation of physiologic data (*e.g.,* ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, requiring a minimum of 30 minutes of time) to the list of Medicare telehealth services.

As we explained in the in CY 2002 PFS final rule with comment period (66 FR 55309), we assigned a status indicator of ''B'' (Payment always bundled into payment for other services not specified) to these services because the associated work is considered part of the pre- and post-service work of an E/M service. We note that many E/M codes are on the list of Medicare telehealth services.

According to section 1834(m)(2)(A) of the Act, Medicare is required to pay for telehealth services an amount equal to the amount that a practitioner would have been paid had such service been furnished without the use of a telecommunications system. Similar to the point noted previously for online E/M services, we do not believe it would be appropriate to make separate payment for services furnished via telehealth when Medicare would not otherwise make separate payment for the services. Moreover, we believe the payment for these data collection services should be bundled into the payment for E/M services, many of which are already on the Medicare telehealth list. Because CPT codes 99090 and 99091 are currently bundled, we did not propose to add data collection services to the list of Medicare telehealth services for CY 2012.

Comment: Two commenters argued that CMS should pay separately for services like data collection since when furnished they often mitigate the need for an in-person visit and in those cases cannot logically be considered to be bundled with other services.

Response: We thank the commenters for conveying their perspective on the value of such services. However, we continue to believe it would be inappropriate to add services that are not otherwise separately payable under the physician fee schedule to the Medicare telehealth benefit, as defined in 1834 (m) of the Act.

After consideration of the public comments we received, we are finalizing our decision not to add data collection services to the list of Medicare telehealth services for CY 2012.

g. Audiology Services

The American Academy of Audiology submitted a request that CMS add services that audiologists provide for balance disorders and hearing loss to the list of Medicare telehealth services. The request did not include specific HCPCS codes. Nevertheless, it is not within our administrative authority to pay audiologists for services furnished via telehealth. The statute authorizes the Secretary to pay for telehealth services only when furnished by a physician or a practitioner as physician or practitioner are defined in sections 1834(m)(4)(D) and (E) of the Act. Therefore, we did not propose to add services that are primarily provided by audiologists to the list of Medicare telehealth services for CY 2012.

Comment: Several commenters stated broad support for the value of audiology services when furnished through telehealth. These commenters urged CMS to consider other ways of implementing programs that allow audiology services to be furnished through telehealth.

Response: We appreciate the commenters' perspective on the value of audiology services. The statute authorizes payment for telehealth services only when furnished by a physician or practitioner as defined in sections 1834(m)(4)(D) and (E) of the Act. Audiologists do not fall within either of these definitions, and we do not believe there is another way to make

payment to audiologists for telehealth services.

After consideration of the public comments we received, we are finalizing our decision not to add audiology services to the list of Medicare telehealth services for CY 2012.

4. The Process for Adding HCPCS Codes as Medicare Telehealth Services

Along with its submission of codes for consideration as additions to the Medicare telehealth list for CY 2012, the American Telemedicine Association (ATA) also requested that CMS consider revising the annual process for adding to or deleting services from the list of telehealth services. The existing process, adopted in the CY 2003 PFS rulemaking cycle (67 FR 43862 through 43863 and 67 FR 79988 through 79989), is described in section II.E.1. of this final rule with comment period. The following discussion includes a summary of recent requests by the ATA and other stakeholders for changes to the established process for adding services to the telehealth list, an assessment of our historical experience with the current process including the request review criteria, and our proposed refinement to the process for adding services to the telehealth list that would be used in our evaluation of candidate telehealth services beginning for CY 2013.

The ATA asked CMS to consider two specific changes to the process, including—

- Broadening the factors for consideration to include shortages of health professionals to provide in-person services, speed of access to in-person services, and other barriers to care for beneficiaries; and
- Equalizing the standard for adding telehealth services with the standard for deleting telehealth services by adopting a standard that allows services that are safe, effective or medically beneficial when furnished via telehealth to be added to the list of Medicare telehealth services. Similarly, we have received recommendations that CMS place all codes payable under the PFS on the telehealth list and allow physicians and practitioners to make a clinical determination in each case about whether a medically reasonable and necessary service could be appropriately furnished to a beneficiary through telehealth. Under this scenario, stakeholders have argued that CMS would only remove services from the telehealth list under its existing policy for service removal; specifically, that a decision to remove a service from the list of telehealth services would be made using evidence-based, peer-reviewed data which indicate that a specific service is not safe, effective, or medically beneficial when furnished via telehealth (67 FR 79988).

While we share the interests of stakeholders in reducing barriers to health care access faced by some beneficiaries, given that section 1834(m)(2)(F)(ii) of the Act requires the Secretary to establish a process that provides, on an annual basis, for the addition or deletion of telehealth services (and HCPCS codes), as appropriate, we do not believe it would be appropriate to add all services for which payment is made under the PFS to the telehealth list without explicit consideration as to whether the candidate service could be effectively furnished through telehealth. For example, addition of all codes to the telehealth list could result in a number of services on the list that could never be furnished by a physician or nonphysician practitioner who was not physically present with the beneficiary, such as major surgical procedures and interventional radiology services. Furthermore, we do not believe it would be appropriate to add services to the telehealth list without explicit consideration as to whether or not the nature of the service described by a candidate code allows the service to be furnished effectively through telehealth. Section 1834(m)(2)(A) of the Act requires that the distant site physician or practitioner furnishing the telehealth service must be paid an amount equal to the amount the physician or practitioner would have been paid under the PFS has such service been furnished without the use of a telecommunications system. Therefore, we believe that candidate telehealth services must also be covered when furnished in-person; and that any service that would only be furnished through a telecommunications system would be a new service and, therefore, not a candidate for addition to the telehealth list. In view of these considerations, we will continue to consider candidate additions to the telehealth list on a HCPCS code-specific basis based on requests from the public and our own considerations.

We also believe it continues to be most appropriate to consider candidate services for the telehealth list based on the two mutually exclusive established categories into which all services fall—specifically, services that are similar to services currently on the telehealth list (category 1) and services that are not similar to current telehealth services (category 2). Under our existing policy, we add services to the telehealth list on a category 1 basis when we determine that they are similar to services on the existing telehealth list with respect to the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter (67 FR 43862). Since CY 2003, we have added 35 services to the telehealth list on a category 1 basis based on public requests and our own identification of such services. We believe it is efficient and valuable to maintain the existing policy that allows us to consider requests for additions to the telehealth list on a category 1 basis and proposed to add them to the telehealth list if the existing criteria are met. This procedure expedites our ability to identify codes for the telehealth list that resemble those services already on this list, streamlining our review process and the public request and information-submission process for services that fall into this category. Therefore, we believe that any changes to the process for adding codes to the telehealth list should be considered with respect to category 2 additions, rather than category 1 additions.

Our existing criteria for consideration of codes that would be category 2 additions, specifically those candidate telehealth services that are not similar to any current telehealth services, include an assessment of whether the use of a telecommunications system to deliver the services produces similar diagnostic findings or therapeutic interventions as compared with a face-to-face in-person delivery of the same service (67 FR 43682). In other words, the discrete outcome of the interaction between the clinician and patient facilitated by a telecommunications system should correlate well with the discrete outcome of the clinician-patient interaction when performed face-to-face. In the CY 2003 PFS proposed rule (67 FR 43862), we explained that requestors for category 2 additions to the telehealth list should submit evidence that the use of a telecommunications systems does not affect the diagnosis or treatment plan as compared to in-person delivery of the service. We indicated that if evidence shows that the candidate telehealth service is equivalent when furnished in person or through telehealth, we would add it to the list of telehealth services. We refer to this standard in further discussion in this final rule with comment period as the ''comparability standard.'' We stated in the CY 2003 PFS proposed rule (67 FR 43862) that if we determine that the use of a telecommunications system changes the nature or outcome of the service, for

example, as compared with the in-person delivery of the service, we would review the telehealth service addition request as a request for a new service, rather than a different method of delivering an existing Medicare service. For coverage and payment of most services, Medicare requires that a new service must: (1) Fall into a Medicare benefit category; (2) be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act; and (3) not be explicitly excluded from coverage. In such a case, the requestor would have the option of applying for a national coverage determination for the new service.

We believe it is most appropriate to address the ATA and other stakeholder requests to broaden the current factors we consider when deciding whether to add candidate services to the telehealth list—to include factors such as the effects of barriers to in-person care and the safety, effectiveness, or medical benefit of the service furnished through telehealth, as potential refinements to our category 2 criteria. We initially established these category 2 criteria in the interest of ensuring that the candidate services were safe, effective, medically beneficial, and still accurately described by the corresponding codes when delivered via telehealth, while also ensuring that beneficiaries furnished telehealth services receive high quality care that is comparable to in-person care. We believed that the demonstration of comparable clinical outcomes (diagnostic findings and/or therapeutic interventions) from telehealth and in-person services would prove to be the best indicator that all of these conditions were met. While we continue to believe that safety, effectiveness, and medical benefit, as well as accurate description of the candidate telehealth services by the CPT or HCPCS codes, are necessary conditions for adding codes to the list of Medicare telehealth services, our recent experience in reviewing public requests for telehealth list additions and our discussions with stakeholders regarding contemporary medical practice and potential barriers to care, have led us to conclude that the comparability standard for category 2 requests should be modified.

In our annual evaluation of category 2 requests since we adopted the process for evaluating additions to the telehealth list almost 10 years ago, we have consistently observed that requestors have difficulty demonstrating that clinical outcomes of a service delivered via telehealth are comparable to the outcomes of the in-person service. The medical literature frequently does not include studies of the outcomes of many types of in-person services that allow for comparison to the outcomes demonstrated for candidate telehealth services. Furthermore, we know that in some cases the alternative to a telehealth service may be no service rather than an in-person service. The comparability standard may not sufficiently allow for the opportunity to add candidate services to the telehealth list that may be safe, effective, and medically beneficial when delivered via telehealth, especially to beneficiaries who experience significant barriers to in-person care. While we continue to believe that beneficiaries receiving services through telehealth are deserving of high quality health care and that in-person care may be very important and potentially preferable for some services when in-person care is possible, we are concerned that we have not added any services to the telehealth list on a category 2 basis as a result of our reviews. While some candidate services appear to have the potential for clinical benefit when furnished through telehealth, the requests have not met the comparability standard.

Therefore, we proposed to refine our category 2 review criteria for adding codes to the list of Medicare telehealth services beginning in CY 2013 by modifying the current requirement to demonstrate similar diagnostic findings or therapeutic interventions with respect to a candidate service delivered through telehealth compared to in-person delivery of the service (the comparability standard). We proposed to establish a revised standard of demonstrated clinical benefit when the service is furnished via telehealth. We refer to this proposed standard in further discussion in this final rule with comment period as the ''clinical benefit standard.'' To support our review using this revised standard, we would ask requestors to specify in their request how the candidate telehealth service is still accurately described by the corresponding HCPCS or CPT code when delivered via telehealth as opposed to in-person.

We proposed that our refined criteria for category 2 additions would be as follows:

- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests would include an assessment of whether the service is accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient.

Requestors should submit evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient.

The evidence submitted should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings and a list and copies of published peer-reviewed articles relevant to the service when furnished via telehealth. Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

We believe the adoption of this clinical benefit standard for our review of candidate telehealth services on a category 2 basis is responsive to the requests of stakeholders that we broaden the factors taken into consideration to include barriers to care for beneficiaries. It allows us to consider the demonstrated clinical benefit of telehealth services for beneficiaries who might otherwise have no access to certain diagnostic or treatment services. Furthermore, we believe the focus on demonstrated clinical benefit in our review of category 2 requests for addition to the telehealth lists is equivalent to our standard for deleting services from the telehealth list that rests upon evidence that a service is not safe, not effective, or not medically beneficial. Finally, we believe the proposed clinical benefit standard for our review of candidate telehealth services on a category 2 basis is fully consistent with our responsibility to ensure that telehealth services are safe, effective, medically beneficial, and still accurately described by the corresponding codes that would be used for the services when delivered in-person.

We solicited public comments on the proposed refinement to our established process for adding codes to the telehealth list, including the information that requestors should furnish to facilitate our full review of requests in preparation for the CY 2013 PFS rulemaking cycle during which we will use the category 2 review criteria finalized in this final rule with comment period.

Comment: Many commenters supported the proposal to revise the category 2 criteria to incorporate the clinical benefit standard. Many of these commenters stated that they expect the revised criteria to result in both an expanded list of telehealth services and better medical care for beneficiaries who might otherwise not have access to certain diagnostic or treatment services. Several of these commenters explicitly stated that the criteria as described in the proposal presented a rigorous evidentiary standard for demonstrating clinical benefit.

Response: We appreciate the broad support for the proposal. We believe that the proposed clinical benefit standard would allow us to consider the demonstrated clinical benefit of telehealth services for beneficiaries who might otherwise have no access to certain diagnostic or treatment services. We also believe that the proposal would ensure that Medicare telehealth services are safe, effective, and medically beneficial.

Comment: Some commenters advocated for eliminating the process for adding and deleting codes. These commenters argued that the determination of which services can be furnished through telehealth should be left to the judgment of individual physicians. One commenter suggested that CMS should evaluate clinical equivalence for telemedicine procedures by limiting the scope to clinical procedures and interventions that would normally be performed in the hospital setting as a part of ongoing care. A commenting organization informed CMS that it had conducted an extensive study of services and determined a list of services that should be eligible based on positive correlation of discrete outcomes of those services furnished through telehealth and those same services furnished in-person. However, the organization did not provide this analysis with their comments.

Response: We understand the commenters' interests in making broader changes to the way that services are added to or deleted from list of Medicare telehealth services. As we stated in the proposal, we believe that because section 1834(m)(2)(F)(ii) of the Act requires the Secretary to establish a process that provides, on an annual basis, for the addition or deletion of telehealth services (and HCPCS codes), as appropriate, we do not believe it would be appropriate to add all services for which payment is made under the PFS to the telehealth list without explicit consideration as to whether the candidate service could be effectively furnished through telehealth. Furthermore, because section 1834(m)(2)(A) of the Act requires that the distant site physician or practitioner furnishing the telehealth service must be paid an amount equal to the amount the physician or practitioner would have been paid under the PFS had such service been furnished without the use of a telecommunications system, we do not believe it would be appropriate to add services to the telehealth list without explicit consideration as to whether or not the nature of the service described by a candidate code allows the service to be furnished as effectively through telehealth as in an in-person encounter. We believe continuing the current annual process, with the proposed amendment to the category 2 criteria, provides the appropriate opportunity to evaluate whether to add or delete specific services to the list of Medicare telehealth services. Although Medicare has not received many studies comparing clinical outcomes for in-person and telehealth delivery of the same service, we encourage stakeholders that conduct such comparison studies to submit such evidence to support category 2 requests for the addition of particular services to the list.

Comment: One commenter expressed support for the proposal but urged CMS to carefully evaluate its impact if implemented. That commenter suggested that the addition of new services under the proposed standard could incentivize changes in practice patterns where Medicare beneficiaries in remote areas receive consistently a lower level of care if clinical benefit has no relationship to the equivalent of an in-person visit. Another commenter disagreed with the proposal to amend the ''comparability standard'' for adding services to the list of Medicare telehealth services. The commenter asserted that telehealth services can be effective as a step to help patients get the care they need, but should not be used to replace in-person care. The commenter argued that paying for telehealth services that may have some minor benefit as equivalent to an in-person service is misleading to patients and would prevent Medicare beneficiaries from getting the actual in-person care they need.

Response: We appreciate these concerns and agree that Medicare beneficiaries in remote areas deserve access to high quality health care. As we noted in the proposal, we also believe that in-person care may be very important and potentially preferable for some services when in-person care is possible. However, we also know that in some cases the alternative to a telehealth service may be no service rather than an in-person service.

We continue to believe safety, effectiveness, and medical benefit, as well as accurate description of the candidate telehealth services by the CPT or HCPCS codes, are necessary conditions for adding codes to the list of Medicare telehealth services. While we believe that in many cases, the existing standard has led to appropriate category 2 determinations not to add services to the telehealth benefit, we also believe that the current standard has prevented consideration of some services that could be clinically beneficial because there are no studies that compare patient outcomes when services are delivered via telehealth versus in person. This does not support our interests in identifying beneficial services for the telehealth benefit. Specifically, we observe that the medical literature frequently does not include studies of the outcomes of many types of in-person services that allow for comparison to the outcomes demonstrated for candidate telehealth services. We believe that the proposed revision to the existing criteria will allow thorough consideration of a greater number of requests for addition to the list. We would also remind commenters that the annual process will continue to provide stakeholders who support or oppose adding particular services to the list the opportunity to contribute to our evaluations of particular requests through public comment.

Additionally, we note that the established process for deleting services from the list would allow Medicare to consider any available evidence suggesting that the addition of particular services to the list of Medicare telehealth services had detrimentally changed the quality of medical care for Medicare beneficiaries in remote areas. Such evidence could be considered in the context of either a public request or internally generated proposal to delete services from the list of Medicare telehealth services during annual PFS rulemaking. This process was

established during CY 2003 PFS rulemaking. (67 FR 7988)

Finally, we agree with the commenter that argued that we should not add services to the telehealth list based on demonstrated evidence of minor benefit. We would like to clarify that our evidentiary standard of clinical benefit would not include minor or incidental benefits.

Comment: Some commenters offered feedback on the specific kind of information that requestors should furnish to facilitate CMS review of requests to add specific services. One commenter suggested that CMS should recognize any biometrics or clinical parameters known to affect morbidity/mortality as appropriate supporting evidence. Another commenter suggested that CMS should make clear that its list of clinical benefits that could be conferred by the use of telehealth services, as featured in the proposed rule, is not exhaustive. Rather, the list is illustrative. The commenter asked CMS to clarify that there are many kinds of clinical benefits that are possible for telehealth services as well as face-to-face services, and that CMS will consider clinical benefits on a case-by-case basis based on studies submitted by requestors. Another commenter expressed concern that the proposed evaluation criteria are inappropriate since they resemble the criteria for a Medicare coverage determination.

Response: We agree with the commenter who stated that the list of examples of demonstrated clinical benefits as presented in the proposed rule (76 FR 42827) is not exhaustive, but rather illustrative. Furthermore, we acknowledge that our proposal allows us to consider clinical benefits on a case-by-case basis depending on studies submitted by requestors, our own internal evaluation, and information submitted by commenters. While we acknowledge a similarity between some of the examples provided in the proposal and Medicare coverage criteria, we believe that such resemblance is appropriate given our interest in ensuring that services the Secretary adds to the telehealth benefit demonstrate clinical benefit to Medicare beneficiaries.

Comment: Several commenters requested that CMS provide more specific information about how the new criteria will be used to evaluate the requests to add services to the list of Medicare telehealth services. One of these commenters asked CMS to provide workshops and other outreach efforts related to the review criteria.

Response: We appreciate the commenters' interest in requesting greater specificity regarding how the new criteria will be used in evaluation of annual requests. In proposing the new category 2 criteria, we provided some examples of demonstrated benefit instead of establishing a series of specified clinical metrics because we expect the choice of appropriate evaluation criteria should be identified on a case-by-case basis specific to the information submitted with requests to add services through the established annual process.

We believe that establishing more rigid evaluation criteria (for example, criteria that rely on measurement of a series of demonstrated clinical outcomes specified by CMS) might present as many problems as has the current category 2 criteria, because under such a process requestors would be required to submit medical literature that passes a series of hurdles established by us prior to receiving a particular request. We would not be able to assess the benefit of the requested service within the context of the submitted evidence and the specific services. We also believe that such a process might lead to greater administrative burden for requestors and might require constant revision through annual rulemaking to adapt any specific criteria to changes in medical and communication technology as well as developments in medical literature.

Additionally, we note that the application of the proposed criteria to each request will remain subject to public notice and comment. Since we implemented the process to add or delete services, including the existing category 2 criteria, we have used the PFS notice and comment rulemaking process to propose, accept public comments, and ultimately explain how the established evaluation criteria apply to each service we evaluate for addition to the list of Medicare telehealth services. We are not proposing a change to that aspect of the process with this proposed change in category 2 criteria.

Comment: One commenter expressed concern regarding the aspect of the proposed criteria that includes CMS' review of whether the service is accurately described by the corresponding code when delivered via telehealth. The commenter asserted that that aspect of the criteria is self-fulfilling and might prevent the addition of otherwise appropriate services to the list of Medicare telehealth services since the codes were written to describe in-person services. Similarly, one commenter was concerned that accurate description of the code when delivered via telehealth might prevent CMS from adding critical care services to the list of Medicare telehealth services because there are category III CPT codes that describe remote real-time interactive videoconferenced critical care services.

Response: In general, we do not believe it would be appropriate to add services to the Medicare telehealth list if those services cannot be accurately described by CPT or HCPCS codes that could otherwise describe in-person services. Medicare payment for the services is based upon the services that the CPT or HCPCS code describes. As we explained in the CY 2012 PFS proposed rule with comment period (76 FR 42826), Section 1834(m)(2)(A) of the Act requires that the distant site physician or practitioner furnishing the telehealth service must be paid an amount equal to the amount the physician or practitioner would have been paid under the PFS had such service been furnished without the use of a telecommunications system. Therefore, we believe that candidate telehealth services must also be covered when furnished in-person; that the CPT and HCPCS code that is the basis for payment must accurately describe the service; and that any service that would only be furnished through a telecommunications system would be a distinct service from an in-person service, and therefore, not a candidate for addition to the Medicare telehealth list even when covered by Medicare. For example, remote services that utilize telecommunications technology are considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology; they are paid under the same conditions as in-person physicians' services (with no requirements regarding permissible originating sites), and should be reported in the same way (that is, without the -GT or -GQ modifier appended). Medicare coverage for these types of services is distinct from the Medicare telehealth benefit.

With regard to the request to add critical care services to the list of Medicare telehealth services, the application of the proposed category 2 criteria to that request is contingent on both the finalization of the proposed criteria and our receipt of a new request to add the services. However, as we noted in the CY 2012 PFS proposed rule with comment period (76 FR 42824), the fact that the CPT Editorial Panel created the Category III CPT codes suggests to us that these video-conferenced critical care services are not the same as the in-person critical care services requested for addition to the telehealth list.

After consideration of the public comments we received, we are

finalizing our proposal to revise the criteria we use to review category 2 requests to add services to the list of Medicare telehealth services beginning in CY 2013. We are modifying the current requirement to demonstrate similar diagnostic findings or therapeutic interventions with respect to a candidate service delivered through telehealth compared to in person delivery of the service (the comparability standard). Instead, we will assess category 2 requests to add services to the telehealth list using a standard of demonstrated clinical benefit (the clinical benefit standard) when the service is furnished via telehealth. To support our review using this revised standard, we ask requestors to specify in their request how the candidate telehealth service is still accurately described by the corresponding HCPCS or CPT code when delivered via telehealth as opposed to in person.

Our revised criteria for category 2 additions are as follows:

- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests will include an assessment of whether the service is accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. Requestors should submit evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient.

The evidence submitted should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit will not include minor or incidental benefits. Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

5. Telehealth Consultations in Emergency Departments

We have recently been asked to clarify instructions regarding appropriate reporting of telehealth services that, prior to our policy change regarding consultation codes, would have been reported as consultations furnished to patients in an emergency department. When we eliminated the use of consultation codes under the PFS beginning in CY 2010, we instructed practitioners, when furnishing a service that would have been reported as a consultation service, to report the E/M code that is most appropriate to the particular service for all office/outpatient or inpatient visits. Since section 1834(m) of the Act includes ''professional consultations'' (including the initial inpatient consultation codes ''as subsequently modified by the Secretary'') in the definition of telehealth services, we established several HCPCS codes to describe the telehealth delivery of initial inpatient consultations. For inpatient hospital and skilled nursing facility care telehealth services, we instructed practitioners to use the inpatient telehealth consultation G-codes listed in Table 12 to report those telehealth services (74 FR 61763, 61774). However, we neglected to account for the fact that E/M emergency department visit codes (99281–99285) are not on the telehealth list. As a result, there has not been a clear means for practitioners to bill a telehealth consultation furnished in an emergency department. In order to address this issue, we proposed to change the code descriptors for the inpatient telehealth consultation G-codes to include emergency department telehealth consultations effective January 1, 2012. However, we requested public comment regarding other options, including creating G-codes specific to these services when furnished to patients in the emergency department.

TABLE 12: INPATIENT TELEHEALTH CONSULTATION G-CODES

HCPCS Code	CY 2011 Long Code Descriptor
G0425	Initial inpatient telehealth consultation, typically 30 minutes communicating with the patient via telehealth
G0426	Initial inpatient telehealth consultation, typically 50 minutes communicating with the patient via telehealth
G0427	Initial inpatient telehealth consultation, typically 70 minutes or more communicating with the patient via telehealth
G0406	Follow-up inpatient telehealth consultation, limited, physicians typically spend 15 minutes communicating with the patient via telehealth
G0407	Follow-up inpatient telehealth consultation, intermediate, physicians typically spend 25 minutes communicating with the patient via telehealth
G0408	Follow-up inpatient telehealth consultation, complex, physicians typically spend 35 minutes or more communicating with the patient via telehealth

Comment: Many commenters supported the proposal to change the code descriptors for the inpatient telehealth consultation G-codes to include emergency department telehealth consultations effective January 1, 2012. These commenters asserted that changing the code descriptors is an appropriate way for CMS to provide a clear means for practitioners to bill telehealth consultations furnished to emergency department patients.

Response: We appreciate the support for the proposal. We agree that changing the code descriptors will ensure that telehealth consultations can be reported appropriately when furnished to emergency department patients.

Comment: A few commenters expressed concerns that the proposal would blur the line between inpatient and outpatient services. One commenter disagreed with the proposal and suggested that CMS should create new G-codes since it is important to maintain the distinction between outpatient and inpatient services.

Response: We thank the commenters for bringing these concerns to our attention. While we understand that emergency department services are considered outpatient services, at this time we believe that allowing practitioners to report the G-codes we created for initial inpatient telehealth consultations when furnishing telehealth consultations to emergency department patients is the most appropriate way to resolve the immediate issue. We note that the G-codes we created for telehealth consultations are used exclusively under the telehealth benefit. In this unique circumstance, we believe that the use of single codes to describe what can be an inpatient or an outpatient emergency department service is an appropriate mechanism to allow practitioners to report these telehealth services.

However, the comments regarding site of service coding distinctions have prompted us to reconsider the need to provide a mechanism for follow-up consultations in the emergency department. While follow-up consultative services are furnished to hospital and SNF inpatients, we do not believe these services are furnished to patients in emergency departments since patients do not spend enough time in the emergency department to warrant a second consultative service by the same practitioner. Therefore, we are amending our proposal to pertain only to the G-codes that describe initial telehealth consultations.

Comment: One commenter disagreed with the code descriptor change based on the assertion that the existing G-codes do not sufficiently cover the intensity, risk and medical judgment involved in providing teleICU services to critically ill patients.

Response: We agree that the telehealth consultation codes do not fully describe critical care services. For additional information regarding the request to add critical care services to the list of Medicare telehealth services, we refer the commenter to our discussion in section II.E.1.b. of this final rule with comment period.

Comment: One commenter requested additional information regarding why Medicare only pays for consultations furnished through telehealth.

Response: While Medicare no longer recognizes CPT consultation codes for payment purposes, practitioners furnishing services that could be described by CPT consultation codes are still paid for those services when they are reported using the the most appropriate office or inpatient evaluation and management code. The telehealth consultation G-codes are intended to provide a mechanism for reporting telehealth consultation services to patients in the inpatient and SNF settings. We created these codes because inpatient and SNF evaluation and management codes were not included in the telehealth benefit and a practitioner could not bill an evaluation and management code when providing consultation services via telehealth furnished to patients in those settings. We refer the reader to our most recent thorough discussion of this issue in the CY 2010 PFS final rule with comment period (74 FR 61763 and 61767 through 61775).

After consideration of the public comments we received, we are finalizing our proposal to change the code descriptors for initial inpatient telehealth consultation G-codes to reflect telehealth consultations furnished to emergency department patients in addition to inpatient telehealth consultations effective January 1, 2012. The descriptors for these codes for CY 2012 appear in table 13. After consideration of the public comments we received, we are not finalizing our proposal to change the code descriptors for follow-up inpatient telehealth consultations, since we do not believe follow-up consultations are furnished to emergency department patients.

TABLE 13: INPATIENT TELEHEALTH CONSULTATION G-CODES

HCPCS Code	CY 2012 Long Code Descriptor
G0425	Telehealth consultation, emergency department or initial inpatient, typically 30 minutes communicating with the patient via telehealth
G0426	Telehealth consultation, emergency department or initial inpatient, typically 50 minutes communicating with the patient via telehealth
G0427	Telehealth consultation, emergency department or initial inpatient, typically 70 minutes or more communicating with the patient via telehealth

6. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act establishes the payment amount for the Medicare telehealth originating site facility fee for telehealth services provided from October 1, 2001, through December 31, 2002, at $20. For telehealth services provided on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The MEI increase for 2012 is 0.6 percent. Therefore, for CY 2012, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or $24.24. The Medicare telehealth originating site facility fee and MEI increase by the applicable time period is shown in Table 14.

TABLE 14: THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE AND MEI INCREASE BY THE APPLICABLE TIME PERIOD

Facility Fee	MEI Increase	Period
$20.00	N/A	10/01/2001 – 12/31/2002
$20.60	3.0%	01/01/2003 – 12/31/2003
$21.20	2.9%	01/01/2004 – 12/31/2004
$21.86	3.1%	01/01/2005 – 12/31/2005
$22.47	2.8%	01/01/2006 – 12/31/2006
$22.94	2.1%	01/01/2007 – 12/31/2007
$23.35	1.8%	01/01/2008 – 12/31/2008
$23.72	1.6%	01/01/2009 – 12/31/2009
$24.00	1.2%	01/01/2010 – 12/31/2010
$24.10	0.4%	01/01/2011 – 12/31/2011
$24.24	0.6%	01/01/2012 – 12/31/2012

III. Addressing Interim Final Relative Value Units (RVUs) From CY 2011, Proposed RVUs From CY 2012, and Establishing Interim RVUs for CY 2012

Under section 1848(c)(2)(B) of the Act, we review and make adjustments to RVUs for physicians' services at least once every 5 years. Under section 1848(c)(2)(K) of the Act (as added by section 3134 of the Affordable Care Act), we are required to identify and revise RVUs for services identified as potentially misvalued. Section 1848(c)(2)(K)(iii) specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In accordance with section 1848(c)(2)(K)(iii) of the Act, we develop and propose appropriate adjustments to the RVUs, taking into account the recommendations provided by the AMA RUC, the Medicare Payment Advisory Commission (MedPAC), and others. To respond to concerns expressed by MedPAC, the Congress, and other stakeholders regarding the accuracy of values for services under the PFS, the AMA RUC has used an annual process to systematically identify, review, and provide CMS with recommendations for revised work values for many existing potentially misvalued services.

For many years, the AMA RUC has provided CMS with recommendations on the appropriate relative values for PFS services. In recent years CMS and the AMA RUC have taken increasingly significant steps to address potentially misvalued codes. In addition to the Five-Year Reviews of Work, over the past several years CMS and the AMA RUC have identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens for codes at risk for being misvalued, such as codes with high growth rates, codes that are frequently billed together in one encounter, and codes that are valued as inpatient services but that are now predominantly performed as outpatient services. This annual review of work RVUs and direct PE inputs for potentially misvalued codes was further bolstered by the Affordable Care Act mandate to examine potentially misvalued codes, with an emphasis on the following categories specified in section 1848(c)(2)(K)(ii) (as added by section 3134 of the Affordable Care Act):

- Codes and families of codes for which there has been the fastest growth.
- Codes or families of codes that have experienced substantial changes in practice expenses.
- Codes that are recently established for new technologies or services.
- Multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes which have not been subject to review since the implementation of the RBRVS (the ''Harvard-valued'' codes).
- Other codes determined to be appropriate by the Secretary. (For example, codes for which there have been shifts in the site-of-service (site-of-service anomalies).)

In addition to providing recommendations to CMS for work RVUs, the AMA RUC's Practice Expense Subcommittee reviews, and then the AMA RUC recommends, direct PE inputs (clinical labor, medical supplies, and medical equipment) for individual services. To guide the establishment of malpractice RVUs for new and revised codes before each Five-Year Review of Malpractice, the AMA RUC also provides crosswalk recommendations, that is, ''source'' codes with a similar specialty mix of practitioners furnishing the source code and the new/revised code.

CMS reviews the AMA RUC recommendations on a code-by-code basis. For AMA RUC recommendations regarding physician work RVUs, we determine whether we agree with the recommended work RVUs for a service (that is, whether we agree the valuation is accurate). If we disagree, we determine an alternative value that

better reflects our estimate of the physician work for the service. Because of the timing of the CPT Editorial Panel decisions, the AMA RUC recommendations, and our rulemaking cycle, we publish these work RVUs in the PFS final rule with comment period as interim final values, subject to public comment. Similarly, we assess the AMA RUC's recommendations for direct PE inputs and malpractice crosswalks, and establish PE and malpractice interim final values, which are also subject to comment. We note that, with respect to interim final PE RVUs, the main aspect of our valuation that is open for public comment for a new, revised, or potentially misvalued code is the direct PE inputs and not the other elements of the PE valuation methodology, such as the indirect cost allocation methodology, that also contribute to establishing the PE RVUs for a code. The public comment period on the PFS final rule with comment period remains open for 60 days after the rule is issued.

If we receive public comments on the interim final work RVUs for a specific code indicating that refinement of the interim final work value is warranted based on sufficient information from the commenters concerning the clinical aspects of the physician work associated with the service (57 FR 55917), we refer the service to a refinement panel, as discussed in further detail in section III.B.1.a. of this final rule with comment period.

In the interval between closure of the comment period and the subsequent year's PFS final rule with comment period, we consider all of the public comments on the interim final work, PE, and malpractice RVUs for the new, revised, and potentially misvalued codes and the results of the refinement panel, if applicable. Finally, we address the interim final RVUs (including the interim final direct PE inputs) by providing a summary of the public comments and our responses to those comments, including a discussion of any changes to the interim final work or malpractice RVUs or direct PE inputs, in the following year's PFS final rule with comment period. We then typically finalize the direct PE inputs and the work, PE, and malpractice RVUs for the service in that year's PFS final rule with comment period, unless we determine it would be more appropriate to continue their interim final status for another year and solicit further public comment.

A. Methodology

We conducted a clinical review of each code identified in this section and reviewed the AMA RUC recommendations for work RVUs, time to perform the ''pre-,'' ''intra-,'' and ''post-'' service activities, as well as other components of the service which contribute to the value. Our clinical review generally includes, but is not limited to, a review of information provided by the AMA RUC, medical literature, public comments, and comparative databases, as well as a comparison with other codes within the Medicare PFS, consultation with other physicians and healthcare care professionals within CMS and the Federal Government, and the views based on clinical experience of the physicians on the clinical team. We also assessed the AMA RUC's methodology and data used to develop the recommendations and the rationale for the recommendations. As we noted in the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), the AMA RUC uses a variety of methodologies and approaches to assign work RVUs, including building block, survey data, crosswalk to key reference or similar codes, and magnitude estimation. The building block methodology is used to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Components may include pre-, intra-, or post-service time and post-procedure visits, or, when referring to a bundled CPT code, the components could be considered to be the CPT codes that make up the bundled code. Magnitude estimation refers to a methodology for valuing physician work that determines the appropriate work RVU for a service by gauging the total amount of physician work for that service relative to the physician work for similar service across the physician fee schedule without explicitly valuing the components of that work. The resource-based relative value system (RBRVS) has incorporated into it cross-specialty and cross-organ system relativity. This RBRVS requires assessment of relative value and takes into account the clinical intensity and time required to perform a service. In selecting which methodological approach will best determine the appropriate value for a service we consider the current physician work and time values, AMA RUC-recommended physician work and time values, and specialty society physician work and time values, as well as the intensity of the service, all relative to other services. During our clinical review to assess the appropriate values for the codes we developed systematic approaches to address particular areas of concern. Specifically, the application of work budget neutrality within clinical categories of CPT codes, CPT codes with site-of-service anomalies, and CPT codes for services typically furnished on the same day as an evaluation and management visit. A description of those methodologies follows.

○ Work Budget Neutrality for Clinical Categories of CPT Codes

We apply work budget neutrality to hold the aggregate work RVUs constant within a set of clinically related CPT codes, while maintaining the relativity of values for the individual codes within that set. In some cases, when the CPT coding framework for a clinically related set of CPT codes is revised by the creation of new CPT codes or existing CPT codes are revalued, the aggregate work RVUs recommended by the AMA RUC within that clinical category of CPT codes may change, although the actual physician work associated with the services has not changed. When this occurs, we may apply work budget neutrality to adjust the work RVUs of each clinically related code so that the sum of the new/revised code work RVUs (weighted by projected utilization) for a set of CPT codes would be the same as the sum of the current work RVUs (weighted by projected utilization) for that set of codes.

When the AMA RUC recommends work RVUs for new or revised CPT codes, we review the work RVUs and adjust or accept the recommended values as appropriate, making note of whether any estimated changes in aggregate work RVUs would result from true change in physician work, or from structural coding changes. We then determine whether the application of budget neutrality within sets of codes is appropriate. If the aggregate work RVUs would increase without a corresponding true increase in physician work, we generally view this as an indication that an adjustment to ensure work budget neutrality within the set of CPT codes is warranted. Ensuring work budget neutrality is an important principle so that structural coding changes are not unjustifiably redistributive among PFS services.

In the CY 2011 PFS final rule with comment period, there were four sets of clinically related CPT codes where we believed that the application of work budget neutrality was appropriate. These codes were in the areas of paraesophageal hernia procedures, esophageal motility and high resolution esophageal pressure topography, skin excision and debridement, and obstetrical care. The CY 2011 interim final values and CY 2012 final values for these services are discussed in section

III.B.1.b. of this final rule with comment period.

○ 23-Hour Stay Site-of-Service Anomaly CPT Codes

Since CY 2009, CMS and the AMA RUC have reviewed a number of CPT codes that have experienced a change in the typical site-of-service since the original valuation of the codes. Specifically, these codes were originally furnished in the inpatient setting, but Medicare claims data show that the typical case has shifted to being furnished in the outpatient setting. As we discussed in the CY 2011 PFS final rule with comment period (75 FR 73221) and the CY 2012 PFS proposed rule (76 FR 42797), when the typical case for a service has shifted from the inpatient setting to an outpatient or physician's office setting, we do not believe the inclusion of inpatient hospital visits in the post-operative period is appropriate. Additionally, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both.

For CY 2009 and CY 2010, the AMA RUC reviewed and recommended—RVUs for 40 CPT codes we identified as being potentially misvalued under the Secretary's discretion to identify other categories of potentially misvalued codes (see section II.B. of this final rule) because a site-of-service anomaly exists. In the CYs 2009 and 2010 PFS final rule with comment period (73 FR 69883 and 74 FR 61776 through 61778, respectively), we indicated that although we would accept the AMA RUC valuations for these CPT codes on an interim basis, we had ongoing concerns about the methodology used by the AMA RUC to value these services, and in the CY 2010 PFS final rule with comment period (74 FR 61777) we encouraged the AMA RUC to utilize the building block methodology when revaluing services with site-of-service anomalies. In the CY 2011 final rule with comment period (75 FR 73221), we requested that the AMA RUC re-examine the site-of-service anomaly codes and adjust the work RVU, times, and post-service visits to reflect those typical of a service furnished in an outpatient or physician's office setting.

Following this request, the AMA RUC re-reviewed these site-of-service anomaly codes and recommended work RVUs to us for these services. Of the 40 CPT codes on the CY 2009 and CY 2010 site-of-service anomaly codes lists, 1 CPT code was not re-reviewed, as it was addressed in the CY 2011 PFS final rule with comment period. Ten of the remaining 39 site-of-service anomaly codes were addressed in the Fourth Five-Year Review of Work (76 FR 32410), and the remaining 29 CPT codes were addressed in the CY 2012 PFS proposed rule (76 FR 72798 through 42809). In addition, several other CPT codes were identified as having site-of-service anomalies and were addressed in the Fourth Five-Year Review of Work (76 FR 32410). In the CY 2012 PFS proposed rule (76 FR 42797), we stated that we would respond to public comments and adopt final work RVUs for these codes in the CY 2012 PFS final rule with comment period.

When Medicare claims data show that the typical setting for a CPT code has shifted from the inpatient setting to the outpatient setting, we believe that the work RVU, time, and post-service visits of the code should reflect a service furnished in the outpatient setting. For nearly all of the codes with site-of-service anomalies, the accompanying survey data suggest they are ''23-hour stay'' outpatient services. As we discussed in detail in the CY 2011 PFS final rule with comment period (75 FR 73226), the Fourth Five-Year Review of Work (76 FR 32410) and the CY 2012 PFS proposed rule (76 FR 42798), the ''23-hour stay service'' is a term of art describing services that typically have lengthy hospital outpatient recovery periods. For these 23-hour stay services, the typical patient is at the hospital for less than 24-hours, but often stays overnight at the hospital. Unless a treating physician has written an order to admit the patient as an inpatient, the patient is considered for Medicare purposes to be a hospital outpatient, not an inpatient, and our claims data support that the typical 23-hour stay service is billed as an outpatient service.

As we discussed in the Five-Year Review of Work (76 FR 32410), and CY 2012 PFS proposed rule (76 FR 42798) we believe that the values of the codes that fall into the 23-hour stay category should not reflect work that is typically associated with an inpatient service. However, as we stated in the CY 2011 PFS final rule with comment period (75 FR 73226 through 73227), while the patient receiving the outpatient 23-hour stay service remains a hospital outpatient, the patient would typically be cared for by a physician during that lengthy recovery period at the hospital. While we do not believe that post-procedure hospital visits would be at the inpatient level since the typical case is an outpatient who would be ready to be discharged from the hospital in 23-hours or less, we believe it is generally appropriate to include the intra-service time of the inpatient hospital visit in the immediate post-service time of the 23-hour stay code under review. In addition, we indicated that we believe it is appropriate to include a half day, rather than a full day, of a discharge day management service.

We finalized this policy in the CY 2011 PFS final rule with comment period (75 FR 73226 through 73227) and applied this methodology when valuing 23-hour stay codes in the Fourth Five-Year Review and CY 2012 PFS proposed rule in order to ensure the consistent and appropriate valuation of the physician work for these services. A full description of our methodology for revaluing the site-of-service anomaly codes can be found in the Fourth Five-Year Review of Work (76 FR 32410), and the CY 2012 PFS proposed rule (76 FR 72798 through 42809). In brief, where Medicare claims data suggested a site-of-service anomaly (more than 50 percent of the Medicare PFS utilization is outpatient) and the AMA RUC's recommended value continued to include inpatient visits in the post-operative period, we removed any post-procedure inpatient visits or subsequent observation care services included in the AMA RUC-recommended values for these codes and adjusted the physician times accordingly. We also consistently included the value of a half day of discharge management service.

Comment: We received a number of comments that disagreed with the premise of the 23-hour site-of-service anomaly methodology arguing that the acuity of the patient as captured in patient status (inpatient or outpatient) is not an indicator of physician work. The commenters believe that if the procedure or service is typically performed in the hospital and the patient is kept overnight and/or admitted, the RUC should evaluate it as an inpatient service or procedure using the hospital visits as a work proxy regardless of the patient's status. Commenters noted that while physicians generally write admitting orders, the hospital frequently makes the determination to categorize a patient's stay as inpatient or outpatient, and that hospital attention to patient status is being driven by a fear of Recover Audit Contractor (RAC) audits and not clinical judgment. Commenters asserted that the AMA RUC-recommended values for site-of-service anomaly codes are based on physician specialty survey responses which identified the actual work performed in caring for these patients and that the physician work to treat the patient does not vary with regard to how the patient is later categorized for facility billing purposes as an inpatient or outpatient.

Response: As we noted in the CY 2011 PFS final rule with comment period (75 FR 73227), these services would be considered for hospital outpatient services, not inpatient services, for the typical patient, and our claims data support that the typical 23-hour stay service, usually a scheduled procedure, is billed as an outpatient service. Since the typical patient commonly remains in the hospital for less than 24 hours, even if the stay extends overnight, and the patient's encounter is relatively brief, the acuity of the typical patient and the risk of adverse outcomes is less than that of a typical inpatient who is admitted to the hospital, and we continue to believe that the intensity of the physician work involved in caring for the hospital outpatient immediately following a 23-hour stay procedure is less than for a hospital inpatient. The typical hospital outpatient for a 23-hour procedure has fewer comorbidities, less complications, lower risk and therefore less need for intensive nursing and physician care of the kind provided during an inpatient admission. Medicare pays for an inpatient admission when, among other criteria, the physician responsible for the care of the patient has an expectation of a minimum 24-hour stay and the patient requires an inpatient level of care, based on assessment of several factors including the severity of the signs and symptoms and the probability of an adverse event (Medicare Benefit Policy Manual 100–02, chapter 1, section 10).

There are many reasons that services move from the inpatient to outpatient setting that reduce the overall risk of adverse outcomes and intensity of physician work. Services frequently move to the outpatient setting when the technique matures; that is, the risk-benefit ratio of the service is better understood and the efficacy of the service is more clearly established. Services may move to the outpatient setting because technological advances decrease the need for intensive monitoring and allow the discharge of sicker patients. Patient-controlled analgesia, for example, reduces the iterative assessment and response work necessary to manage post-operative pain and allows earlier discharge. Technological advances in the procedures themselves also reduce the risk of adverse outcomes. Electronic imaging and robotic surgery both allow procedures to be performed with increasingly smaller incisions, decreasing post-operative morbidity. Accordingly, we believe that, generally, the valuation of the codes that fall into the 23-hour stay category should not reflect physician work that is typically associated with an inpatient service.

○ CPT Codes Typically Billed on the Same Day as an Evaluation and Management Service

Since CY 2011, we have reviewed a number of CPT codes that are typically billed with an E/M service on the same day. In cases where a service is typically furnished with an E/M service on the same day, we believe that there may be overlap between the two services in some of the activities conducted during the pre- and post-service times of the procedure code. Accordingly, in cases where the most recently available Medicare PFS claims data show the code is typically billed with an E/M visit on the same day, and where we believe that the AMA RUC did not adequately account for overlapping activities in the recommended value for the code, we systematically adjusted the physician times for the code to account for the overlap. After clinical review of the pre- and post-service work, we believe that at least one-third of the physician time in both the pre-service evaluation and post-service period is duplicative of the E/M visit in this circumstance. Therefore, for a number of CPT codes discussed in the following paragraphs, we adjusted the pre-service evaluation portion of the pre-service time to two-thirds of the AMA RUC-recommended time. Similarly, we also adjusted the post-service time to two-thirds of the AMA RUC-recommended time.

B. Finalizing CY 2011 Interim and CY 2012 Proposed Values for CY 2012

In this section, we address the interim final values published in Appendix C of the CY 2011 PFS final rule with comment period (75 FR 73810 through 73815), as subsequently corrected in the January 11, 2011 (76 FR 1670) correction notice; the proposed values published in the Fourth Five-Year Review of Work (76 FR 32410 through 32813); and the proposed values published in the CY 2012 PFS proposed rule (76 FR 42772 through 42947). We discuss the results of the CY 2011 multi-specialty refinement panel, respond to public comments received on specific interim final and proposed values (including direct PE inputs), and address the other new, revised, or potentially misvalued codes with interim final or proposed values. In section II.B.3. of this final rule with comment period, we emphasized the importance of reviewing the full value for services (the work, PE, and malpractice components of codes) that are identified as part of the potentially misvalued code initiative in order to maintain appropriate relativity and key relationships within the components of codes. The final CY 2012 direct PE database that lists the direct PE inputs is available on the CMS Web site under the downloads for the CY 2012 PFS final rule with comment period at: *https://www.cms.gov/PhysicianFeeSched/.* The final CY 2011 work, PE, and malpractice RVUs are displayed in Addendum B to this final rule with comment period at: *https://www.cms.gov/PhysicianFeeSched/.*

1. Finalizing CY 2011 Interim and Proposed Work Values for CY 2012

a. Refinement Panel

(1) Refinement Panel Process

As discussed in the 1993 PFS final rule with comment period (57 FR 55938), we adopted a refinement panel process to assist us in reviewing the public comments on CPT codes with interim final work RVUs for a year and in developing final work values for the subsequent year. We decided that the panel would be comprised of a multispecialty group of physicians who would review and discuss the work involved in each procedure under review, and then each panel member would individually rate the work of the procedure. We believed that establishing the panel with a multispecialty group would balance the interests of the specialty societies who commented on the work RVUs with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services.

Historically, the refinement panel's recommendation to change a work value or to retain the interim value had hinged solely on the outcome of a statistical test on the ratings (an F-test of panel ratings among the groups of participants). Depending on the number and range of codes that specialty societies request be subject to refinement through their public comments, we establish refinement panels with representatives from 4 groups of physicians: Clinicians representing the specialty most identified with the procedures in question; physicians with practices in related specialties; primary care physicians; and contractor medical directors (CMDs). Typically, the refinement panels meet in the summer prior to the promulgation of the PFS final rule with comment period that finalizes the RVUs for the codes. Typical panels have included 8 to 10 physicians across the 4 groups. Over time, we found that the statistical test

used to evaluate the RVU ratings of individual panel members became less reliable as the physicians in each group have tended to select a previously discussed value, rather than developing a unique value, thereby reducing the observed variability needed to conduct a robust statistical test. In addition, reliance on values developed using the F-test also occasionally resulted in rank order anomalies among services (that is, a more complex procedure is assigned lower RVUs than a less complex procedure).

Recently, section 1848(c)(2)(K) of the Act (as added by section 3134 of the Affordable Care Act) authorized the Secretary to review potentially misvalued codes and make appropriate adjustments to the relative values. In addition, MedPAC has encouraged CMS to critically review the values assigned to the services under the PFS. As detailed in the CY 2011 PFS final rule with comment period (75 FR 73306), we believed the refinement panel process may provide an opportunity to review and discuss the proposed and interim final work RVUs with a clinically diverse group of experts, which then provides informed recommendations. Therefore, we indicated that we would like to continue the refinement process, including the established composition that includes representatives from the 4 groups of physicians, but with administrative modification and clarification. We eliminated the use of the statistical F-test and instead indicated that we would base revised RVUs on the median work value of the individual panel members' ratings. We believed this approach would simplify the refinement process administratively, while resulting in a final panel recommendation that reflects the summary opinion of the panel members based on a commonly used measure of central tendency that is not significantly affected by outlier values. We clarified that we have the final authority to set the RVUs, including making adjustments to the work RVUs resulting from refinement process if policy concerns warrant modification (75 FR 73307).

Due to the major increase in the number of codes reviewed by the CY 2011 multi-specialty refinement panels as compared to refinement panels in recent years, and public comments requesting more clarification about the refinement panels, we would like to remind readers that historically the refinement panels were not intended to review every code for which we did not propose to accept the AMA RUC-recommended RVUs. Furthermore, in the past, we have asked commenters requesting refinement panel review to submit sufficient information concerning the clinical aspects of the work assigned for a service to indicate that referral to the refinement panel is warranted (57 FR 55917). We note that the majority of the information that was presented during the CY 2011 refinement panel discussions was duplicative of the information provided to the AMA RUC during its development of recommendations. As detailed in section III.B. of this final rule with comment period, we consider information and recommendations from the AMA RUC when assigning proposed and interim final RVUs to services. To facilitate the selection of services for the refinement panels, we would like to remind specialty societies seeking reconsideration of proposed or interim final work RVUs, including consideration by a refinement panel, to specifically request refinement panel review in their public comment letters. Also, we request that commenters seeking refinement panel review of work RVUs submit supporting information that has not already been considered by the AMA RUC in creating recommended work RVUs or by CMS in assigning proposed and interim final work RVUs. In order to make the best use of the agency's limited resources and avoid inefficient duplicative consideration of information by the AMA RUC, CMS, and then a refinement panel, CMS will more critically evaluate the need to refer codes to refinement panels in future years, specifically considering any new information provided by commenters.

(2) Proposed and Interim Final Work RVUs Referred to the Refinement Panels in CY 2011

We referred to the CY 2011 refinement panel 143 CPT codes with proposed or interim final work values for which we received comments from least one major specialty society. For these 143 CPT codes, all commenters requested increased work RVUs. For ease of discussion, we will be referring to these services as ''refinement codes.'' Consistent with past practice (62 FR 59084), we convened a multi-specialty panel of physicians to assist us in the review of the comments. The panel was moderated by our physician advisors, and consisted of the following voting members:

- One to two clinicians representing the commenting organization;
- One to two primary care clinicians nominated by the American Academy of Family Physicians and the American College of Physicians;
- One to three contractor medical directors (CMDs); and
- One to two clinicians with practices in related specialties who were expected to have knowledge of the services under review.

The panel process was designed to capture each participant's independent judgment and his or her clinical experience which informed and drove the discussion of the refinement code during the refinement panel proceedings. Following the discussion, each voting participant rated the physician work of the refinement code. Ratings were obtained individually and confidentially, with no attempt to achieve consensus among the panel members.

As finalized in the CY 2011 PFS final rule with comment period (75 FR 73307), we reviewed the ratings from each panel member and determined the median value for each service that was reviewed by the refinement panels. Our decision to convene multi-specialty panels of physicians has historically been based on our need to balance the interests of those who commented on the interim final work values with the redistributive effects that would occur in other specialties if the work values were changed. We refer readers to section III.I. of the CY 2011 PFS final rule with comment period for a full discussion of the changes to the refinement process that we adopted for refinement panels beginning in CY 2011.

We note that individual codes, including those that were reviewed by the refinement panels, and their final work RVUs are discussed in section III.B.1.b. of this final rule with comment period. Also, see Table 15 for the refinement panel ratings and the final work RVUs for the codes that were reviewed by the CY 2011 multi-specialty refinement panels.

b. Code-Specific Issues

In this section we discuss all code families for which we received a comment on an interim final physician work value in CY 2011 PFS final rule with comment period, on a proposed value in the Fourth Five-Year Review of Work, or on a proposed value in the CY 2012 PFS proposed rule. Table 15 provides a comprehensive list of all final values.

(1) Integumentary System: Skin, Subcutaneous, and Accessory Structures (CPT codes 10140, 10160, 11010–11012, 11042–11047) and Active Wound Care Management (CPT codes 97597 and 97598)

For the Fourth Five-Year Review, we identified CPT codes 10140 and 10160

as potentially misvalued though the Harvard-Valued—Utilization > 30,000 screen. The related specialty societies surveyed their members, and the AMA RUC issued recommendations to us for the Fourth Five-Year Review.

As detailed in the Fourth Five-Year Review, for CPT codes 10140 (Incision and drainage of hematoma, seroma or fluid collection) and 10160 (Puncture aspiration of abscess, hematoma, bulla, or cyst) we believed that the current (CY 2011) work RVUs continued to accurately reflect the work of these services. For CPT code 10140 we proposed a work RVU of 1.58, and for CPT code 10160 we proposed a work RVU of 1.25. The AMA RUC recommended maintaining the current work RVUs for these services as well. For CPT code 10160, the AMA RUC recommended a pre-service evaluation time of 7 minutes. As CPT codes 10160 and 10140 have the same description of pre-service work, we believed that they should have the same pre-service time. Therefore, we reduced the pre-service evaluation time for CPT code 10140 from 17 minutes to 7 minutes, to match the pre-service evaluation time of CPT code 10160 (76 FR 32431 through 32432).

Comment: In its public comment to CMS on the Fourth Five-Year Review, the AMA RUC wrote that there was a typographical error in its recommendation to CMS for CPT code 10160, and the correct pre-service evaluation time for that code should have been 17 minutes. The AMA RUC wrote that they agree that CPT codes 10140 and 10160 should have the same pre-service time, but that both should have 17 minutes of pre-service evaluation time, and not 7 minutes. They requested that CMS change the pre-service time for both CPT codes 10140 and 10160.

Response: In response to comments, we re-reviewed CPT codes 10140 and 10160. After reviewing the descriptions of pre-service work and the recommended pre-service time packages, we agree that both CPT codes 10140 and 10160 should have 17 minutes of pre-service evaluation work. We thank the AMA RUC for pointing out this time error. For CPT code 10140 we are finalizing a work RVU of 1.50 and a pre-service evaluation time of 17 minutes. For CPT code 10160 we are finalizing a work RVU of 1.25 and a pre-service evaluation time of 17 minutes. CMS time refinements can be found in Table 16.

CPT codes 11043 (Debridement; skin, subcutaneous tissue, and muscle) and 11044 (Debridement; skin, subcutaneous tissue, muscle, and bone) were identified by the AMA RUC's Five-Year Review Identification Workgroup through the ''site-of-service anomalies'' potentially misvalued codes screen in September 2007. The AMA RUC recommended that the entire family of services described by CPT codes 11040 through 11044, and 97597 and 97598 be referred to the CPT Editorial Panel because the current descriptors allowed reporting of the codes for a bimodal distribution of patients and also to better define the terms excision and debridement. The CPT Excision and Debridement Workgroup and the CPT Editorial Panel reviewed and revised the CPT code descriptors for CPT codes 11042 through 11047, along with the descriptors for other related CPT codes. Following the descriptor changes, the related specialty societies surveyed their members, gathering information for work RVU and time recommendations for these services, and the AMA RUC issued recommendations to us for CY 2011. We reviewed these CPT codes, and published the CY 2011 interim final work RVUs in the CY 2011 PFS final rule with comment period (75 FR 73329 through 73330). Based on comments received during the public comment period, we referred CPT codes 11042 through 11047 to the CY 2011 multi-specialty refinement panel for further review.

As detailed in the CY 2011 PFS final rule with comment period, for CPT code 11042 (Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less) we assigned a work RVU of 0.80 on an interim final basis for CY 2011. After clinical review, we believed that the then current (2010) work RVU of 0.80 continued to accurately reflect the work of the service relative to similar services, including reference CPT code 16020 (Dressings and/or debridement of partial-thickness burns, initial or subsequent; small (less than 5 percent total body surface area)). We found no grounds to increase the work RVU for this service. The AMA RUC recommended a work RVU of 1.12 for CPT code 11042 for CY 2011 (75 FR 73329).

Comment: Commenters disagreed with the interim final work RVU of 0.80 assigned to CPT code 11042 by CMS and believe that the AMA RUC-recommended work RVU of 1.12 is more appropriate for this service. Commenters reiterated the arguments that the specialty societies presented to the AMA RUC that—(1) the 2005 survey for this code did not include podiatry, which is now the dominant specialty for this service; and (2) the original Harvard valuation of this code was based on a 10-day global period, and that since the original valuation CMS has reduced the work RVU and changed global period for this service through the refinement process in previous years. Commenters also noted that, while CMS indicated that the AMA RUC-recommended work RVU of 1.12 was based on an old surveyed value, the AMA RUC agreed that a work RVU of 1.12 continues to be an appropriate valuation for this service relative to other services.

Response: Based on the comments received, we referred CPT code 11042 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 11042 was 1.01. As a result of the refinement panel ratings and our clinical review, we are assigning a work RVU of 1.01 to CPT code 11042 as the final value for CY 2012.

As detailed in the CY 2011 PFS final rule with comment period, for CPT code 11045 (Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)) we assigned a work RVU of 0.33 on an interim final basis for CY 2011. CPT code 11045 is the add-on code to CPT code 11042. To obtain the appropriate RVU for this add-on service, we started with the CMS-assigned CY 2011 interim final RVU of 0.80 for the primary code (CPT code 11042), and removed the work RVUs corresponding to the pre- and post-service time (add-on codes generally do not have pre- and post-service time because that work is captured by the primary service). The AMA RUC recommended a work RVU of 0.69 for CPT code 11045 for CY 2011 (75 FR 73329 and 73330).

Comment: Commenters disagreed with the interim final work RVU of 0.33 assigned to CPT code 11045 by CMS and believe that the AMA RUC-recommended work RVU of 0.69 is more appropriate for this service. Commenters noted that removing the RVUs related to the pre- and post-service time results in a work RVU of 0.34, not a work RVU of 0.33. Commenters offered reference service CPT code 36575 (Repair of tunneled or non-tunneled central venous access catheter, without subcutaneous port or pump, central or peripheral insertion site) to support the AMA RUC-recommended work RVU of 0.69.

Response: Based on the comments received, we referred CPT code 11045 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 11045 was 0.50. As a result of the refinement panel ratings and our

clinical review, we are assigning a work RVU of 0.50 to CPT code 11045 as the final value for CY 2012.

As detailed in the CY 2011 PFS final rule with comment period, for CPT code 11043 (Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); first 20 sq cm or less) we assigned a work RVU of 2.00 on an interim final basis for CY 2011. After clinical review, we believed that the work RVU of 2.00 (the survey low) appropriately reflected the AMA RUC-recommended decrease in clinical time and follow-up E/M visits attributed to the performance of this service (CY 2010 work RVU=3.14). The AMA RUC recommended a work RVU of 3.00 for CPT code 11043 for CY 2011. (75 FR 73330)

Comment: Commenters disagreed with the interim final work RVU of 2.00 assigned to CPT code 11043 by CMS and believe that the AMA RUC-recommended work RVU of 3.00 is more appropriate for this service. Commenters noted that the AMA RUC-recommended value for this service corresponds to the specialty society survey 25th percentile value, and that the CMS-assigned value corresponds to the survey low. Commenters asserted that CMS ignored the survey results by selecting the survey low, noting that the low of any survey could be construed as an outlier and that they believe it is not appropriate to value services based on the survey low.

Response: Based on the comments received, we referred CPT code 11043 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 11043 was 2.70. As a result of the refinement panel ratings and our clinical review, we are assigning a work RVU of 2.70 to CPT code 11043 as the final value for CY 2012.

As detailed in the CY 2011 PFS final rule with comment period, for CPT code 11046 (Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)) we assigned a work RVU of 0.70 on an interim final basis for CY 2011. After clinical review, we believed that the work RVU of 0.70 (the survey low) appropriately placed this add-on service relative to its primary service, CPT code 11043. The AMA RUC recommended a work RVU of 1.29 for CPT code 11046 for CY 2011 (75 FR 73330).

Comment: Commenters disagreed with the interim final work RVU of 0.70 assigned to CPT code 11046 by CMS and believe that the AMA RUC-recommended work RVU of 1.29 is more appropriate for this service. Commenters noted that the AMA RUC-recommended value for this service corresponds to the specialty society survey 25th percentile value, and that the CMS-assigned value corresponds to the survey low. Commenters asserted that CMS ignored the survey results by selecting the survey low, noting that the low of any survey could be construed as an outlier and that they believe it is not appropriate to value services based on the survey low.

Response: Based on the comments received, we referred CPT code 11046 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 11046 was 1.03. As a result of the refinement panel ratings and our clinical review, we are assigning a work RVU of 1.03 to CPT code 11046 as the final value for CY 2012.

As detailed in the CY 2011 PFS final rule with comment period, for CPT code 11044 (Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less) we assigned a work RVU of 3.60 on an interim final basis for CY 2011. After clinical review, we believed that the work RVU of 3.60 (the survey low) appropriately reflected the AMA RUC-recommended decrease in clinical time and follow-up E/M visits attributed to the performance of this service (CY 2010 work RVU = 4.26). The AMA RUC recommended a work RVU of 4.56 for CPT code 11044 for CY 2011 (75 FR 73330).

Comment: Commenters disagreed with the interim final work RVU of 3.60 assigned to CPT code 11044 by CMS and believe that the AMA RUC-recommended work RVU of 4.56 is more appropriate for this service. Commenters noted that the AMA RUC-recommended value for this service corresponds to the specialty society survey 25th percentile value, and that the CMS-assigned value corresponds to the survey low. Commenters asserted that CMS ignored the survey results by selecting the survey low, noting that the low of any survey could be construed as an outlier and that they believe it is not appropriate to value services based on the survey low.

Response: Based on the comments received, we referred CPT code 11044 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 11044 was 4.10. As a result of the refinement panel ratings and our clinical review, we are assigning a work RVU of 4.10 to CPT code 11044 as the final value for CY 2012.

As detailed in the CY 2011 PFS final rule with comment period, for CPT code 11047 (Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)) we assigned a work RVU of 1.20 on an interim final basis for CY 2011. After clinical review, we believed that the work RVU of 1.20 (the survey low) appropriately placed this add-on service relative to its primary service, CPT code 11044. The AMA RUC recommended a work RVU of 2.00 for CPT code 11047 for CY 2011 (FR 75 73330).

Comment: Commenters disagreed with the interim final work RVU of 1.20 assigned to CPT code 11047 by CMS and believe that the AMA RUC-recommended work RVU of 2.00 is more appropriate for this service. Commenters noted that the AMA RUC-recommended value for this service corresponds to the specialty society survey 25th percentile value, and that the CMS-assigned value corresponds to the survey low. Commenters asserted that CMS ignored the survey results by selecting the survey low, noting that the low of any survey could be construed as an outlier and that they believe it is not appropriate to value services based on the survey low.

Response: Based on the comments received, we referred CPT code 11047 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 11047 was 1.80. As a result of the refinement panel ratings and our clinical review, we are assigning a work RVU of 1.80 to CPT code 11047 as the final value for CY 2012.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73338 and 73339), in the excision and debridement set of services, for CY 2011 two CPT codes were deleted and the services that would previously have been reported under those CPT codes are now reported under two revised codes, CPT code 97597 (Debridement (*e.g.,* high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (*e.g.,* fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less) and CPT code 97598 (Debridement (*e.g.,* high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and

forceps), open wound, (*e.g.,* fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)). These two revised wound management CPT codes were restructured from describing two distinct procedures reported based on wound surface area to describing a primary procedure and an add-on procedure that would additionally be reported in the case of a larger wound. We believed that the increase in aggregate work RVUs that would results from adoption of the RVUs, even after the adjustments we later discuss, did not represent a true increase in physician work for these procedures. Therefore, we believed it would be appropriate to apply work budget neutrality to this set of CPT codes. After reviewing the HCPAC-recommended work RVUs, we adjusted the work RVU for CPT code 97598, and then applied work budget neutrality to these two CPT codes, which constitute the set of clinically related CPT codes. The work budget neutrality factor for these 2 codes was 0.9422. The HCPAC-recommended work RVU, CMS-adjusted work RVU prior to the budget neutrality adjustment, and the CY 2011 interim final work RVU for these skin excision and debridement codes (CPT code 97597 and 97598) follow.

CPT Code	Short Descriptor	HCPAC-recommended work RVU	CMS-adjusted work RVU, pre-BN	CY 2011 interim final work RVU
97597	Rmvl devital tis 20 cm/<	0.54	0.54	0.51
97598	Rmvl devital tis addl 20 cm<	0.40	0.25	0.24

As mentioned previously, and detailed in the CY 2011 PFS final rule with comment period, for CPT code 97598, we disagreed with the HCPAC-recommended work RVU of 0.40 and assigned alternate work RVU of 0.25 prior to the application of work budget neutrality (75 FR 73330). We believed that a work RVU of 0.25, which corresponded to the specialty society survey low value, was consistent with new CY 2011 add-on CPT code 11045 (Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)), which we assigned a CY 2011 interim final work RVU of 0.33.

Comment: Commenters agreed with the application of work budget neutrality to CPT codes 97597 and 97598, and requested that the codes be re-reviewed after additional claims data are available to ensure that the frequency estimates were accurate. Commenters disagreed with the CMS pre-budget neutrality work RVU of 0.25 for CPT code 97598 and believed that the HCPAC-recommended work RVU of 0.40 is more appropriate for this service. Commenters asserted that CMS ignored the survey results by selecting the survey low, noting that the low of any survey could be construed as an outlier and that they believe it is not appropriate to value services based on the survey low.

Response: Based on the comments received, we referred CPT codes 97597 and 97598 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel result supported the HCPAC-recommended work RVU of 0.54 for CPT code 97597, and the CY 2011 interim final work RVU of 0.24 for CPT code 97598. Thus, the refinement panel result was in line with the pre-work budget neutrality work RVU for CPT code 97597, and in line with the post-work budget neutrality interim final work RVU for CPT code 97598. The refinement panel does not consider whether the application of work budget neutrality is appropriate. We continue to believe that these codes, although revalued, do not constitute new physician work in aggregate and that the application of work budget neutrality is appropriate for this set of clinically related CPT codes. Additionally, we continue to believe that the post-budget neutrality work RVU of 0.24, which was supported by the refinement panel result, appropriately reflects the work associated with CPT code 97598. After consideration of the public comments, refinement panel results, and our clinical review, we are finalizing a work RVU of 0.51 for CPT code 97597, and a work RVU of 0.24 for CPT code 97598 for CY 2012.

For CY 2012, we received no comments on the CY 2011 interim final work RVUs of 4.19 for CPT code 11010 (Debridement including removal of foreign material at the site of an open fracture and/or an open dislocation (*e.g.,* excisional debridement); skin and subcutaneous tissues), 4.94 for CPT code 11011(Debridement including removal of foreign material at the site of an open fracture and/or an open dislocation (*e.g.,* excisional debridement); skin, subcutaneous tissue, muscle fascia, and muscle), and 6.87 for CPT code 11012 (Debridement including removal of foreign material at the site of an open fracture and/or an open dislocation (*e.g.,* excisional debridement); skin, subcutaneous tissue, muscle fascia, muscle, and bone). We believe these values continue to be appropriate and are finalizing them without modification.

(2) Integumentary System: Nails (CPT Codes 11732 and 11765)

For the Fourth Five-Year Review, we identified CPT codes 11732 and 11765 as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen. The related specialty societies surveyed their members and the HCPAC issued recommendations to us for the Fourth Five-Year Review.

As detailed in the Fourth Five-Year Review, for CPT code 11732 (Avulsion of nail plate, partial or complete, simple; each additional nail plate (List separately in addition to code for primary procedure)) we proposed a work RVU of 0.44, with refinement to time. After clinical review, we believed that Multi-Specialty Points of Comparison (MPC) CPT code 92250 (Fundus photography with interpretation and report) (work RVU=0.44) provided an appropriate crosswalk work RVU for this service. We found the HCPAC-recommended decrease in work RVU (from 0.57 to 0.48) to be too small, given the recommended reduction in time (from 20 minutes total time in CY 2011, to a recommended 15 minutes total time for CY 2012). Additionally, we refined the post-service time for CPT code 11732 to 1 minute, as we believed the HCPAC-recommended 3 minutes of post-service time was excessive for this service (76 FR 32459).

Comment: Commenters disagreed with the proposed work RVU of 0.44 assigned to CPT code 11732 by CMS and believe that the HCPAC-recommended work RVU of 0.48 is more appropriate for this service. Commenters recommended that CMS utilize the survey data when valuing this service rather than a crosswalk methodology. Commenters noted that the HCPAC reviewed the survey results from 38 podiatrists and determined that the 25th percentile work RVU of 0.48 and total time of 15 minutes appropriately accounted for the work and times required to perform this service. Commenters wrote that the CMS-proposed reduction in time is unsubstantiated. Commenters reiterated the HCPAC recommendation stating that a work RVU of 0.48 maintains the proper relativity between this service and the comparison services of CPT codes 99212 (Level 3 Office or other outpatient visit) (work RVU=0.48) and 11721 (Debridement of nail(s) by any method(s); 6 or more) (work RVU=0.54). Commenters requested that CMS accept the HCPAC-recommended work RVU of 0.48 and total time of 15 minutes for CPT code 11732.

Response: Based on the comments received, we re-reviewed CPT code 11732. We continue to believe that a work RVU of 0.44 accurately reflects the work associated with this service and that MPC CPT code 92250 is a more appropriate comparison for this service than CPT codes 99212 or 11721. After reviewing the pre-, intra-, and post-service work descriptions for this service, we continue to believe that the recommended pre-, and intra- service times are appropriate, and that the recommended post-service time is in excess of the time required to perform the post-service work. We continue to believe that one minute of post-service time is sufficient for this add-on service. We are maintaining the interim final value, assigning a work RVU of 0.44, with 13 minutes of total time, as the final values for CPT code 11732 for CY 2012. A complete listing of the times associated with this, and all CPT codes, is available on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

As detailed in the Fourth Five-Year Review, for CPT code 11765 (Wedge excision of skin of nail fold (*e.g.,* for ingrown toenail)) we proposed a work RVU of 1.22, with refinement to time. We compared CPT code 11765 with reference CPT code 11422 (Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 1.1 to 2.0 cm) (work RVU=1.68), as well as with CPT code 10060 (Incision and drainage of abscess (*e.g.,* carbuncle, suppurative hidradenitis, cutaneous or subcutaneous abscess, cyst, furuncle, or paronychia); simple or single) (work RVU=1.22), and determined that CPT code 10060 was more similar in intensity and complexity to CPT code 11765, and thus the better comparator code for this service. We also refined the time associated with this service. CPT code 11765 is typically performed on the same day as an E/M visit and we believed that some of the activities conducted during the pre- and post-service times of the procedure code and the E/M visit overlap. To account for this overlap, we reduced the pre-service evaluation and post-service time by one third (76 FR 32459 through 32460).

Comment: Commenters disagreed with the CMS-proposed work RVU of 1.22 for CPT code 11765, and believe that the HCPAC-recommended work RVU of 1.48 is more appropriate for this service. Commenters noted that CMS crosswalked the work RVU for CPT code 11765 to CPT code 10060 which, commenters pointed out, is a revised code for this final rule with comment period. Commenters urged CMS not to crosswalk CPT code 11765 to CPT code 10060 as it is currently under review and asserted that a direct crosswalk is inappropriate when survey data are available. Commenters also noted that CY 2009 Medicare claims data indicated that CPT code 11765 was billed with an E/M less than 50 percent of the time. Commenters reiterated the HCPAC recommendation stating that the HCPAC compared CPT code 11765 to CPT code 11422 (work RVU=1.68) and noted that the reference code requires more intra-service time, more mental effort and judgment, and higher psychological stress to perform as compared to CPT code 11765. Ultimately, commenters requested that CMS accept the HCPAC-recommended work RVU of 1.48 and total time of 59 minutes for CPT code 11765.

Response: Based on comments received, we re-reviewed CPT code 11765. We continue to believe that a work RVU of 1.22 accurately reflects the work associated with this service and that CPT code 10060 is an appropriate comparison code for this service. CPT code 10060 recently was surveyed by related specialty society members, and the AMA RUC issued a new recommendation to us for CPT code 10060 for this final rule with comment period. As discussed in section III.C.1.b. of this final rule with comment period after a review of the new survey results for 10060, the AMA RUC recommendations, and our clinical review, we are setting an interim final work RVU of 1.22 for CPT code 10060 for CY 2012, which maintains the current (CY 2011) value. As such, we believe that the crosswalk work RVU of 1.22 for CPT code 11765 continues to be appropriate. For CY 2012 we are finalizing a work RVU of 1.22 for CPT code 11765.

In response to commenters' note that CPT code 11765 was billed with an E/M visit less than 50 percent of the time and therefore, should not be subject to the same day E/M adjustment, we looked back at the data for this and all other Five-Year Review CPT codes for which we proposed a same day E/M adjustment. When calculating the number of times a service was performed on the same day as an E/M visit, we likely over-counted multiple billings of a CPT code and depending on billing patterns may have identified an inappropriately higher percentage of same day E/M billing. We recalculated these figures using combined occurrence pairs, which we now believe is the more appropriate measure of same day E/M billings for this purpose. We note that for all codes reviewed for the CY 2012 PFS proposed and final rules we used figures calculated based on combined occurrence pairs. After recalculating the same day E/M percentages for the Five-Year Review CPT codes, CPT code 11765 was the only code that had originally appeared to be billed over 50 percent with an E/M visit, but under the revised calculation is billed less than 50 percent with an E/M visit. As such, we no longer believe it is appropriate to remove one-third of the pre-service evaluation time and one-third of the post service time to account for the E/M visit on the same date of service. For CY 2012 we are finalizing the HCPAC-recommended times of 17 minutes of pre-service evaluation time, 1 minute of pre-service positioning time, 5 minutes of pre-service dress, scrub and wait time, 5 minutes of intra-service time, 5 minutes of post-service time, and 1 CPT code 99212 office or outpatient visit for CPT code 11765.

(3) Integumentary System: Repair (Closure) (CPT Codes 11900–11901, 12001–12018, 12031–12057, 13100–13101, 15120–15121, 15260, 15732, 15823)

In the Fourth Five-Year Review, we identified CPT codes 12031, 12051, 13101, and 15260 as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen. CPT codes 12032–12047, 12052–12057, and 13100 were added as part of the

family of services for review. Also for the Fourth Five-Year Review, we identified CPT code 15732 as potentially misvalued through the site-of-service anomaly screen. CPT code 15121 was added as part of the family of services for review. The related specialty societies surveyed their members and the AMA RUC issued recommendations to us for the Fourth Five-Year Review.

As detailed in the Fourth Five-Year Review, in its review of this set of CPT codes, the AMA RUC determined that the original Harvard-valued work RVUs led to compression within these code families, which the AMA RUC recommended correcting by reducing the relative values for the smallest wound size repair codes and increasing the relative values for the larger wound size repair codes. Our proposed range of work RVUs for these CPT codes, while not as large as the range that would have resulted from our adoption of the AMA RUC recommendations, nevertheless is greater than the current range of work RVUs for the variety of wound sizes described by the repair codes (76 FR 32431 through 32432).

For CPT codes 12035 (Repair, intermediate, wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); 12.6 cm to 20.0 cm), 12036 (Repair, intermediate, wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); 20.1 cm to 30.0 cm), 12037 (Repair, intermediate, wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); over 30.0 cm), 12045 (Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; 12.6 cm to 20.0 cm), 12046 (Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; 20.1 cm to 30.0 cm), 12047 (Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; over 30.0 cm), 12055 (Repair, intermediate, wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 12.6 cm to 20.0 cm), 12056 (Repair, intermediate, wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 20.1 cm to 30.0 cm), and 12057 (Repair, intermediate, wounds of face, ears, eyelids, nose, lips and/or mucous membranes; over 30.0 cm), we proposed specialty society survey 25th percentile work RVU. The specialty society surveys of physicians furnishing these services indicated that the work of performing these services has not changed in the past 5 years and that the complexity of patients requiring the services has also remained constant. The survey 25th percentile work RVUs were somewhat higher than the current work RVUs for CPT codes 12035–12037, 12045–12047, 12055 and 12056, and the survey 25th percentile work RVU for CPT code 12057 was the same as the current (CY 2011) work RVU. Given the survey responses indicating that the work and complexity of these services has remained constant, we believed that adopting the survey 25th percentile work RVUs both accurately valued the work associated with these services and addressed the compression-related relativity adjustments recommended by the AMA RUC. For CPT codes 12035–12037, 12045–12047, and 12055–12057 the AMA RUC recommended the survey median work RVU, which was higher than both the current (CY 2011) and survey 25th percentile work RVU. The CY 2011, CMS-proposed survey 25th percentile, and AMA RUC-recommended survey median work RVUs are listed in Table 15.

In addition to proposed changes to the AMA RUC-recommended work RVUs for these services, we also refined the time associated with several of these services. For CPT codes 12036, and 12055–12057, we found the survey median intra-service times to be more appropriate for these services than the higher AMA RUC-recommended times. After clinical review, we believed that these survey median times accurately reflected the work associated with performing these services. We also refined the times for CPT codes 12046 and 12047. Both CPT codes are typically performed on the same day as an E/M visit and we believed that some of the activities conducted during the pre- and post- service times of the procedure code and the E/M visit overlap. To account for this overlap, we reduced the pre-service evaluation and post-service time by one third.

Comment: Commenters disagreed with the CMS-proposed work RVUs for CPT codes 12035–12037, 12045–12047, and 12055–12057, and recommended that CMS accept the AMA RUC-recommended work RVUs. Commenters believe that the proposal by CMS to select the survey 25th percentile survey value for these codes is flawed because, since these codes are not provided by a homogeneous group of providers, selecting a consistent survey marker does not ensure relativity between services. Commenters noted that CMS stated that use of the 25th percentile survey value was appropriate because survey respondents indicated that there has not been a change in complexity in these services in the last 5 years. Commenters asserted that a change in work was irrelevant, and that the revaluation was intended to correct compression within the family of services. Furthermore, commenters noted that the proposed work RVUs create rank order anomalies between similar services.

Commenters also disagreed with the CMS-proposed reductions in time for CPT codes 12036, 12046–12047, and 12055–12057, and recommended that CMS accept the AMA RUC-recommended times. For CPT codes 12036, 12055, and 12057 commenters noted that a significant number of providers who do not typically perform the procedure responded to the survey, resulting in an artificially reduced median intra-service time. Commenters asserted that in this case it is more valid to utilize the results from the providers with experience performing this service. For CPT codes 12046 and 12047 commenters asserted that it was not appropriate for CMS to reduce the pre-evaluation and post service time to account for a same day E/M visit. Commenters noted that these services have very low utilization, and that the CMS data showing that these services are typically billed with an E/M may be incorrect. Commenters also noted that the recommended pre-service time for these two codes was already reduced from 19 minutes to 13 minutes so they believed that a further reduction was not justified.

Response: Based on comments received, we referred CPT codes 12035–12037, 12045–12047, and 12055–12057 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel results largely supported the AMA RUC-recommended work RVUs for these services. However, we are going to maintain the CMS-proposed work RVUs and times for these services as interim, pending the AMA RUC review of the complex wound repair codes which we anticipate will be complete for CY 2013. Following the receipt of the AMA RUC recommendations for the complex wound repair codes, we will reevaluate the work RVU and times for these services, especially relative to the complex wound repair services. With regards to the accuracy of the same day E/M data, for this final rule with comment period, for all the five-year review CPT codes, we recalculated the percentage of time they are billed with an E/M visit using combined occurrence pairs, as discussed under III.B.1.b.(2). of this final rule with comment period. Using a 5 percent sample of CY 2009 Medicare claims data, CPT code 12046 is billed with an E/M visit for 50 percent of the services, and CPT code 12047 is billed with an E/M for 60 percent of the services. Therefore, we continue to believe that it is appropriate to reduce the pre-service evaluation and post

service times by one-third. We recognize that these services are low volume and we will take this into consideration when reevaluating the times and work RVUs for these codes for CY 2013.

In sum, we are holding as interim for CY 2012 the Fourth Five-Year Review proposed work RVUs and times for CPT codes 12035–12037, 12045–12047, and 12055–12057 (the larger of the intermediate wound repair services), so we can review these services alongside the complex wound repair codes before finalizing their values. For clarification, we do not expect that the AMA RUC would resurvey these codes. For CY 2012 the interim work RVUs are as follows: A work RVU of 3.50 for CPT code 12035, a work RVU of 4.23 for CPT code 12036, a work RVU of 5.00 for CPT code 12037, a work RVU of 3.75 for CPT code 12045, a work RVU of 4.30 for CPT code 12046, a work RVU of 4.95 for CPT code 12047, a work RVU of 4.50 for CPT code 12055, a work RVU of 5.30 for CPT code 12056, and a work RVU of 6.00 for CPT code 12057. A complete listing of the times associated with these, and all CPT codes, is available on the CMS web site at: *https://www.cms.gov/PhysicianFeeSched/*.

As detailed in the Fourth Five-Year Review, for CPT code 13100 (Repair, complex, trunk; 1.1 cm to 2.5 cm) and 13101 (Repair, complex, trunk; 2.6 cm to 7.5 cm) the AMA RUC reviewed the specialty society survey results and determined that the current (CY 2011) work RVUs maintain the appropriate relativity for these services. We noted that the AMA RUC reviewed only two CPT codes in the complex wound repair family. We agreed with the AMA RUC-recommended work RVUs for these two services, and requested that, in order to ensure consistency, the AMA RUC review the entire set of codes in the complex wound repair family and assess the appropriate gradation of the work RVUs in this family. We maintained the current (CY 2011) work RVUs and times for CPT codes 13100 and 13101 pending the AMA RUC review of the other CPT codes in this family (76 FR 32434 through 32435).

Comment: Commenters requested that CMS adopt the AMA RUC-recommended times for CPT codes 13100 and 13101. Commenters believe it would be unfair to ask the specialty to re-survey these services and that the review of other complex repair codes is unlikely to change the AMA RUC-recommended times for CPT code 13100 and 13101. Commenters note that the current (CY 2011) Harvard times are very similar to the AMA RUC-recommended times.

Response: In response to comments received, we re-reviewed CPT code 13100 and 13101. While we appreciate commenters' assertion that the review of other complex repair codes is unlikely to change the AMA RUC-recommended times for CPT code 13100 and 13101, we would like to refrain from revising the current (CY 2011) times and work RVUs for these codes until we can review them alongside the other complex wound repair codes. In the CY 2013 PFS final rule with comment period, we anticipate publishing interim final values for CPT codes 13100 and 13101 along with the other complex wound repair codes.

In the Fourth Five-Year Review (76 FR 32435), we identified CPT codes 15120 and 15732 as potentially misvalued through the site-of-service anomaly screen. CPT code 15121 was added as part of the family of services for AMA RUC review. In addition, we identified CPT code 15260 as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen. For CPT code 15120 (Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1 percent of body area of infants and children (except 15050)), we proposed a work RVU of 10.15 for CY 2012, which was in agreement with the AMA RUC-recommended work RVU for this CPT code. Because the most recent Medicare PFS claims data showed that CPT code 15120 is a code with a site-of-service anomaly, we adjusted the times in accordance with the policy discussed in section III.A. of this final rule with comment period. Specifically, we removed the current (CY 2011) 0.5 subsequent hospital care day, added 5 minutes to the immediate post-operative period, and reduced the discharge day management service to one-half. These time changes were reflected in the Five-Year Review physician time file available on the CMS Web site at: *http://www.cms.gov/PhysicianFeeSched/PFSFRN/*. Though this time refinement was listed in the physician time file, we unintentionally did not note this time refinement in the Fourth Five-Year Review proposed notice text. As such, we are holding CPT code 15120 as interim final for CY 2012, with the previously discussed AMA RUC-recommended work RVU of 10.15 and the site-of-service time refinement discussed previously. A complete listing of the times assigned to CPT code 15120 follow in Table 16.

For CPT code 15732 (Muscle, myocutaneous, or fasciocutaneous flap; head and neck (*e.g.,* temporalis, masseter muscle, sternocleidomastoid, levator scapulae)), we proposed a work RVU of 16.38 for CY 2012, with refinements to the time. The most recent Medicare PFS claims data showed that CPT code 15732 is a code with a site-of-service anomaly. Upon review, it was clear that this code was being billed for services furnished to hospital outpatients, and we had no reason to believe that miscoding was the main reason that outpatient settings were the dominant place of service for this code in historical PFS claims data. Therefore, in accordance with the policy discussed in section III.A. of this final rule with comment period, we removed the inpatient hospital visit, reduced the discharge day management service to one-half, and adjusted times. These adjustments resulted in a work RVU of 16.38.

The AMA RUC asserted that claims data indicating that this service was furnished in an outpatient setting was the result of miscoding but, until the claims data indicate that this service typically was furnished in the inpatient setting (greater than 50 percent), we believed it was inappropriate for the service to be valued including inpatient E/M building blocks. We also stated that we will continue to monitor site-of-service utilization for this code and may consider reviewing the work RVU for this code again in the future if utilization patterns change (76 FR 32435).

Comment: Commenters disagreed with the proposed work RVU of 16.38 for CPT code 15732, and supported the AMA RUC-recommended work RVU of 19.83. Commenters noted that the proposed value was derived from the reverse building block methodology, which removed the subsequent hospital care codes and reduced the full hospital discharge day code to a half day. Commenters stated that the service described by CPT code 15732 is furnished in the inpatient setting, and that data showing otherwise are the result of miscoding. Commenters noted that education is still needed for this family of codes. Commenters noted that the AMA RUC-recommended value is more similar to the key reference code 15734 (Muscle, myocutaneous, or fasciocutaneous flap; trunk) (work RVU=19.86). Commenters expressed concerns that the proposed work RVU will create a rank order anomaly within the family, and requested that CMS accept the AMA RUC-recommended work RVU of 19.83 for CPT code 15732.

Response: Based on comments we received, we referred CPT code 15732 to the CY 2011 multi-specialty refinement panel for further review. The refinement

panel voted for a work RVU of 17.38 for CPT code 15732. We appreciate commenters' interest in physician education to alleviate the potential for miscoding. However, the Medicare PFS data show that this service is typically furnished in the outpatient setting. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. As stated previously, we will continue to monitor site-of-service utilization for this code and may consider reviewing the work RVU for this code again in the future if utilization patterns change. In order to ensure consistent and appropriate valuation of physician work, we are upholding the application of our methodology to address 23-hour stay site-of-service anomalies. After consideration of the public comments, refinement panel results, and our clinical review, we are finalizing a work RVU of 16.38 for CPT code 15732 and our proposed refinements to physician time. CMS time refinements can be found in Table 16.

For CY 2012, we received no comments on the CY 2011 interim final work RVUs for CPT codes 11900, 11901, 12001–12018, and 15823. Additionally, for CY 2012, we received no comments on the Fourth Five-Year Review proposed work RVUs for CPT codes 12041–12044, 12051–12054, 15120, 15121, and 15260. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(4) Integumentary System: Destruction (CPT Codes 17250–17286)

In the Fourth Five-Year Review (76 FR 32436), we identified CPT codes 17271, 17272 and 17280 as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen. The dominant specialty for this family—dermatology—identified several other codes in the family to be reviewed concurrently with these services and submitted to the AMA RUC recommendations for CPT codes 17260 through 17286. The AMA RUC concluded that, with the exception of one CPT code, 17284, the survey data validated the current values of the destruction of skin lesion services. We agreed with this assessment, with a few refinements to physician time.

As detailed in the Fourth Five-Year Review (76 FR 32436), we proposed work RVUs of 1.37 for CPT codes 17270 (Destruction, malignant lesion (*e.g.,* laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less); 1.54 for CPT code 17271 (Destruction, malignant lesion (*e.g.,* laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 0.6 to 1.0 cm); and 2.64 for CPT code 17274 (Destruction, malignant lesion (*e.g.,* laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 3.1 to 4.0 cm) with refinements to physician time. The AMA RUC recommended a work RVU of 1.37 for CPT code 17270, a work RVU of 1.54 for CPT code 17271, and a work RVU of 2.64 for CPT code 17274. For CPT codes 17270, 17271, and 17274, we believed that the survey median intra-service times accurately reflected the time required to conduct the intra-service work associated with these services, the survey median. Therefore, for CPT code 17270, we increased the intra-service time from 15 minutes to 16 minutes. For CPT code 17271, we maintained the intra-service time of 18 minutes, the survey median. For CPT code 17274, we increased the intra-service time from 32 minutes to 33 minutes.

Comment: In their public comment on the Fourth Five-Year Review, the AMA RUC noted that there was a typographical error in specialty society's recommendation to CMS for CPT codes 17270, 17271, and 17274, which the specialty society later corrected. They requested that CMS change the intra-service times to the AMA RUC-recommended times of 15 minutes for CPT code 17270, the corrected 19 minutes for CPT code 17271, and 32 minutes for CPT code 17274.

Response: In response to comments, we re-reviewed CPT codes 17270, 17271, and 17274. We thank the AMA RUC for pointing out this time error. After reviewing the descriptions of intra-service work, we agree that CPT codes 17270, 17271, and 17274 should have 15 minutes, 19 minutes, and 32 minutes of intra-service physician time, respectively. For CPT code 17270, we are finalizing a work RVU of 1.37 and an intra-service time of 15 minutes. For CPT code 17271, we are finalizing a work RVU of 1.54 and an intra-service time of 19 minutes. For CPT code 17274, we are finalizing a work RVU of 2.64 and an intra-service time of 32 minutes.

For CY 2012, we received no comments on the Fourth Five-Year Review proposed work RVUs for CPT codes 17250, 17260–17264, 17266, 17272, 17273, 17276, 17280–17284, and 17286. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(5) Integumentary System: Breast (CPT Codes 19302–19357)

In the Fourth Five-Year Review (76 FR 32437), we identified CPT code 19302 as potentially misvalued through the site-of-service anomaly screen. For CPT code 19302 (Mastectomy, partial (*e.g.,* lumpectomy, tylectomy, quadrantectomy, segmentectomy); with axillary lymphadenectomy), we proposed a work RVU of 13.87. We agreed with the AMA RUC that CPT code 19302 is similar in work intensity and time to CPT code 38745 (Axillary lymphadenectomy; complete) (work RVU = 13.87), which overlaps significantly with CPT code 19302. As such, we believed these two procedures should have the same work RVU of 13.87. The AMA RUC recommended a work RVU of 13.99 for CPT code 19302 (76 FR 32437).

Comment: Commenters disagreed with the CMS-proposed work RVU of 13.87 for CPT code 19302, and asserted that the AMA RUC-recommended work RVU of 13.99 is more appropriate for this service. Commenters noted that we compared CPT code 19302 with CPT code 38745, which has an intra-service time of 90 minutes. Commenters stated that the slightly greater intra-service time of CPT code 19302 supports the current work RVU of 13.99, and request that we accept the AMA RUC-recommended work RVU of 13.99.

Response: Based on the comments we received, we referred CPT code 19302 to the CY 2011 multi-specialty refinement panel for further review. Refinement panel results supported the AMA RUC recommendation and validated the current work RVU of 13.99. As a result of the refinement panel ratings and our clinical review, for CY 2012 we are finalizing a work RVU of 13.99 for CPT code 19302.

For CY 2012, we received no comments on the Fourth Five-Year Review proposed work RVU for CPT code 19357. We believe this value continue to be appropriate and are finalizing it without modification (Table 15).

(6) Musculoskeletal: Spine (Vertebral Column) (CPT Codes 22315, 22520–22525, 22551, 22552, 22554, 22585, and 22851)

In the Fourth Five-Year Review, we identified CPT code 22521 as potentially misvalued through the site-of-service anomaly screen. CMS also requested that the AMA RUC review other CPT codes in the family including

CPT codes 22520, 22522, 22523, 22524 and 22525.

In the Fourth Five-Year Review, we proposed a work RVU of 8.01 for CPT code 22521 (Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; lumbar); a work RVU of 8.62 for CPT code 22523 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (*e.g.,* kyphoplasty); thoracic); and a work RVU of 8.22 for CPT code 22524 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (*e.g.,* kyphoplasty); lumbar). The current valuation of these codes includes one full discharge management day consistent with performance in an inpatient setting for these services. As these CPT codes are typically performed in the outpatient setting, the AMA RUC recommended, and we agreed, that the discharge management day should be reduced by half as this is consistent with our adjustment methodology for site-of-service anomaly codes. Although the AMA RUC reduced the discharge day management by half, it discovered that an inadvertent clerical error had led these codes to appear as if they had been valued with one full discharge management day. The AMA RUC stated that these codes were valued as outpatient services using only half a discharge management day during the 2006 Third Five-Year Review of Work (71 FR 37271). The AMA RUC concluded that the current (CY 2011) work RVU for these codes should not be reduced to reflect the removal of the half discharge day. The AMA RUC recommended maintaining the current work RVU of 8.65 for CPT code 22521, 9.26 for CPT code 22523, and 8.86 for CPT code 22524 (76 FR 32437).

Comment: Commenters disagreed with our proposed work RVUs of 8.01 for CPT code 22521, 8.62 for CPT code 22523, and 8.22 for CPT code 22524. Additionally, commenters stated that our action to reduce the work RVUs of codes 22521, 22523 and 22524 disregarded that the AMA RUC previously had accounted for the outpatient location in its recommendation. Moreover, commenters disagreed with CMS removing the value of the half discharge management day which is 0.64 of a work RVU from each code, and recommended that we accept the AMA RUC-recommended values for these three CPT codes.

Response: Based on the public comments received, we referred CPT codes 22521, 22523, and 22524 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs were 8.65 for CPT code 22521, 9.04 for CPT code 22523, and 8.54 for CPT code 22524. In response to the AMA RUC's comments on the Fourth Five-Year Review, we re-reviewed the Medicare PFS claims data for CPT codes 22521, 22523, and 22524. The PFS claims data showed that these services were utilized in outpatient settings more than 50 percent of the time at the time these codes were last reviewed. These codes are not considered to be site-of-service anomaly codes since they were previously valued as outpatient services. We do not believe it would be appropriate to apply our site-of-service methodology of removing a half discharge day management (work RVU = 0.64) from the current (CY 2011) values in this final rule with comment period. Instead, we are finalizing the refinement panel median work RVUs of 8.65 for CPT code 22521, 9.04 for CPT code 22523, and 8.54 for CPT code 22524 for CY 2012. We received no comments on the CY 2012 proposed work RVUs for CPT codes 22315, 22520, 22522, and 22525. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

The AMA RUC identified CPT code 22554 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2) through the ''Codes Reported Together'' potentially misvalued code screen. After review, the AMA RUC referred CPT code 22554 to the CPT Editorial Panel to create a new coding structure for this family of services. For CY 2011, the CPT Editorial Panel created 2 new CPT codes—22551 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2) and 22552 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)—to describe fusion and discectomy of the anterior cervical spine.

In the CY 2011 PFS final rule with comment period (75 FR 73331), we assigned a work RVU of 25.00 to CPT code 22551 on an interim final basis for CY 2011. The AMA RUC recommended a work RVU of 24.50. The specialty society requested a work RVU of 25.00. Upon review of the AMA RUC-recommended value and the reference codes used, it was unclear why the AMA RUC decided not to accept the specialty society's recommended work RVU of 25.00. We agreed with the specialty society and believed a work RVU of 25.00 was appropriate for this service. We also requested that the specialty society, with the AMA RUC, re-review the pre-service times for codes in this family since concerns were noted in the AMA RUC recommendation about the pre-service time for this service.

We did not receive any public comments that disagreed with the interim final work values. Therefore, we are finalizing a work RVU of 25.00 for CPT code 22551. For CY 2012, we received no comments on the CY 2011 interim final work RVUs for CPT codes 22552, 22554, 22585, and 22851. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(7) Musculoskeletal: Forearm and Wrist (CPT Codes 25116—25605)

In the Fourth Five-Year Review, we identified CPT codes 25600 (Closed treatment of distal radial fracture (*e.g.,* Colles or Smith type) or epiphyseal separation, includes closed treatment of fracture of ulnar styloid, when performed; without manipulation) and 25605 (Closed treatment of distal radial fracture (*e.g.,* Colles or Smith type) or epiphyseal separation, includes closed treatment of fracture of ulnar styloid, when performed; with manipulation) as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen.

As detailed in the Fourth Five-Year Review of Work, for CPT code 25600, we proposed a work RVU of 2.64 for CY 2012. After clinical review, we believed that CPT code 25600 required more work than key reference CPT code 26600 (Closed treatment of metacarpal fracture, single; without manipulation, each bone), and found that CPT code 27767 (Closed treatment of posterior malleolus fracture; without manipulation) (work RVU = 2.64) is similar in complexity and intensity to CPT code 25600. In addition to the work RVU adjustment for CPT code 25600, we refined the time associated with this CPT code. We believed some of the activities conducted during the pre- and post-service times of the procedure code and the E/M visit overlap. Therefore, to account for this overlap, we refined the

time for CPT code 25600 by reducing the pre-service evaluation and post service time by one-third. Specifically, we believed that 5 minutes pre-service evaluation time and 7 minutes post-service time accurately reflect the time required to conduct the work associated with this service. The AMA RUC recommended that CMS continue the current work RVU of 2.78 for CPT code 25600 (76 FR 32438) based on the results of a recent survey.

Comment: Commenters disagreed with the CMS-proposed work RVU of 2.64 for CPT 25600 and believe that the AMA RUC-recommended work RVU of 2.78 is more appropriate for this service. Furthermore, the commenters noted that the AMA RUC and the surveying specialty societies had already taken account of pre-operative work by reducing the specialty society recommended pre-service time from 9 minutes to 7 minutes. Commenters noted that AMA RUC submission to CMS mistakenly failed to allocate the 7 minutes of pre-service time between pre-service evaluation and pre-service positioning, and noted that they had intended to recommend 5 minutes of pre-service evaluation time and 2 minutes of pre-service positioning time. They also argued that there is no overlapping post-operative work because the patient E/M visit would have been completed prior to the surgical service and thus, by definition, prior to the post-service period. As such, commenters requested that CMS accept the clarified pre-service times of 5 minutes for pre-service evaluation and 2 minutes for pre-service positioning, as well as the recommended 10 minutes of post-service time. Additionally, commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU of 2.78.

Response: Based on comments received, we referred CPT code 25600 to the CY 2011 multi-specialty refinement panel for further review. The median refinement panel work RVU was 2.78. As a result of the refinement panel rating and our clinical review, we are assigning a work RVU of 2.78 to CPT code 25600 as the final value for CY 2012. In response to comments received regarding the times associated with CPT code 25600, we re-reviewed our proposed pre- and post-service minutes. We agree with the AMA RUC that 5 minutes of pre-service evaluation work adequately accounts for the time required to furnish this service and appropriately accounts for the E/M visit performed on the same day. However, for the pre-service positioning time, we believe that 1 minute of pre-service positioning time, rather than the revised recommendation of 2 minutes, is appropriate. CPT code 25605 (Closed treatment of distal radial fracture (*e.g.,* Colles or Smith type) or epiphyseal separation, includes closed treatment of fracture of ulnar styloid, when performed; with manipulation) is assigned 1 minute of pre-service positioning time and includes manipulation, while CPT code 25600 is used for the same service, but without manipulation. As such, we do not believe that CPT code 25600 should have more pre-service positioning time than CPT code 25605. Therefore, for CPT code 25600, we are finalizing a pre-service evaluation time of 5 minutes and a pre-service positioning time of 1 minute.

With regard to the post-service time, though the procedure described by CPT code 25600 would occur after the E/M service, after a review of the post-service work associated with the E/M visit and the procedure, we continue to believe that there is overlap, and that this overlap was appropriately accounted for by removing one-third of the post-service minutes from CPT code 25600, thereby reducing the post-service time from 10 minutes to 7 minutes. In sum, for CY 2012 we are finalizing the refinement panel result median work RVUs of 2.78 and the following pre- and post-service times: 5 minutes pre-service evaluation time, 1 minute pre-service positioning time, and 7 minutes post-service time for CPT code 25600. CMS time refinements are listed in Table 16.

As detailed in the Fourth Five-Year Review of Work, for CPT code 25605, we proposed a work RVU of 6.00 for CY 2012. After clinical review, including comparison to CPT code 28113 (Ostectomy, complete excision; fifth metatarsal head), we believed that an RVU of 6.00 (the survey low) correctly reflected relativity across these services. The AMA RUC recommended a work RVU of 6.50 for CPT code 25605 for CY 2011 (76 FR 32438). In addition to the work RVU adjustment for CPT code 25605, we refined the time associated with this code. Recent Medicare PFS claims data show that this service is typically performed on the same day as an E/M visit. We believed that, in its time recommendation to us, the AMA RUC accounted for duplicate E/M work associated with the pre-service period, but not the post service period. To account for this post-service overlap, we proposed to reduced the post service time by one-third.

Comment: Commenters disagreed with the proposed work RVU of 6.00 for CPT code 25605 and believe that the AMA RUC-recommended work RVU of 6.50 is more appropriate. In addition, commenters noted that the AMA RUC-recommended value for this service corresponds to the specialty society survey 25th percentile, whereas the CMS-assigned value corresponds to the survey low. Commenters noted that making a recommendation based on the survey low value which is potentially an outlier data point is not statistically sound methodology and assert that it is inappropriate to value services based on the survey low. Furthermore, the commenters noted that the AMA RUC and the surveying societies had already taken account of pre-operative overlap in work and reduced estimated times accordingly, and that there is no overlapping post-operative work because the patient E/M would have been completed prior to the surgical service and thus, by definition, prior to the post-service period. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, and requested CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 25605 to the CY 2011 multi-specialty refinement panel for further review. The median refinement panel work RVU was 6.25. In response to comments received regarding the times associated with CPT code 25605, we re-reviewed out proposed pre- and post-service minutes. We note that we did not propose a reduction in pre-service minutes from the AMA RUC-recommended time, and that we did propose a one-third reduction in post-service minutes to account for the same day E/M visit. After a review of the post-service work associated with the E/M visit and the procedure, we continue to believe that there is overlap, and that this overlap was appropriately accounted for by removing one-third of the post-service minutes from CPT code 25605, thereby reducing the post-service time from 20 minutes to 13 minutes. In sum, for CY 2012 we are finalizing the refinement panel result median work RVUs of 6.25 and the following pre- and post-service times: 14 minutes of pre-service evaluation time, 1 minute of pre-service positioning time, 5 minutes of pre-service dress, scrub and wait time, and 13 minutes of post-service time for CPT code 25605. CMS time refinements can be found in Table 50.

(8) Musculoskeletal: Femur (Thigh Region) and Knee Joint (CPT Codes 27385–27530)

In the Fourth Five-Year Review, we identified CPT codes 27385 and 27530 as potentially misvalued through the site-of-service anomaly screen.

As detailed in the Fourth Five-Year Review of Work, for CPT code 27385 (Suture of quadriceps or hamstring muscle rupture; primary), we proposed a work RVU of 6.93 for CY 2012. Medicare PFS claims data indicated that CPT code 27385 is typically performed as an outpatient rather than inpatient service. In accordance with our methodology to address 23-hour stay and site-of-service anomalies described in section III.A. of this final rule with comment period, for CPT code 27385, we removed the hospital visit, reduced the discharge day management service by one-half, and increased the post-service time to 30 minutes. The AMA RUC recommended a work RVU of 8.11 for CPT code 27385 (76 FR 32438). The AMA RUC reviewed the survey results from physicians who frequently perform this service and decided that the work required to perform this service had not changed. The AMA RUC recommended that this service be valued as a service performed predominately in the inpatient setting, as the survey data indicated that half of patients have an overnight stay.

Comment: Commenters disagreed with the CMS-proposed work RVU of 6.93 for CPT code 27385 and believe that that AMA RUC-recommended work RVU of 8.11 is more appropriate for this service. Commenters asserted that CPT code 27385 is not a site-of-service anomaly code because it is utilized more than 50 percent of the time in the inpatient setting. Commenters noted that the CMS value was derived from the reverse building block methodology, which removed the subsequent hospital care code and reduced the full hospital discharge day management code to a half day, along with the associated work RVUs and times. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on the public comments received, we referred CPT code 27385 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 7.77 for CPT code 27385. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. The most recent Medicare PFS claims data indicates that this service is now typically furnished in the outpatient setting. As such, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time and intensity. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is necessary in the case of CPT code 27385 to apply the methodology, described previously, to address 23-hour stay site-of-service anomalies. Therefore, we are finalizing the proposed work RVU of 6.93 for CPT code 27385. Additionally, we are finalizing a pre-service evaluation time of 33 minutes, a pre-service positioning time of 9 minutes, pre-service dress, scrub, and wait time of 15 minutes, an intra-service time of 60 minutes, and a post-service time of 30 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 27385. CMS time refinements can be found in Table 16.

As detailed in the Fourth Five-Year Review of Work, for CPT code 27530 (Closed treatment of tibial fracture, proximal (plateau); without manipulation), we proposed a work RVU of 2.65 for CY 2012. Recent Medicare PFS claims data has shown that this service is typically performed on the same day as an E/M visit. We believed there was some overlap in the activities conducted during the pre- and post-service times between the procedure code and the E/M visit and, therefore, the time should not be counted twice in developing the procedure's work value. As described earlier in section III.A. of this final rule with comment period, to account for this overlap, we reduced the pre-service evaluation and post-service time by one-third. We believed that 5 minutes pre-service evaluation time and 7 minutes post-service time accurately reflected the time required to conduct the work associated with this service. We also removed the 2 minutes of pre-service positioning time, as it does not appear from the vignette that positioning is required for a non-manipulated extremity.

In order to determine the appropriate work RVU for this service given the time changes, we calculated the value of the extracted time and subtracted it from the AMA RUC-recommended work RVU. The AMA RUC recommended a work RVU of 2.81 for CPT code 27530 (76 FR 32438).

Comment: Commenters disagreed with the CMS-proposed work RVU of 2.65 for CPT code 27530 and believe that the AMA RUC-recommended work RVU of 2.81 is more appropriate for this service. Commenters disagree with CMS' use of the reverse building block methodology, which reduced pre- and post-service times because of overlap with same day E/M services. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested that CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on the public comments received, we referred CPT code 27530 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 2.76 for CPT code 27530. In response to comments received, we reviewed the pre- and post- service time and work for this procedure. We continue to believe some of the activities conducted during the pre- and post-service times of the procedure code and the E/M visit overlap and should not be counted in developing this procedure's work value. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply the methodology, described previously for services typically billed in conjunction with an E/M service, and remove a total of 7 minutes from the AMA RUC-recommended pre- and post-service time, which amounts to the removal of 0.16 of a work RVU as described previously. Therefore, we are finalizing a work RVU of 2.65 for CPT code 27530. In addition, after reviewing the descriptions pre- and post-service work, we are finalizing a pre-service time of 4 minutes, an intra-service time of 15 minutes, and a post-service time of 7 minutes. CMS time refinements can be found in Table 16.

(9) Musculoskeletal: Leg (Tibia and Fibula) and Ankle Joint (CPT Code 27792)

In the Fourth Five-Year Review, we identified CPT code 27792 (Open treatment of distal fibular fracture (lateral malleolus), includes internal fixation, when performed) as potentially

misvalued through the site-of-service anomaly screen. In addition, we proposed a work RVU of 8.75 for CPT code 27792. Medicare PFS claims data indicated that CPT code 27792 is typically performed in an outpatient setting. However, the current AMA RUC-recommended values for this code reflect work that is typically associated with an inpatient service. Therefore, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described in section III.A. of this final rule with comment period, for CPT code 27792, we removed the subsequent observation care service, reduced the discharge day management service by one-half, and adjusted the physician times accordingly. For CPT code 27792, the AMA RUC used magnitude estimation and recommended that the current value of this service, 9.71 RVUs, be maintained; and the AMA RUC replaced the current inpatient hospital E/M visit included in the value with a subsequent observation care service while maintaining a full discharge day management service (76 FR 32439).

Comment: Commenters disagreed with the CMS-proposed work RVU of 8.75 for CPT code 27792 and believe that that AMA RUC-recommended work RVU of 9.71 is more appropriate for this service. Commenters disagreed with CMS' use of the reverse building block methodology, which removed the subsequent observation care code and reduced the full hospital discharge day management code to a half day, along with the associated work RVUs and times. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on the public comments received, we referred CPT 27792 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 9.71, which was consistent with the AMA RUC recommendation to maintain the current (CY 2011) work RVU for CPT code 27792. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply the methodology described previously to address 23-hour stay site-of-service anomalies. Therefore, we are finalizing a work RVU of 8.75 for CPT code 27792. In addition, after reviewing the descriptions of the pre- and post-service work, we are finalizing a pre-service evaluation time of 33 minutes, a pre-service positioning time of 10 minutes, a pre-service dress, scrub, and wait time of 15 minutes, an intra-service time of 60 minutes, and a post-service time of 30 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 27792. CMS time refinements can be found in Table 16.

(10) Musculoskeletal: Foot and Toes (CPT Codes 28002–28825)

For the Fourth Five-Year Review, we identified CPT codes 28002, 28715, 28820 as potentially misvalued though the site-of-service anomaly screen. CPT code 28003 was added as a part of the family of services for review. We also identified CPT code 28285 as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen. The related specialty societies surveyed these codes and the AMA RUC issued recommendations to us for the Fourth Five-Year Review of Work.

CPT codes 28120 and 28122 were identified in 2007 by the AMA RUC Relativity Assessment Workgroup as potentially misvalued through the site-of-service anomaly screen. The related specialty societies surveyed these codes and the AMA RUC issued recommendations to us for CY 2010. As described in section III.A. of this final rule with comment period, we accepted these CY 2010 site-of-service anomaly code values on an interim basis but requested that the AMA RUC re-examine the site-of-service anomaly codes and adjust the work RVUs, times, and post-operative visits to reflect those typical of a service furnished in an outpatient or physician's office setting. The AMA RUC re-reviewed the survey data for these codes and issued recommendations to us for the Fourth Five-Year Review of Work.

We reviewed CPT codes 28002–28003, 28120–21822, 28285, 28715, 28820, and 28825, and published proposed work RVUs in the Fourth Five-Year Review of Work (76 FR 32440). Based on comments received during the public comment period, we referred CPT codes 28002, 28120–21822, 28285, 28715, 28820, and 28825 to the CY 2011 multi-specialty refinement panel for further review.

As detailed in the Fourth Five-Year Review of Work, for CPT code 28002 (Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space), we proposed a work RVU of 4.00 for CY 2012. After clinical review, including comparison to CPT code 58353 (Endometrial ablation, thermal, without hysteroscopic guidance) (work RVU=3.60), we believed that the survey low value work RVU of 4.00 accurately reflected the work associated with this service. The AMA RUC recommended a work RVU of 5.34 for CPT code 28002 for CY 2011 (76 FR 32440).

Comment: Commenters disagreed with the CMS-proposed work RVU of 4.00 for CPT code 28002 and believe that the AMA RUC-recommended work RVU of 5.34 is more appropriate for this service. Commenters disagreed with the reference service put forward by CMS, and asserted that the AMA RUC-chosen reference service is a strong comparison code. Commenters noted that the AMA RUC-recommended value for this service corresponds to the specialty society survey 25th percentile value, and that the CMS-assigned value corresponds to the survey low. Commenters asserted that establishing a value based on the survey low, which potentially is an outlier data point, is not a statistically sound methodology, and believe that it is inappropriate to value services based on the survey low.

Response: Based on the comments received, we referred CPT code 28002 to the CY 2011 multi-specialty refinement panel for further review. The median refinement panel work RVU was 5.34. As a result of the refinement panel ratings and clinical review by CMS, we are assigning the AMA RUC-recommended work RVU of 5.34 to CPT code 28002 as the final value for CY 2012. For CY 2012, we received no comments on the proposed CY 2012 work RVU for CPT code 28003. We believe this value continues to be appropriate and are finalizing it without modification (Table 15).

As detailed in the Fourth Five-Year Review of Work, for CPT code 28120 (Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (*e.g.,* osteomyelitis or bossing); talus or calcaneus), we proposed a work RVU of 7.31 for CY 2012. Medicare PFS claims data indicated that CPT code 28120 is typically performed in an outpatient

setting. However, the current and AMA RUC-recommended values for this code reflected work that is typically associated with an inpatient service. Therefore, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described previously, for CPT code 28120, we removed the subsequent observation care service, reduced the discharge day management service by one-half, and adjusted the physician times accordingly. The AMA RUC recommended maintaining the current work RVU of 8.27 for CPT code 28120 for CY 2012 (76 FR 32440).

Comment: Commenters disagreed with the CMS-proposed work RVU of 7.31 for CPT code 28120 and believe that the AMA RUC-recommended work RVU of 8.27 is more appropriate for this service. Commenters disagreed with CMS' use of the reverse building block methodology, which removed the subsequent observation care code and reduced the full hospital discharge management code to a half day, and the associated work RVUs and times. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested that CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 28120 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 8.27, which is consistent with the AMA–RUC recommendation to maintain the current work RVU for this service. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU of 7.31 to CPT code 28120 as the final value for CY 2012. In addition, after reviewing the descriptions pre- and post-service work, we are finalizing a pre-service evaluation time of 33 minutes, a pre-service positioning time of 10 minutes, a pre-service dress, scrub, and wait time of 15 minutes, an intra-service time of 50 minutes, and a post-service time of 30 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 28120. CMS time refinements can be found in Table 16.

As detailed in the Fourth Five-Year Review of Work, for CPT code 28122 (Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (*e.g.,* osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus), we proposed a work RVU of 6.76 for CY 2012. Medicare PFS claims data indicated that CPT code 28122 is typically performed in an outpatient setting. However, the current and AMA RUC-recommended values for this code reflected work that is typically associated with an inpatient service. Therefore, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described previously, for CPT code 28122, we removed the subsequent observation care service, reduced the discharge day management service by one-half, and adjusted the physician times accordingly. The AMA RUC recommended maintaining the current work RVU of 7.72 for CPT code 28122 for CY 2012 (76 FR 32440).

Comment: Commenters disagreed with the CMS-proposed work RVU of 6.76 for CPT code 28122 and believe that the AMA RUC-recommended work RVU of 7.72 is more appropriate for this service. Commenters noted that the CMS value was derived from the reverse building block methodology, which removed the subsequent observation care code and reduced the full hospital discharge management code to a half day, along with the associated work RVUs and times. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested that CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 28122 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 7.72, which was consistent with the AMA RUC recommendation to maintain the current work RVU for this service. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU of 6.76 to CPT code 28122 as the final value for CY 2012. In addition, after reviewing the descriptions of pre- and post-service work, we are finalizing a pre-service evaluation time of 33 minutes, a pre-service positioning time of 10 minutes, a pre-service dress, scrub, and wait time of 15 minutes, an intra-service time of 45 minutes, and a post-service time of 30 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 28122. CMS time refinements can be found in Table 16.

As detailed in the Fourth Five-Year Review of Work, for CPT code 28285 (correction, hammertoe (*e.g.,* interphalangeal fusion, partial or total phalangectomy), we proposed a work RVU of 4.76 for CY 2012. The AMA RUC recommended a work RVU of 5.62 for CPT code 28285. We disagreed with the AMA RUC-recommended work RVU for CPT code 28285 and believed that a work RVU of 4.76, the current work RVU, was more appropriate for this service. The majority of survey respondents indicated that the work of performing this service has not changed in the past 5 years (67 percent), and that there has been no change in complexity among the patients requiring this service (81 percent) (76 FR 32440).

Comment: Commenters disagreed with the CMS-proposed work RVU of 4.76 for CPT code 28285 and believe that the AMA RUC-recommended work RVU of 5.62 is more appropriate for this service. Commenters contend that compelling evidence for changes in work, technology, and/or patient

complexity should not be restricted to the previous 5 years, and generally that CPT code 28285 is misvalued because there has been a change in the way this procedure is performed today resulting in more complex and more intense work as compared to 15 to 20 years ago. Commenters also noted that the Harvard study did not involve podiatrists, which were then and are now the dominant provider of this service.

Response: Based on the comments received, we referred CPT code 28285 to the CY 2011 multi-specialty refinement panel for further review. The median refinement panel work RVU was 5.62. As a result of the refinement panel ratings and clinical review by CMS, we are assigning a work RVU of 5.62 to CPT code 28285 as the final value for CY 2012.

As detailed in the Fourth Five-Year Review of Work, for CPT code 28715 (Arthrodesis; triple), we proposed a work RVU of 13.42 for CY 2012. Medicare PFS claims data indicated that CPT code 28715 is typically performed in an outpatient setting. However, the current and AMA RUC-recommended values for this code reflected work that is typically associated with an inpatient service. Therefore, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described previously, for CPT code 28715, we removed the subsequent hospital care service, reduced the discharge day management service by one-half, and adjusted the physician times accordingly. The AMA RUC recommended maintaining the current work RVU of 14.60 for CPT code 28715 for CY 2012 (76 FR 32441).

Comment: Commenters disagreed with the CMS-proposed work RVU of 13.42 for CPT code 28715 and believe that the AMA RUC-recommended work RVU of 14.60 is more appropriate for this service. Commenters noted that the CMS value was derived from the reverse building block methodology, which removed the subsequent hospital care code and reduced the full hospital discharge management code to a half day, along with the associated work RVUs and time. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested that CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 28715 to the CY 2011 multi-specialty refinement panel for further review. The median refinement panel work RVU was 14.60, which was consistent with the AMA RUC-recommendation to maintain the current work RVU for this service. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we are believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU of 13.42 to CPT code 28715 as the final value for CY 2012. In addition, after reviewing the descriptions pre- and post-service work, we are finalizing a pre-service evaluation time of 40 minutes, a pre-service positioning time of 3 minutes, a pre-service dress, scrub, and wait time of 15 minutes, an intra-service time of 125 minutes, and a post-service time of 40 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 28715. CMS time refinements can be found in Table 16.

As discussed in the CY 2012 MPFS proposed rule, for CPT code 28725 (Arthrodesis; subtalar) and 28730 (Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse), we proposed work RVUs of 11.22 for CPT code 28725, and work RVUs of 10.70 for CPT code 28730 respectively. The most recently available Medicare claims data suggested that these site-of-service anomaly codes could be ''23-hour stay'' outpatient services. As detailed in the CY 2012 MPFS proposed rule, for CY 2010, CPT codes 28725 and 28730 were identified as potentially misvalued through the site-of-service anomaly screen and were reviewed by the AMA RUC. For both of these services, based on reference services and specialty survey data, the AMA RUC recommended maintaining the current (CY 2009) work RVU, which saw a slight increase based on the redistribution of RVUs that resulted from the CY 2010 policy to no longer recognize the CPT consultation codes (74 FR 61775). The AMA RUC re-reviewed CPT codes 28725 and 28730 for CY 2012 and, contrary to the 23-hour stay valuation policy we finalized in the CY 2011 PFS final rule with comment period (75 FR 73226 through 73227), recommended replacing the hospital inpatient post-operative visit in the current work values with a subsequent observation care service, specifically CPT code 99224 (Level 1 subsequent observation care, per day) and recommended maintaining the current interim value for the two CPT codes. Specifically, for CY 2012 the AMA RUC recommended a work RVU of 12.18 for CPT code 28725 and a work RVU of 12.42 for CPT code 28730 (76 FR 42798).

We disagreed with the AMA RUC-recommended values for CPT codes 28725 and 28730. We believed the appropriate methodology for valuing these codes entails accounting for the removal of the inpatient visits in the work value for the site-of-service anomaly codes since these services are no longer typically furnished in the inpatient setting. We did not believe it is appropriate to simply exchange the inpatient post-operative visits in the original value with subsequent observation care visits and maintain the current work RVUs.

Comment: Commenters stated that just because the patient may be discharged prior to 24-hours post-operatively does not mean that the post-operative visit would not include the standard pre-service and post-service work and instead would only include intra-service work. Furthermore, the commenters noted that physicians do not conduct shorter or less intense inpatient post-operative visits based on when the patient may be discharged. Commenters also stated that CMS is not consistent in the application of its methodology of applying intra-service time and value only. Commenters encouraged CMS to accept the RUC-recommended values for 28725 and 28730.

Response: Based on the public comments received, we referred CPT codes 28725 and 28730 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 12.18 for CPT code 28725 and 12.42 for CPT code 28730. The current (CY 2011) work RVUs for these services were developed based on these services being typically furnished in the inpatient setting. As these services are now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical

practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for these services, which are typically performed on an outpatient basis, to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. Therefore, we are finalizing a work RVU of 11.22 for CPT code 28725 and a work RVU of 10.70 for CPT code 28730 with refinements to physician time. CMS time refinements can be found in Table 16.

As detailed in the Fourth Five-Year Review of Work, for CPT code 28820 (Amputation, toe; metatarsophalangeal joint), we proposed a work RVU of 5.82 for CY 2012. Medicare PFS claims data indicated that CPT code 28820 is typically performed in an outpatient setting. However, the current and AMA RUC-recommended values for this code reflected work that is typically associated with an inpatient service. Therefore, in accordance with our methodology described previously to address 23-hour stay and site-of-service anomalies, for CPT code 28820, we removed the subsequent hospital care service, reduced the discharge day management service to one-half, and adjusted the physician times accordingly. The AMA RUC recommended the survey median work RVU of 7.00 for CPT code 28820 for CY 2012 (76 FR 32441).

Comment: Commenters disagreed with the CMS-proposed work RVU of 5.82 for CPT code 28820 and believe that the AMA RUC-recommended work RVU of 7.00 is more appropriate for this service. Commenters disagreed with CMS' use of the reverse building block methodology, which removed the subsequent hospital care code and reduced the full hospital discharge management code to a half day, as well as the associated work RVUs and time. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested that CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 28820 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 7.00, which was consistent with the AMA–RUC recommendation for this service. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting, and the CY 2012 AMA RUC recommendation continued to include building blocks typical of an inpatient service. Because we removed those building blocks, we believe that it is appropriate to reduce the work RVU to reflect the reduction in physician work, as measured by time and intensity. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU of 5.82 to CPT code 28820 as the final value for CY 2012. In addition, after reviewing the descriptions pre- and post- service work, we are finalizing a pre-service evaluation time of 33 minutes, a pre-service positioning time of 10 minutes, a pre-service dress, scrub, and wait time of 15 minutes, an intra-service time of 30 minutes, and a post-service time of 30 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 28820. CMS time refinements can be found in Table 16.

As detailed in the Fourth Five-Year Review of Work, for CPT code 28825 (Amputation, toe; interphalangeal joint), we proposed a work RVU of 5.37 for CY 2012. Medicare PFS claims data indicated that CPT code 28825 is typically performed in an outpatient setting. However, the current and AMA RUC recommended values for this code reflected work that is typically associated with an inpatient service. Therefore, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described previously, for CPT code 28825, we reduced the discharge day management service to one-half, and adjusted the physician times accordingly. The AMA RUC recommended maintaining the current work RVU of 6.01 for CPT code 28825 for CY 2012 (76 FR 32441).

Comment: Commenters disagreed with the CMS proposed work RVU of 5.37 for CPT code 28825 and believe that the AMA RUC-recommended work RVU of 6.01 is more appropriate for this service. Commenters disagreed with CMS' use of the reverse building block methodology, which reduced the full hospital discharge management code to a half day, along with the associated work RVUs and time. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested that CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 28825 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 6.01, which was consistent with the AMA–RUC recommendation to maintain the current work RVU of 6.01 for this service. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU of 5.37 to CPT code 28825 as the final value for CY 2012. In addition, we are finalizing a pre-service evaluation time of 33 minutes, a pre-service positioning time of 10 minutes, a pre-service dress, scrub, and wait time of 15 minutes, an intra-service time of 30 minutes, and a post-service time of 20 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 28825. CMS time refinements can be found in Table 16.

(11) Musculoskeletal: Application of Casts and Strapping (CPT codes 29125–29916)

In the Fourth Five-Year Review, we identified CPT code 29125 (Application of short arm splint (forearm to hand); static), as potentially misvalued through the Harvard-Valued-Utilization > 30,000

screen. CPT codes 29126 (Application of short arm splint (forearm to hand); dynamic) and 29425 were added as part of the family of services for AMA RUC review.

As detailed in the Fourth Five-Year Review of Work, for CPT code 29125 (Application of short arm splint (forearm to hand); static), we proposed a work RVU of 0.50 for CY 2012. Medicare PFS claims data affirmed that this service is typically performed on the same day as an E/M visit. We believed some of the activities conducted during the pre- and post-service times of the procedure code and the E/M visit overlap and, therefore, should not be counted twice in developing the procedure's work value. As described earlier in section III.A. to account for this overlap, we reduced the pre-service evaluation and post-service time by one third. We believed that 5 minutes pre-service evaluation time and 3 minutes post-service time accurately reflect the time required to conduct the work associated with this service as described by the CPT code-associated specialties to the AMA RUC. The AMA RUC recommended maintaining the current work RVU of 0.59 for CPT code 29125 (76 FR 32441).

Comment: Commenters disagreed with the CMS-proposed work RVU of 0.50 for CPT code 29125 and believe that the AMA RUC-recommended work RVU of 0.59 is more appropriate. Commenters noted that the CMS value was derived from the reverse building block methodology, which removed the pre- and post-service time by one-third. Furthermore, commenters recommended CMS change our proposed values for this code and accept the RUC-recommended value as the pre-service time and values are already reduced to account for E/M work on the same day. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested that CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on the public comments received, we referred CPT 29125 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel results agreed with the CMS-assigned work RVU of 0.50 for CPT code 29125. Our clinical review confirmed that this value reflects our methodology described previously to reduce the pre-service evaluation and post-service time by one-third for codes for which there is typically a same-day E/M service. Based on the comments received, we re-reviewed the pre- and post-service time and work assigned to this service. We continue to believe that there is overlap in the pre- and post-service work between the E/M visit and service described by CPT code 29125. We believe that this overlap was appropriately accounted for by removing one-third of the pre-service evaluation minutes, and one-third of the post service minutes, thereby reducing the pre-service evaluation time from 7 minutes to 5 minutes, and the post-service time from 5 minutes to 3 minutes. Therefore, for CY 2012 we are finalizing a work RVU for CPT code 29125 of 0.50, with a pre-service evaluation time of 5 minutes, and a post-service time of 3 minutes. CMS time refinements can be found in Table 16.

As detailed in the Fourth Five-Year Review of Work, for CPT code 29126 (Application of short arm splint (forearm to hand); dynamic), we proposed a work RVU of 0.68 for CY 2012. Medicare PFS claims data affirmed that this service is typically performed on the same day as an E/M visit. We believed some of the activities conducted during the pre- and post-service times of the procedure code and the E/M visit overlap and, therefore, should not be counted twice in developing the procedure's work value. As described earlier in section III.A. of this final rule with comment period, to account for this overlap, we reduced the pre-service evaluation and post-service time by one-third. The AMA RUC recommended maintaining the current work RVU of 0.77 for CPT code 29126 (76 FR 32442).

Comment: Commenters disagreed with the CMS-proposed work RVU of 0.68 for CPT code 29126 and believe that the AMA RUC-recommended work RVU of 0.77 is more appropriate. Commenters noted that the CMS value was derived from the reverse building block methodology, which reduced the pre- and post service time by one-third. Furthermore, commenters recommended CMS change the proposed values for this code and accept the RUC-recommended values because, commenters asserted, the AMA RUC-recommended pre-service time as values were already reduced to account for E/M work on the same day. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested that CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on the comments received, we referred CPT code 29126 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 0.77, which supported the AMA RUC recommendation to maintain the current work RVU for this service. Based on the comments received, we re-reviewed the pre- and post-service time and work assigned to this service. We continue to believe that there is overlap in the pre- and post-service work between the E/M visit and service described by CPT code 29126. We believe that this overlap was appropriately accounted for by removing one-third of the pre-service evaluation minutes, and one-third of the post service minutes, thereby reducing the pre-service evaluation time from 7 minutes to 5 minutes, and the post-service time from 5 minutes to 3 minutes. We do not believe it is appropriate for the work RVU of this service to reflect the aforementioned overlap in pre- and post-service work between the E/M visit and the service described by CPT code 29126. Therefore, for CY 2012 we are finalizing the proposed work RVU of 0.68, with a pre-service evaluation time of 5 minutes, and a post-service time of 3 minutes. CMS time refinements can be found in Table 16.

As detailed in the Fourth Five-Year Review, for CPT code 29515 (Application of short leg splint (calf to foot)) we believed that the current (CY 2011) work RVU continued to accurately reflect the work of this service. For CPT code 29515 we proposed the current (CY 2011) work RVU of 0.73. The AMA RUC recommended maintaining the current work RVUs for this service as well. For CPT code 29515, the AMA RUC recommended 7 minutes of pre-service evaluation time and 5 minutes of post-service time. We proposed to reduce the AMA RUC-recommended times to 5 minutes of pre-service evaluation time and 3 minutes of post-service time for CPT code 29515 (76 FR 32442).

Comment: In its public comments to CMS on the Fourth Five-Year Review, the AMA RUC wrote that CMS agreed with the AMA RUC-recommended work RVU, but noted that CMS disagreed with the AMA RUC-recommended pre-service and post-service time components due to an E/M service typically being provided on the same day of service. Commenters recommended that CMS accept the AMA RUC-recommended pre-service evaluation time of 7 minutes and

immediate post-service time of 5 minutes for CPT code 29515.

Response: Based on the comments received, we re-reviewed the pre- and post-service time and work assigned to this service. We continue to believe that there is overlap in the pre- and post-service work between the E/M visit and service described by CPT code 29126. We believe that this overlap was appropriately accounted for by removing one-third of the pre-service evaluation minutes, and one-third of the post service minutes, thereby reducing the pre-service evaluation time from 7 minutes to 5 minutes, and the post-service time from 5 minutes to 3 minutes. In sum, for CPT code 29515 for CY 2012, we are finalizing the Five-Year Review proposed and AMA RUC-recommended work RVU of 0.73, with a pre-service evaluation time of 5 minutes, and a post-service time of 3 minutes. CMS time refinements can be found in Table 16. In CPT code 29540 (Strapping; ankle and/or foot) was identified by the Five-Year Review Identification Workgroup through the HarvardValued—Utilization > 100,000 screen. Upon review, the AMA RUC recommended this family of services be surveyed.

As detailed in the CY 2011 final rule with comment period (75 FR 73331), for CPT code 29540, we assigned an interim final work RVU of 0.32. The HCPAC-recommended a work RVU of 0.39. The HCPAC compared the total time required for CPT code 29540 to CPT code 29580 (Strapping; Unna boot), 18 and 27 minutes, respectively, and noted that CPT code 29540 requires less time, mental effort/judgment, technical skill and psychological stress than CPT code 29580. The HCPAC determined that CPT code 29540 was approximately 30 percent less intense and complex than CPT code 29580, resulting in work RVUs of 0.39 for CPT code 29540 (75 FR 73331). We disagreed with the HCPAC-recommended work RVU for this service and believed work RVUs of 0.32 were appropriate. We believed CPT code 11720 (Debridement of nail(s) by any method(s); 1 to 5) (work RVUs = 0.32) was a more appropriate crosswalk (75 FR 73331).

Comment: Commenters disagreed with the CMS-proposed work RVU of 0.32 for CPT code 29540 and believe that the HCPAC work RVU of 0.39 is more appropriate for this service. Additionally, commenters supported HCPAC's original recommendation of 0.39 for code 29540 because they believe this code is more closely related to reference code 29580 (work RVU = 0.55). Commenters disagreed with the reference service put forward by CMS, and asserted that the HCPAC-chosen reference service is a stronger comparison code.

Response: Based on the comments received, we referred CPT code 29540 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 0.39. As a result of the refinement panel ratings and clinical review by CMS, we are assigning a work RVU of 0.39 to CPT code 29540 as the final value for CY 2012.

As detailed in the CY 2011 final rule with comment period (75 FR 73331), for CPT code 29550 (Strapping; toes), we assigned an interim final work RVU of 0.15. The HCPAC recommended a work RVU of 0.25. The HCPAC compared this service to CPT code 97762 (Checkout for orthotic/prosthetic use, established patient, each 15 minutes) (work RVU = 0.25), which it believed requires the same intensity and complexity to perform as CPT code 29550. The HCPAC recommended crosswalking the work RVUs for 29550 to reference CPT code 97762. The HCPAC reviewed the survey time and determined that 7 minutes pre-service, 5 minutes intra-service, and 1 minute immediate post-service time were appropriate to perform this service. We disagreed with the HCPAC-recommended value for this service and believed a work RVU of 0.15, the survey low value, was appropriate, with 5 minutes of pre- and intra-service time and 1 minute of post-service time, as we believed the HCPAC-recommended pre-service time of 7 minutes was excessive (75 FR 73331).

Comment: Commenters expressed concerns noting that CMS has recommended the interim value be set equal to the survey low, which they believe goes against the spirit of the surveys and in fact may be based on the response of an outlier, and without a reference service to further support the interim recommendation. Commenters agreed with the HCPAC request, and requested that CMS accept the HCPAC-recommended work RVU of 0.25 and 7 minutes pre-service time, 5 minutes intra-service time and 1 minute post-service time for CPT code 29550.

Response: Based on the comments received, we referred CPT code 29550 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 0.25. As a result of the refinement panel ratings and clinical review by CMS, we are assigning a work RVU of 0.25, with 5 minutes of pre- and intra-service time and 1 minute of post-service time, to CPT code 29550 as the final values for CY 2012. For CY 2012, we received no comments on the CY 2011 interim final work RVUs for CPT codes 29914, 29915, and 29916. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(12) Respiratory: Lungs and Pleura (CPT Codes 32405, 32851–32854, 33255)

We discussed CPT code 32851 (Lung transplant, single; without cardiopulmonary bypass) in the Fourth Five-Year Review of Work (76 FR 32444). As noted in the proposed notice, the AMA RUC reviewed the survey responses and concluded that the survey 25th percentile work RVU of 63.00 appropriately accounted for the physician work required to perform this service. We disagreed with the AMA RUC-recommended work RVU for CPT code 32851 and upon a clinical review where we compared this service to other services, we concluded that a work RVU of 59.64 was more appropriate for this service. Comparing CPT code 33255 (Operative tissue ablation and reconstruction of atria, extensive (*e.g.,* maze procedure); without cardiopulmonary bypass) (work RVU = 29.04) with CPT code 33256 (Operative tissue ablation and reconstruction of atria, extensive (*e.g.,* maze procedure); with cardiopulmonary bypass) (work RVU = 34.90), there is a difference in work RVU of 5.86. We stated that we believed this difference in work RVUs reflects the additional time and physician work performed while the patient is on cardiopulmonary bypass.

In addition, we stated that we believed this was the appropriate interval in physician work distinguishing CPT code 32852 (Lung transplant, single; with cardiopulmonary bypass), from CPT code 32851 (Lung transplant, single; without cardiopulmonary bypass). Since we proposed a work RVU of 65.05 for CPT code 32852 (see below), we believed a work RVU of 59.64 accurately reflects the work associated with CPT code 32851 and maintains appropriate relativity among similar services. Therefore, we proposed an alternative work RVU of 59.64 for CPT code 32851 for CY 2012.

For CPT code 32852 (Lung transplant, single; with cardiopulmonary bypass), the AMA RUC reviewed the survey responses and concluded that the survey 25th percentile work RVU was too low and the median work RVU was too high. Therefore, the AMA RUC recommended a work RVU of 74.37 for CPT code 32582. We disagreed with the AMA RUC-recommended work RVU for CPT code 32582 and believed that the survey 25th percentile value of a work RVU of 65.50 was more appropriate for

this service. Therefore, we proposed an alternative work RVU of 65.50 for CPT code 32582 for CY 2012.

Comment: The commenters disagreed with CMS' rationale to use the survey 25th percentile work RVU for CPT code 32852 and then use a reverse building block methodology to determine the proposed work RVUs for CPT code 32851. The commenters asserted that the AMA RUC considered and rejected the 25th percentile survey result for CPT code 32852, noting that the AMA RUC believed that the survey 25th percentile work RVU is insufficient to reflect the physician work involved in furnishing this service.

Response: Based on the comments received, we referred CPT codes 32851 and 32852 to the CY 2011 multi-specialty refinement panel for further review. CPT code 32851 has a current (CY 2011) work RVU of 41.61, in the Five-Year Review we proposed a work RVU of 59.64, and the AMA RUC recommended a work RVU of 63.00. The median refinement panel work RVU was 63.00. CPT code 32852 has a current (CY 2011) work RVU of 45.48, in the Five-Year Review we proposed a work RVU of 65.50, and the AMA RUC recommended a work RVU of 74.37. The median refinement panel work RVU was 74.37. For CPT codes 32851 and 32852, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 59.64 for CPT code 32851 and 65.50 for CPT code 32852, are more appropriate in order to preserve appropriate relativity across code families. Accordingly, we are assigning a work RVU of 59.64 to CPT code 32851 and 65.50 to CPT code 32852 as final values for CY 2012.

We discussed CPT code 32853 (Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass) in the Fourth Five-Year Review of Work (76 FR 32444). As noted in the proposed notice the AMA RUC reviewed the survey responses and concluded that the survey median work RVU of 90.00 appropriately accounted for the physician work required to perform this service. We disagreed with the AMA RUC-recommended work RVU for CPT code 32853 and believed that the survey 25th percentile value of 84.48 was more appropriate for this service as a reflection of the time and intensity of the service in relation to other major surgical procedures. Therefore, we proposed an alternative work RVU of 84.48 for CPT code 32853 for CY 2012.

For CPT code 32854 (Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass), the AMA RUC reviewed the survey responses and concluded that the survey median work RVU of 95.00 appropriately accounted for the physician work required to perform this service. We disagreed with the AMA RUC-recommended work RVU for CPT code 32854 and believed that the survey 25th percentile value of 90.00 was more appropriate for this service. We stated that a work RVU of 90.00 maintains the relativity between CPT code 32851 (Lung transplant, single; without cardiopulmonary bypass) and CPT code 32854, which describes a double lung transplant. We believed this work RVU reflects the increased intensity in total service for CPT code 32584 when compared to CPT code 32851. Therefore, we proposed an alternative work RVU of 90.00 for CPT code 32854 for CY 2012.

Comment: The commenters disagreed with CMS' rationale to use the survey 25th percentile values for CPT codes 32853 and 32584. The commenters asserted that the AMA RUC recommendations were based on a careful and deliberate evaluation of the work involved in the provision of double lung transplantation, as compared with the work involved in other services.

Response: Based on the comments received, we referred CPT codes 32853 and 32854 to the CY 2011 multi-specialty refinement panel for further review. CPT code 32853 has a current (CY 2011) work RVU of 50.78, in the Five-Year Review we proposed a work RVU of 84.48, and the AMA RUC recommended a work RVU of 90.00. The median refinement panel work RVU was 85.00, slightly higher than the proposed work RVU. CPT code 32854 has a current (CY 2011) work RVU of 54.74, in the Five-Year Review we proposed a work RVU of 90.00, and the AMA RUC recommended a work RVU of 95.00. The median refinement panel work RVU was 95.00. For CPT codes 32853 and 32854, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 84.48 to CPT code 32853 and 90.00 to CPT code 32854, are more appropriate. Accordingly, we are assigning a work RVU of 84.48 to CPT code 32853 and 90.00 to CPT code 32854 as final values for CY 2012.

We note that CPT code 32405 (Biopsy, Lung or mediastinum) was also reviewed in this family for the Fourth Five-Year Review. We agreed with the AMA RUC's methodology and recommended value for this code. Accordingly, we are finalizing a work RVU of 1.93 for CPT code 32405. We note the CY 2012 final values for the codes in this family are summarized in Table 15.

(13) Cardiovascular: Heart and Pericardium (CPT Codes 33030–37766)

We discussed CPT code 33030 (Pericardiectomy, subtotal or complete; without cardiopulmonary bypass) in the Fourth Five-Year Review of Work (76 FR 32444) where we noted the AMA RUC reviewed the survey responses and concluded that the survey median work RVUs of 39.50 for CPT code 33030 appropriately accounted for the work required to perform this service.

We disagreed with the AMA RUC-recommended work RVUs for CPT code 33030. Following comparison with similar codes, we believed that the survey 25th percentile value of 36.00 was more appropriate for this service. Therefore, we proposed an alternative work RVUs of 36.00 for CPT code 33030 for CY 2012.

Comment: The commenters disagreed with this proposed value and stated that they preferred that CMS accept the AMA RUC-recommended work RVUs of 39.50 based on the AMA RUC rationale. The commenters believed this would place the value of CPT code 33030 appropriately as far as time and intensity of physician work in relation to 33031.

Response: Based on the comments received, we referred CPT code 33030 to the CY 2011 multi-specialty refinement panel for further review. CPT code 33030 has current (CY 2011) work RVUs of 22.29, in the Five-Year Review we proposed work RVUs of 36.00, and the AMA RUC recommended work RVUs of 39.50. The median refinement panel work RVUs were 37.10, between the proposed work RVUs and the AMA RUC recommendation. For CPT code 33030, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant

increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 36.00, which are the survey 25th percentile work RVUs, are more appropriate. Accordingly, we are assigning work RVUs of 36.00 to CPT code 33030 as the final value for CY 2012.

We discussed CPT code 33120 (Excision of intracardiac tumor, resection with cardiopulmonary bypass) in the Fourth Five-Year Review of Work (76 FR 32444), where we noted the AMA RUC reviewed the survey responses and concluded that the 25th percentile work RVUs for CPT code 33120 appropriately accounted for the work required to furnish this service. The AMA RUC recommended work RVUs of 42.88 for CPT code 33120.

We disagreed with the AMA RUC-recommended work RVUs for CPT code 33120 and believed that work RVUs of 38.45 were more appropriate for this service. We compared CPT code 33120 with CPT code 33677 (Closure of multiple ventricular septal defects; with removal of pulmonary artery band, with or without gusset) (work RVUs = 38.45) and found the codes to be similar in complexity and intensity. We believed that work RVUs of 38.45 accurately reflect the work associated with CPT code 33677 and properly maintains the relativity of similar services. Therefore, we proposed an alternative work RVUs of 38.45 for CPT code 33120 for CY 2012.

Comment: The commenters noted that CMS' proposed value, based on a direct crosswalk to 33677, (Closure of multiple ventricular septal defects; with removal of pulmonary artery band, with or without gusset), was less than the 25th percentile RUC-recommended value of 42.88. Commenters strongly disagreed with the direct crosswalk and requested that CMS review CPT code 33120 in relation to the key reference code selected by physicians who furnish the procedure, CPT code 33426 (Valvuloplasty, mitral valve, with cardiopulmonary bypass; with prosthetic ring). The commenters stated that this procedure is very similar to operating to remove the typical left atrial tumor, utilizing the same cardiac incision and the same cannulation strategy for cardiopulmonary bypass. The commenters also noted that CPT code 33426 is also an MPC list code and is furnished frequently by adult cardiac surgeons who also perform CPT code 33120.

Response: Based on the comments received, we referred CPT code 33120 to the CY 2011 multi-specialty refinement panel for further review. CPT code 33120 has current (CY 2011) work RVUs of 27.45, in the Five-Year Review we proposed work RVUs of 38.45, and the AMA RUC recommended work RVUs of 42.88. The median refinement panel work RVUs were also 42.88. For CPT code 33120, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe that a comparison of CPT code 33120 with CPT code 33677 (Closure of multiple ventricular septal defects; with removal of pulmonary artery band, with or without gusset) (work RVUs = 38.45) shows the codes to be similar in complexity and intensity. Therefore, we believe that work RVUs of 38.45 accurately reflect the work associated with CPT code 33677 and properly maintains the relativity of similar services. Accordingly, we are assigning work RVUs of 38.45 to CPT code 33120 as the final value for CY 2012.

We discussed CPT code 33412 (Replacement, aortic valve; with transventricular aortic annulus enlargement (Konno procedure)) in the Fourth Five-Year Review of Work (76 FR 32444) where we noted the AMA RUC reviewed the survey responses and concluded that the survey median work RVUs for CPT code 33412 appropriately accounted for the work required to furnish this service. The AMA RUC recommended work RVUs of 60.00 for CPT code 33412. We disagreed with the AMA RUC-recommended work RVUs for CPT code 33412 and believed that the survey 25th percentile value of 59.00 was more appropriate for this service. Therefore, we proposed alternative work RVUs of 59.00 for CPT code 33412 for CY 2012.

Comment: Commenters disagreed with CMS' proposed value and asserted that the AMA RUC workgroup closely reviewed this service and compared it to key reference service CPT code 33782 (Aortic root translocation with ventricular septal defect and pulmonary stenosis repair (*i.e.,* Nikaidoh procedure); without coronary ostium reimplantation) (work RVUs = 60.08 and intra-time = 300 minutes). The commenters believed that these two services require the same intensity and complexity, physician work and time to furnish.

Response: Based on the comments received, we referred CPT code 33412 to the CY 2011 multi-specialty refinement panel for further review. CPT code 33412 has current (CY 2011) work RVUs of 43.94, in the Five-Year Review we proposed work RVUs of 59.00, and the AMA RUC recommended work RVUs of 60.00. The median refinement panel work RVUs were 59.00, which were also the proposed work RVUs. For CPT code 33412, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 59.00, which are consistent with the refinement panel median RVUs, are more appropriate. Accordingly, we are assigning work RVUs of 59.00 to CPT code 33412 as the final value for CY 2012.

We discussed CPT code 33468 (Tricuspid valve repositioning and plication for Ebstein anomaly) in the Fourth Five-Year Review of Work (76 FR 32444) where we noted the AMA RUC reviewed the survey responses and concluded that the survey median work RVUs for CPT code 33468 appropriately accounted for the work required to furnish this service. The AMA RUC recommended work RVUs of 50.00 for CPT code 33468. We disagreed with the AMA RUC-recommended work RVUs for CPT code 33468 and believed that the survey 25th percentile value of 45.13 was more appropriate for this service. Therefore, we proposed alternative work RVUs of 45.13 for CPT code 33468 for CY 2012.

Comment: Commenters disagreed with CMS' proposed value and stated that the AMA RUC workgroup closely reviewed this service and compared CPT code 33468 to key reference service CPT code 33427, (Valvuloplasty, mitral valve, with cardiopulmonary bypass; radical reconstruction, with or without ring) (work RVUs = 44.83 and intra-time = 221 minutes). The commenters asserted that CPT code 33468 is more intense and complex, and requires more physician work and time to perform

than the key reference service CPT code 33427.

Response: Based on the comments received, we referred CPT code 33468 to the CY 2011 multi-specialty refinement panel for further review. CPT code 33468 has current (CY 2011) work RVUs of 32.94, in the Five-Year Review we proposed work RVUs of 45.13, and the AMA RUC recommended work RVUs of 50.00. The median refinement panel work RVUs were 46.00. For CPT code 33468, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 45.13, which are the survey 25th percentile work RVUs, are more appropriate. Accordingly, we are assigning work RVUs of 45.13 to CPT code 33468 as the final value for CY 2012.

We discussed CPT code 33645 (Direct or patch closure, sinus venosus, with or without anomalous pulmonary venous drainage) in the Fourth Five-Year Review of Work (76 FR 32445) where we noted the AMA RUC reviewed survey responses and concluded that the survey median work RVUs for CPT code 33645 appropriately accounts for the work required to perform this service. The AMA RUC recommended work RVUs of 33.00 for CPT code 33645. We disagreed with the AMA RUC-recommended work RVUs for CPT code 33645 and believed that the survey 25th percentile value of 31.30 appropriately captures the total work for the service. Therefore, we proposed alternative work RVUs of 31.30 for CPT code 33645 for CY 2012.

Comment: Commenters disagreed with CMS' proposed value and stated that the AMA RUC workgroup closely reviewed this service and compared 33645 to key reference service CPT codes 33641, (Repair atrial septal defect, secundum, with cardiopulmonary bypass, with or without patch) (work RVUs = 29.58 and intra-time = 164 minutes) and 33681, (Closure of single ventricular septal defect, with or without patch) (work RVUs = 32.34 and intra-time = 150 minutes). The commenters asserted that 33645, (Surveyed intra-service time = 175 minutes) requires more intensity and complexity to furnish compared to these reference services.

Response: Based on the comments received, we referred CPT code 33645 to the CY 2011 multi-specialty refinement panel for further review. CPT code 33645 has current (CY 2011) work RVUs of 28.10, in the Five-Year Review we proposed work RVUs of 31.30, and the AMA RUC recommended work RVUs of 33.00. The median refinement panel work RVUs were 31.50, slightly higher than the proposed work RVUs. For CPT code 33645, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 31.30, which are the survey 25th percentile work RVUs, are more appropriate. Accordingly, we are assigning work RVUs of 31.30 to CPT code 33645 as the final value for CY 2012.

We discussed CPT code 33647 (Repair of atrial septal defect and ventricular septal defect, with direct or patch closure) in the Fourth Five-Year Review of Work (76 FR 32445) where we noted the AMA RUC reviewed survey responses and concluded that the survey median work RVUs for CPT code 33467 appropriately account for the work required to furnish this service. The AMA RUC recommended work RVUs of 35.00 for CPT code 33647. We disagreed with the AMA RUC-recommended work RVUs for CPT code 33647 and believed that the survey 25th percentile value of 33.00 was more appropriate for this service. Therefore, we proposed alternative work RVUs of 33.00 for CPT code 33647 for CY 2012.

Comment: Commenters disagreed with CMS' proposed value and stated that the AMA RUC workgroup closely reviewed this service and compared CPT code 33647 to key reference service CPT code 33681, (Closure of single ventricular septal defect, with or without patch) (work RVUs = 32.34 and intra-time = 150 minutes). The commenters asserted that CPT code 33647 are similarly intense and complex, and requires more physician work and time to furnish compared to the key reference service.

Response: Based on the comments received, we referred CPT code 33647 to the CY 2011 multi-specialty refinement panel for further review. CPT code 33647 has current (CY 2011) work RVUs of 29.53, in the Five-Year Review we proposed work RVUs of 33.00, and the AMA RUC recommended work RVUs of 35.00. The median refinement panel work RVUs were 33.00, the same as the proposed work RVUs. For CPT code 33647, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 33.00, which are consistent with the refinement panel median work RVUs, are more appropriate. Accordingly, we are assigning work RVUs of 33.00 to CPT code 33647 as the final value for CY 2012.

Fourth Five-Year Review of Work (76 FR 32445) where we noted the AMA RUC reviewed survey responses, and recommended the survey median work RVUs of 38.75 for CPT code 33692. We disagreed with the AMA RUC-recommended work RVUs for CPT code 33692 and believed that the survey 25th percentile value of 36.15 was more appropriate for this service. Therefore, we proposed alternative work RVUs of 36.15 for CPT code 33692 for CY 2012.

Comment: Commenters disagreed with CMS' proposed value and stated that the AMA RUC workgroup closely reviewed this service and compared the service to key reference service CPT code 33684, (Closure of single ventricular septal defect, with or without patch; with pulmonary valvotomy or infundibular resection (acyanotic)) (work RVUs = 34.37 and intra-time = 200 minutes). Commenters asserted that CPT code 33692 is similarly intense and complex, and requires more physician work and time to furnish than the key reference service.

Response: Based on the comments received, we referred CPT code 33692 to the CY 2011 multi-specialty refinement panel for further review. CPT code 33692 has current (CY 2011) work RVUs of 31.54, in the Five-Year Review we proposed work RVUs of 36.15, and the AMA RUC recommended work RVUs of 38.75. The median refinement panel work RVUs were 38.75. For CPT code 33692, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended

work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 36.15, which are the survey 25th percentile work RVUs, are more appropriate. Accordingly, we are assigning work RVUs of 36.15 to CPT code 33692 as the final value for CY 2012.

We recommended work RVUs of 43.00 for CPT code 33710, the survey median work RVUs. We disagreed with the AMA RUC-recommended work RVUs for CPT code 33710 and believed that the survey 25th percentile value of 37.50 was more appropriate for this service. We believed the physician time and intensity for CPT code 33710 reflected the appropriate incremental adjustment when compared to the key reference service, CPT code 33405 (Replacement, aortic valve, with cardiopulmonary bypass; with prosthetic valve other than homograft or stentless valve) (work RVUs = 41.32 and intra-service time = 198 minutes). Therefore, we proposed alternative work RVUs of 37.50 for CPT code 33710 for CY 2012.

Commenters disagreed with CMS' proposed value and stated that the AMA RUC workgroup closely reviewed this service and compared 33710 to key reference service CPT code 33405. The commenters asserted that 33710 is similarly intense and complex, and requires more physician work and time to furnish than the key reference service.

Response: Based on the comments received, we referred CPT code 33710 to the CY 2011 multi-specialty refinement panel for further review. CPT code 33710 has current (CY 2011) work RVUs of 30.41, in the Five-Year Review we proposed work RVUs of 37.50, and the AMA RUC recommended work RVUs of 43.00. The median refinement panel work RVUs were also 43.00. For CPT code 33710, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 37.50, which are the survey 25th percentile work RVUs, and more comparable to the reference service, are more appropriate. Accordingly, we are assigning work RVUs of 37.50 to CPT code 33710 as the final value for CY 2012.

We discussed CPT code 33875 (Descending thoracic aorta graft, with or without bypass) in the Fourth Five-Year Review of Work (76 FR 32445) and noted that the AMA RUC reviewed survey responses and concluded that the 25th percentile work RVUs for code 33875 appropriately account for the work required to furnish this service. The AMA RUC recommended work RVUs of 56.83 for CPT code 33875. We disagreed with the AMA RUC-recommended work RVUs for CPT code 33875 and believed that work RVUs of 50.72 were more appropriate for this service. We compared CPT code 33875 with CPT code 33465 (Replacement, tricuspid valve, with cardiopulmonary bypass) (work RVUs = 50.72) and believed that CPT code 33875 was similar to CPT code 33465, with similar inpatient and outpatient work. We believed these work RVUs corresponded better to the value of the service than the survey 25th percentile work RVUs. Therefore, we proposed alternative work RVUs of 50.72 for CPT code 33875 for CY 2012.

Comment: Commenters disagreed with CMS' proposed direct crosswalk to CPT code 33465, and stated that patients and procedures are substantially different for CPT 33875. The commenters requested that CMS reconsider its proposed work value of 50.72 and, instead, accept the AMA RUC-recommended values of 56.83, which are the 25th percentile of the physician survey.

Response: Based on the comments received, we referred CPT code 33875 to the CY 2011 multi-specialty refinement panel for further review. CPT code 33875 has current (CY 2011) work RVUs of 35.78, in the Five-Year Review we proposed work RVUs of 50.72, and the AMA RUC recommended work RVUs of 56.83. The median refinement panel work RVUs were also 56.83. For CPT code 33875, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We compared CPT code 33875 with CPT code 33465 and believed that CPT code 33875 is similar to CPT code 33465, with similar inpatient and outpatient work. We continue to believe these work RVUs corresponds better to the value of the service than the survey 25th percentile work RVUs. Accordingly, we are assigning work RVUs of 50.72 to CPT code 33875 as the final value for CY 2012.

We discussed CPT code 33910 (Pulmonary artery embolectomy; with cardiopulmonary bypass) in the Fourth Five-Year Review of Work (76 FR 32445) and noted that after reviewing the service, the AMA RUC recommended work RVUs of 52.33 for CPT code 33910. We disagreed with the AMA RUC-recommended work RVUs for CPT code 33910 and believed that work RVUs of 48.21 were more appropriate for this service. We compared CPT code 33910 with CPT code 33542 (Myocardial resection (*e.g.,* ventricular aneurysmectomy)) (work RVUs = 48.21). We recognized that CPT code 33542 is not an emergency service. Nevertheless, this procedure requires cardiopulmonary bypass and has physician time and visits that are consistently necessary for the care required for the patient that are similar to CPT code 33910. We believed that work RVUs of 48.21 accurately reflected the work associated with CPT code 33910 and properly maintained the relativity for a similar service. Therefore, we proposed alternative work RVUs of 48.21 for CPT code 33910 for CY 2012.

Comment: Commenters requested that CMS reconsider the proposed work value of 48.21, and accept the AMA RUC-recommended work value of 52.33, the survey median value. Commenters disagreed with the CMS-proposed direct crosswalk to the value of CPT code 33542. Commenters asserted that, although some of the technical composition of the two codes (time and visits) is similar, the intensity and complexity measures are different and easily account for the additional RVUs of 4.12 that would result from utilizing the survey median work value.

Response: Based on the comments received, we referred CPT code 33910 to the CY 2011 multi-specialty refinement panel for further review. CPT code 33910 has current (CY 2011) work RVUs of 29.71, in the Five-Year Review we proposed work RVUs of 48.21, and the AMA RUC recommended work RVUs of 52.33. The median refinement panel work RVUs were 52.33. For CPT code 33910, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the

even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 48.21, which are the survey 25th percentile work RVUs and properly maintain the relativity with CPT code 33542 are more appropriate. Accordingly, we are assigning work RVUs of 48.21 to CPT code 33910 as the final value for CY 2012.

Fourth Five-Year Review of Work (76 FR 32445) and noted that the AMA RUC reviewed survey responses and recommended work RVUs of 100.00, the survey median work RVUs, for CPT code 33935. We disagreed with the AMA RUC-recommended work RVUs for CPT code 33935 and believed that the survey 25th percentile value of 91.78 was more appropriate for this service. We believed this service is more intense and complex than the reference CPT code 33945 (Heart transplant, with or without recipient cardiectomy) (work RVU = 89.50) and that the survey 25th percentile work RVUs accurately reflected the increased intensity and complexity when compared to the reference CPT code 33945. Therefore, we proposed alternative work RVUs of 91.78 for CPT code 33935 for CY 2012.

Comment: Commenters requested that CMS reconsider its proposed work RVUs of 91.78 and accept the RUC-recommended survey median work RVUs of 100.00 for CPT code 33935. Commenters noted that CMS acknowledged the increased intensity, complexity, and physician work compared to the key reference service CPT code 33945 Heart Transplant. However, commenters asserted that CPT code 33935 has substantially higher intensity and complexity than CPT code 33945, and CMS did not adequately account for the additional physician work.

Response: Based on the comments received, we referred CPT code 33935 to the CY 2011 multi-specialty refinement panel for further review. CPT code 33935 has current (CY 2011) work RVUs of 62.01, in the Five-Year Review we proposed work RVUs of 91.78, and the AMA RUC recommended work RVUs of 100.00. The median refinement panel work RVUs were also 100.00. For CPT code 33935, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe work RVUs of 91.78, which are the survey 25th percentile work RVUs, are more appropriate. Accordingly, we are assigning work RVUs of 91.78 to CPT code 33935 as the final value for CY 2012.

We discussed CPT code 33980 (Removal of ventricular assist device, implantable intracorporeal, single ventricle) in the Fourth Five-Year Review of Work (76 FR 32445). We noted the AMA RUC reviewed the survey results and recommended the survey median work RVUs of 40.00. Additionally, the AMA RUC recommended a global period change from 090 (Major surgery with a 1-day pre-operative period and a 90-day postoperative period included in the fee schedule amount) to XXX (the global concept does not apply to the code). We agreed with the AMA RUC-recommended global period change from 090 to XXX. However, we disagreed with the AMA RUC-recommended work RVUs for CPT code 33980. We believed the work RVUs of 33.50 were more appropriate, given the significant reduction in physician times and decrease in the number and level of post-operative visits that the AMA RUC included in the value of CPT code 33980. For CY 2012, we proposed alternative work RVUs of 33.50, the survey 25th percentile work RVUs.

Comment: Commenters disagreed with the proposed work RVUs, and asserted that CPT code 33980 was surveyed as an XXX code with no post-operative visits. Commenters stated that CPT code 33980 is one of the most intense, complex, and demanding procedures that their specialty furnishes. The commenters noted that this is an obligatory reoperation, which is almost always furnished during a one-six month time frame when the adhesions are new, tenacious, and very vascular. The commenters asserted that the reoperation CPT code 33530 (Reoperation, coronary artery bypass procedure or valve procedure, more than 1 month after original operation (List separately in addition to code for primary procedure)) its value (work RVUs = 10.13) should be considered. Commenters noted, however, that because CPT code 33530 is a ZZZ code (code is related to another service and is included in the global period of the other service) its value would not apply here. Secondly, the commenters noted this procedure requires reconstruction of the large bore defect in the apex of the left ventricle, which is technically demanding, particularly in patients destined for survival with a fragile and compromised left ventricle that must now support the circulation without VAD support. The commenters believed these features justify the higher AMA RUC-recommended RVUs of 40.00.

Response: Based on the comments received, we referred CPT code 33980 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs of 40.00, which were consistent with the AMA RUC recommendation. We believe work RVUs of 33.50, which are the survey 25th percentile work RVU are more appropriate, given the significant reduction in physician times and decrease in the number and level of post-operative visits that the AMA RUC included in the value of CPT code 33980. Accordingly, we are assigning work RVUs of 33.50 to CPT code 33980 as the final value for CY 2012.

We discussed CPT code 35188 (Repair, acquired or traumatic arteriovenous fistula; head and neck) in the Fourth Five-Year Review of Work (76 FR 32446) and noted the AMA RUC reviewed the survey results and recommended the survey median work RVUs of 18.50 for CPT code 35188. We disagreed with the AMA RUC-recommended work RVUs for CPT code 35188 and proposed alternative work RVUs of 18.00, which are the survey 25th percentile work RVUs. We believed the work RVUs of 18.00 are more appropriate, given the decrease in the number and level of post-operative visits that the AMA RUC included in the value of CPT code 35188.

Comment: Commenters noted the AMA RUC compared the service to key reference CPT code 35011 (Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm and associated occlusive disease, axillary-brachial artery, by arm incision) (work RVUs = 18.58) and agreed they were similar services in the sense that they are both vascular operations on similar sized vessels in the upper body. The AMA RUC also compared 35188 to MPC codes 19318 Reduction mammoplasty (work RVUs = 16.03) and 44140 Colectomy, partial; with anastomosis (work RVUs = 22.59), which are similarly intensive surgical procedures requiring technical skill to successfully complete the operation. Commenters asserted the differences between CPT codes 35188, 19318, and 44140 lie in the post-operative work, which are quite different, yet in proper

rank order, and requested that CMS reconsider this issue.

Response: Based on the comments received, we referred CPT code 35188 to the CY 2011 multi-specialty refinement panel for further review. CPT code 35188 has current (CY 2011) work RVUs of 15.16, in the Five-Year Review we proposed work RVUs of 18.00, and the AMA RUC recommended work RVUs of 18.50. The median refinement panel work RVUs were also 18.50. For CPT code 35188, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 18.00, which are the survey 25th percentile work RVUs, are more appropriate, given the decrease in the number and level of post-operative visits that the AMA RUC included in the value of CPT code 35188. Accordingly, we are assigning work RVUs of 18.00 to CPT code 35188 as the final value for CY 2012.

We discussed CPT code 35612 (Bypass graft, with other than vein; subclavian) in the Fourth Five-Year Review of Work (76 FR 32446) and noted the AMA RUC reviewed the survey results and recommended work RVUs of 22.00 for CPT code 35612. We disagreed with the AMA RUC-recommended work RVUs for CPT code 35612 and proposed alternative work RVUs of 20.35, which were the survey 25th percentile work RVUs. We believed the work RVUs of 20.35 were more appropriate, given the decrease in the number and level of post-operative visits that the AMA RUC included in the value of CPT code 35612.

Comment: Commenters disagreed with the proposed RVUs for CPT code 35612. Commenters noted that the AMA RUC compared the service to key reference CPT code 35661 (Bypass graft, with other than vein; femoral-femoral) (work RVUs = 20.35) and agreed the work value for CPT code 35612 should be higher than for the work value for CPT code 35661. The AMA RUC also compared the surveyed code to MPC codes 22595 (Arthrodesis, posterior technique, atlas-axis (C1–C2)) (work RVUs = 20.46) and 62165 (Neuroendoscopy, intracranial; with excision of pituitary tumor, transnasal or trans-sphenoidal approach) (work RVUs = 23.23), which have similar work intensities. Commenters requested that CMS accept the AMA RUC-recommended work RVUs of 22.00 for CPT code 35612.

Response: Based on the comments received, we referred CPT code 35612 to the CY 2011 multi-specialty refinement panel for further review. CPT code 35612 has current (CY 2011) work RVUs of 16.82, in the Five-Year Review we proposed work RVUs of 20.35, and the AMA RUC recommended work RVUs of 22.00. The median refinement panel work RVUs were also 22.00. For CPT code 35612, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 20.35, which are the survey 25th percentile work RVUs, are more appropriate, given the decrease in the number and level of post-operative visits that the AMA RUC included in the value of CPT code 35612. Accordingly, we are assigning work RVUs of 20.35 to CPT code 35612 as the final value for CY 2012.

We discussed CPT code 35800 (Exploration for postoperative hemorrhage, thrombosis or infection; neck) in the Fourth Five-Year Review of Work (76 FR 32446) and noted the AMA RUC used magnitude estimation to recommend work RVUs for CPT code 35800 between the survey 25th percentile (12.00 RVUs) and median (15.00 RVUs) work value. Accordingly, the AMA RUC recommended work RVUs of 13.89 for CPT code 35800. We disagreed with the AMA RUC-recommended work RVUs for CPT code 35800 and proposed alternative work RVUs of 12.00, which were the survey 25th percentile work RVUs. We believed the work RVU of 12.00 were more appropriate, given that two of the key reference codes to which this service has been compared have identical intra-service time (60 minutes), but significantly lower work RVUs.

Comment: Commenters noted that the AMA RUC compared the service to key reference codes. Commenters agreed with the intensity, physician work, and proper rank order amongst the comparison codes achieved when CPT code 35800 was valued between the survey 25th percentile (12.00 RVUs) and median work value (15.00 RVUs) with work RVUs of 13.89. Commenters believed it was inappropriate for CMS to reduce the value of CPT code 35800 based on a comparison to two services with much less total time. Commenters requested that CMS accept the AMA RUC-recommended work RVUs of 13.89.

Response: Based on the comments received, we referred CPT code 35800 to the CY 2011 multi-specialty refinement panel for further review. CPT code 35800 has current (CY 2011) work RVUs of 8.07, in the Five-Year Review we proposed work RVUs of 12.00, and the AMA RUC recommended work RVUs of 13.89. The median refinement panel work RVU were also 13.89. For CPT code 35800, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be an appropriate when compared to other codes with similar physician time and intensity in different code families. That is, as when considering the values for the two reference services previously discussed, comparing CPT code 35800 to codes outside of the code family but with identical intra-service time (60 minutes) demonstrates that in order to maintain inter-family relativity in the PFS, the 25th percentile survey work RVUs of 12.00 are more appropriate than the higher work RVUs recommended by the AMA RUC and the refinement panel. Accordingly, we are assigning work RVUs of 12.00 to CPT code 35800 as the final value for CY 2012.

We discussed CPT code 35840 (Exploration for postoperative hemorrhage, thrombosis or infection; abdomen) in the Fourth Five-Year Review of Work (76 FR 32446) and noted the AMA RUC used magnitude estimation to recommend work RVUs for CPT code 35840 between the survey 25th percentile (19.25 RVU) and survey median (22.30 RVUs) work value. Accordingly, the AMA RUC recommended a work RVU of 21.19 for CPT code 35840. We disagreed with the AMA RUC-recommended work RVU for CPT code 35840 and proposed alternative work RVUs of 20.75, which were between the survey 25th percentile and survey median work RVUs. We believed the work RVUs of 20.75 were more appropriate given the comparison to the two reference codes.

Comment: Commenters disagreed with the proposed work RVUs for CPT code 35840. Commenters noted that the AMA RUC compared CPT code 35840 to the following two services: CPT code 49002 (Reopening of recent laparotomy) (work RVUs = 17.63, 75 minutes intra-service time), and CPT code 37617 (Ligation, major artery (*e.g.,* post-traumatic, rupture); abdomen) (work RVUs = 23.70, 120 minutes intraservice time). Commenters agreed with the intensity, physician work, and proper rank order amongst the comparison codes when code 35840 was valued between the survey 25th percentile (19.25 RVUs) and median work value (22.30 RVUs). Commenters requested that CMS accept the AMA RUC-recommended work RVUs of 21.19.

Response: Based on the comments received, we referred CPT code 35840 to the CY 2011 multi-specialty refinement panel for further review. CPT code 35840 has current (CY 2011) work RVUs of 10.96, in the Five-Year Review we proposed work RVUs of 20.75, and the AMA RUC recommended work RVUs of 21.19. The median refinement panel work RVUs were also 21.19. For CPT code 33840, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be an appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 20.75 are more appropriate given the two reference codes to which this service has been compared. Accordingly, we are assigning work RVUs of 20.75 to CPT code 35840 as the final value for CY 2012.

We discussed CPT code 35860 (Exploration for postoperative hemorrhage, thrombosis or infection; extremity) in the Fourth Five-Year Review of Work (76 FR 32446–32447) and noted the AMA RUC used magnitude estimation to recommend work RVUs between the survey 25th percentile (15.25 RVUs) and median work value (18.00 RVUs). The AMA RUC recommended work RVUs of 16.89 for CPT code 35860. We disagreed with the AMA RUC-recommended work RVUs for CPT code 35860 and proposed alternative work RVUs of 15.25, which were the survey 25th percentile work RVUs. We believed these work RVU maintained appropriate relativity within the family of related services for the exploration of postoperative hemorrhage.

Comment: Commenters disagreed with CMS' proposed RVUs of 15.25 for CPT code 35860. Commenters stated the complexity and intensity of this service is higher because it is typically furnished to elderly patients for whom reoperation imposes more risks. Commenters asserted that the family of services was undervalued in the Harvard study. Commenters disagreed with CMS's assertion that the proposed work value is more relative to similar services in comparison to the RUC recommendation. During its review, the AMA RUC compared CPT code 35860 to two similar services: CPT code 34203 (Embolectomy or thrombectomy, popliteal-tibioperoneal artery, by leg incision) (work RVU = 17.86, 108 minutes intra-service time) and CPT code 44602 (Suture of small intestine for perforation) (work RVU = 24.72, 90 minutes intra-service time). Commenters agreed with the intensity, physician work, and proper rank order amongst the comparison codes achieved when CPT code 35860 is valued between the survey 25th percentile (15.25 RVUs) and median work value (18.00 RVUs), at 16.89 work RVUs. Commenters requested that CMS accept the RUC recommended work RVUs of 16.89 for CPT code 35860.

Response: Based on the comments received, we referred CPT code 35860 to the CY 2011 multi-specialty refinement panel for further review. CPT code 35860 has current (CY 2011) work RVUs of 6.80, in the Five-Year Review we proposed work RVUs of 15.25, and the AMA RUC recommended work RVUs of 16.89. The median refinement panel work RVUs were also 16.89. For CPT code 35860, as well as the other CPT codes in this family, the Five-Year Review proposed work RVUs represent a significant increase over the current (CY 2011) work RVUs. We believe that the even higher AMA RUC-recommended work RVUs and refinement panel results would create a new higher standard of relativity for codes within this family that would not be appropriate when compared to other codes with similar physician time and intensity in different code families. We continue to believe the work RVUs of 15.25, which are the survey 25th percentile work RVUs, maintain appropriate relativity. Accordingly, we are assigning work RVUs of 15.25 to CPT code 35860 as the final value for CY 2012.

As detailed in the Fourth Five-Year Review, for CPT code 36600 (Arterial puncture, withdrawal of blood for diagnosis) we believed that the current (CY 2011) work RVUs continued to accurately reflect the work of these services and, therefore, proposed work RVUs of 0.32 for CPT code 36600. The AMA RUC also recommended maintaining the current (CY 2011) work RVUs for these services. For CPT code 36600, the AMA RUC recommended a pre-service evaluation time of 5 minutes and immediate post service time of 5 minutes. We proposed a pre-service evaluation time for CPT code 36600 of 3 minutes and a post service time of 3 minutes (76 FR 32447).

Comment: In its public comments to CMS on the Fourth Five-Year Review, the AMA RUC wrote that CMS agreed with the AMA RUC-recommended work RVU, but noted that CMS disagreed with the AMA RUC-recommended pre-service and post-service time components due to an E/M service typically being provided on the same day of service. The AMA RUC recommends that CMS accept the AMA RUC-recommended pre-service evaluation time of 5 minutes and immediate post-service time of 5 minutes for CPT code 36600.

Response: In response to comments, we re-reviewed CPT code 36600. After reviewing the descriptions of pre-service work and the recommended pre-service time packages, we disagree with the times recommended by the AMA RUC. For CPT code 36600 we are finalizing a work RVU of 0.32 and a pre-service evaluation time of 3 minutes. In addition, we are finalizing an intra-service time of 10 minutes, and a post-service time of 3 minutes for CPT code 36600. CMS time refinements can be found in Table 16.

We discussed CPT code 36247 (Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family) in the Fourth Five-Year Review of Work (76 FR 32445) and proposed a CY 2012 work RVU of 6.29 and a global period change from 90-days (Major surgery with a 1-day pre-operative period and a 90-day postoperative period included in the fee schedule amount) to XXX (the global concept does not apply to the code). The AMA RUC recommended the survey median work RVU of 7.00 for this service. We disagreed with the RUC-recommended value noting that a reduced global period would support a reduction in the RVUs.

Comment: Commenters noted that the dominant specialty for CPT code 36247 has changed since the original Harvard valuations that therefore physician practice also has changed. Commenters pointed out that CMS' discussion of the

global period was not correct, that the specialty societies had surveyed the code based on a change to the global period of 000 (endoscopic or minor procedure with related preoperative and post-operative relative values on the day of the procedure only included in the fee schedule payment amount; evaluation and management services on the day of the procedure generally not payable) from the current global period indicator of XXX. Commenters also asserted that there had been a change in the physician work for CPT code 36247 due to patient population changes and the inclusion of moderate sedation as inherent in the procedure. Finally, commenters argued that the creation of the lower extremity revascularization codes in CY 2011 PFS final rule with comment period (75 FR 73334) increased the complexity of procedures described by CPT code 36247. Commenters requested that CMS reconsider the proposed value and global period.

Response: Based on the comments received, we referred CPT code 36247 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median value was a work RVU of 7.0, the AMA RUC-recommended value. Upon clinical review, we believe that our proposed value of 6.29 in more appropriate. We observe a significant decrease in the physician times reported for this service that argue for a lower value, notwithstanding that the survey was conducted for a 0-day global period, which includes an evaluation and management service on the same day. We agree with commenters that our discussion of the global period in the Fourth Five-Year review of work was inconsistent with the commenters' original request. Therefore, we are assigning the work RVU of 6.29 and a global period of 000 to CPT code 37247on an interim basis for CY 2012 and invite additional public comment on this code.

We discussed CPT code 36819 (Arteriovenous anastomosis, open; by upper arm basilic vein transposition) in the Fourth Five-Year Review of Work (76 FR 32447) where we noted this code was identified as a code with a site-of-service anomaly. Medicare PFS claims data indicated that this code is typically furnished in an outpatient setting. However, the current and AMA RUC-recommended values for this code reflected work that is typically associated with an inpatient service. As discussed in section III.A. of this final rule with comment period, our policy is to remove any post-procedure inpatient and subsequent observation care visits remaining in the values for these codes and adjust physician times accordingly. It is also our policy for codes with site-of-service anomalies to consistently include the value of half of a discharge day management service. While the AMA RUC recommended maintaining the current (CY 2011) work RVU of 14.47, utilizing our methodology, we proposed an alternative work RVU for CY 2012 of 13.29 with refinements in time for CPT code 36819.

Comment: Commenters disagreed with the CMS-proposed work RVU and requested that CMS accept the AMA RUC-recommended work RVU of 14.47 for 36819. Furthermore, commenters asked that the AMA RUC-recommended physician time should also be restored. Commenters disagreed with CMS' use of the reverse building block methodology. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time. Commenters noted that the AMA RUC reviewed the survey data, compared this service to other services, and concluded that there was no was no compelling evidence to suggest a change in the current work RVUs was warranted.

Response: Based on comments received, we referred CPT code 36819 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 14.47, which was consistent with the AMA RUC recommendation to maintain the current (CY 2011) work value. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a final work RVU of 13.29 with refinements in time for CPT code 36819 for CY 2012.

We discussed CPT code 36825 (Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); autogenous graft) in the Fourth Five-Year Review of Work (76 FR 32445 and 32446) where we noted this code was identified as a code with a site-of-service anomaly. Medicare PFS claims data indicated that this code is typically furnished in an outpatient setting. However, the current and AMA RUC-recommended values for this code reflected work that is typically associated with an inpatient service. As discussed in section III.A. of this final rule with comment period, consistent with that methodology, we removed the subsequent observation care service, reduced the discharge day management service by one-half, and adjusted times for CPT code 36825. While the AMA RUC recommended maintaining the current (CY 2011) work RVU of 15.13, utilizing our methodology for codes with site-of-service anomalies, we proposed an alternative work RVU of 14.17 with refinements to the time for CPT code 36825 for CY 2012.

Comment: Commenters disagreed with the CMS proposed work RVU of 14.17. Commenters disagreed with CMS' use of the reverse building block methodology, which removed the subsequent observation care code and reduced the full hospital discharge day management code to a half day, along with the associated work RVUs and times. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time. Commenters contend that if the patient is stable and can safely be discharged on a day subsequent to the day of the procedure, then there should be no reduction in discharge management work. Commenters requested that CMS reconsider this issue and accept the AMA RUC-recommended work RVU of 15.13 as a valid relative measure using magnitude estimation and comparison to codes with similar work and intensity.

Response: Based on comments received, we referred CPT code 36825 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 15.13, which is consistent with AMA RUC recommendation to maintain the current (CY 2011) work RVU for this service.

The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU for CY 2012 of 14.17 with refinements to the time for CPT code 36825 for CY 2012. CMS time refinements can be found in Table 16.

For CY 2012, we received no comments on the Fourth Five-Year Review of Work proposed work RVUs for CPT codes 33916, 33975, 33976, 33977, 33978, 33979, 33981, 33982, 33983, 36200, 36246, 36470, 36471, 36600, 36821, 37140, 37145, 37160, 37180, and 37181. Additionally, we received no comments on the CY 2011 final rule with comment period work RVUs for CPT codes 33620, 33621, 33622, 33860, 33863, 33864, 34900, 35471, 36410, 37205, 37206, 37207, 37208, 37220, 37221, 37222, 37223, 37224, 37225, 37226, 37228, 37229, 27230, 37231, 37232, 37233, 37234, 37235, 37765, 37766. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(14) Digestive: Salivary Glands and Ducts (CPT Codes 42415–42440)

In the Fourth Five-Year Review, we identified CPT codes 42415 and 42420 as potentially misvalued through the site-of-service anomaly screen. The related specialty societies surveyed these codes and the AMA RUC issued recommendations to us for the Fourth Five-Year Review of Work.

As detailed in the Fourth Five-Year Review of Work (76 FR 32447), for CPT code 42415 (Excision of parotid tumor or parotid gland; lateral lobe, with dissection and preservation of facial nerve), we proposed a work RVU of 17.16 for CY 2012. Medicare PFS claims data indicated that CPT code 42415 is typically furnished in an outpatient setting. However, the current AMA RUC-recommended values for this code reflected work that is typically associated with an inpatient service. Therefore, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described in section III.A. of this final rule with comment period, for CPT code 42415, we removed the observation care service, reduced the discharge day management service by one-half, and adjusted the physician times accordingly. The AMA RUC recommended maintaining the current work RVU of 18.12 for CPT code 42415.

Furthermore, as detailed in the Fourth Five-Year Review of Work (76 FR 32447), for CPT code 42420 (Excision of parotid tumor or parotid gland; total, with dissection and preservation of facial nerve) we proposed a work RVU of 19.53 for CY 2012. Medicare PFS claims data indicated that CPT code 42420 is typically furnished in an outpatient setting. However, the current AMA RUC-recommended values for this code reflected work that is typically associated with an inpatient service. Therefore, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described in section III.A. of this final rule with comment period, for CPT code 42420, we removed the subsequent observation care service, reduced the discharge day management service by one-half, and adjusted the physician times accordingly. The AMA RUC recommended maintaining the current work RVU of 21.00 for CPT code 42420.

Comment: Commenters disagreed with the proposed work RVUs for CPT codes 42415 and 42420 and requested that CMS accept the AMA RUC-recommended RVUs of 18.12 and 21.00, respectively, for these services. Commenters stated that patients typically stay overnight, receiving these specific services require close monitoring for airway patency, formation of hematoma, and facial nerve function, and for 42420, intervention for any noted deficits, drain function, and control of nausea. Moreover, commenters stated that survey data show that the typical patient receives this procedure in the hospital (91 percent for 42415 and 97 percent for 42420) and receives an E/M service on the same date (53 percent for 42415 and 64 percent for 42420). Commenters also noted that whether or not the service is designated outpatient or inpatient, the physician work is the same. Commenters requested that CMS not apply the site-of-service anomaly reductions to work RVUs and physician times, and accept the AMA RUC recommended RVUs of 18.12 for 42415 and 21.00 for 42420.

Response: Based on the public comments received, we referred both CPT codes 42415 and 42420 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs were 18.12 for 42415 and 21.00 for 42420, which was consistent with the AMA RUC recommendation to maintain the current (CY 2011) work RVUs. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. Therefore, we removed the subsequent observation care services, reduced the discharge day management service to one-half, and increased the post-service times. We are finalizing work RVUs of 17.16 for CPT code 42415 and 19.53 for CPT code 42420 with refinements to physician time. CMS time refinements can be found in Table 16.

As detailed in the CY 2012 PFS proposed rule (76 FR 42799), for CPT code 42440 (Excision of submandibular (submaxillary) gland), we proposed a work RVU of 6.14 for CY 2012. As stated in section III.A. of this final rule with comment period, we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. To appropriately revalue this CPT code to reflect an outpatient service we started with the original CY 2008 work RVU of 7.05 then, in accordance with the policy discussed in section III.A. of this final rule with comment period, we removed the value of the subsequent hospital care service and one-half discharge day management service, and added back the subsequent hospital care intra-service time to the immediate post-operative care service.

The AMA RUC recommended maintaining the current work RVU of 7.13 for CPT code 42440 (76 FR 42799).

Comment: Commenters disagreed with the CMS-proposed work RVU of 6.14 for CPT code 42440 and believe that the AMA RUC-recommended work RVU of 7.13 was more appropriate for this service. Commenters disagreed with CMS' use of the reverse building block methodology, which removed the work RVUs associated with the subsequent hospital care code and half a hospital discharge day management service. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time. Commenters also noted that there was an increase in intensity of office visits, because rather than an overnight stay in the hospital, the typical patient is discharged the same day with tubes in their neck, and a more intense office visit is needed to remove the tube and manage other dressings.

Response: Based on the public comments received, we referred CPT code 42440 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work was 7.13, which was consistent with AMA RUC recommendation to maintain the current (CY 2011) work RVU for this service. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation does not reflect a decrease in physician work. We believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. Furthermore, we believe it is appropriate to remove the value of the subsequent hospital care service and one-half discharge day management service, and add back the subsequent hospital care intra-service time to the immediate post-operative care service. Therefore, we are finalizing a work RVU for CPT code 42440 of 6.14 with refinements to time. CMS time refinements can be found in Table 16.

(15) Digestive: Esophagus (CPT codes 43262, 43327–43328, and 43332–43338)

As detailed in the Fourth Five-Year Review (76 FR 32448), for CPT code 43262 (Endoscopic retrograde cholangiopancreatography (ERCP); with sphincterotomy/papillotomy), we believed that the current (CY 2011) work RVU of 7.38 continued to accurately reflect the work of this service. We proposed to maintain the current work RVU and physician times for CPT code 43262. The AMA RUC recommended maintaining the current work RVUs for these services as well. However, the AMA RUC recommended a pre-service evaluation time of 15 minutes and immediate post service time of 20 minutes. Additionally, the AMA RUC recommended a pre-service positioning time of 5 minutes; a pre-service dress/scrub time of 5 minutes; and an intra-service time of 45 minutes. We noted that based on a preliminary review of the intra-service times for these codes, we were concerned the codes in this family are potentially misvalued. We requested that the AMA RUC undertake a comprehensive review of the entire family of ERCP codes, including the base CPT code 43260, and provide us with work RVU recommendations.

Comment: In its public comments to CMS on the Fourth Five-Year Review, the AMA RUC stated that it intends to review this family of codes in 2012. The AMA RUC also noted that CMS disagreed with the AMA RUC-recommended physician times for CPT code 43262. The AMA RUC requested that CMS accept the AMA RUC-recommended times be utilized for CY 2012.

Response: We appreciate the AMA RUC accepting family of ERCP codes for review in 2012. We continue to have concerns about the recommended intra-service times for this code, and believe it is appropriate to maintain the current physician times. CMS time refinements can be found in Table 16.

For CY 2012, we did not receive any public comments on the Fourth Five-Year Review proposed work RVUs for CPT code 43262. We believe this value continues to be appropriate and are finalizing it without modification (Table 15).

For CY 2011 the CPT Editorial Panel deleted six existing CPT codes and created ten new CPT codes (CPT codes 43283, 43327–43328, 43332–43338) to better report current surgical techniques for paraesophageal hernia procedures. The specialty societies surveyed their members, and the AMA RUC issued recommendations to us for the CY 2011 PFS final rule with comment period.

As stated in the CY 2011 PFS final rule with comment period, after reviewing these new CPT codes, we believed that this coding change resulted in more codes that describe the same physician work with a greater degree of precision, and that the aggregate increase in work RVUs that would result from the adoption of the CMS-adjusted pre-budget neutrality RVUs would not represent a true increase in physician work. Therefore, we believed it was appropriate to apply work budget neutrality to this set of CPT codes. After reviewing the AMA RUC-recommended work RVUs, we adjusted the work RVUs for two CPT codes (CPT code 43333 and 43335), and then applied work budget neutrality to the set of clinically related CPT codes. The work budget neutrality factor for the 10 paraesophageal hernia procedure CPT codes was 0.7374. The AMA RUC-recommended work RVU, CMS-adjusted work RVU prior to the budget neutrality adjustment, and the CY 2011 interim final work RVU for these paraesophageal hernia procedure codes follow (CPT codes 43283, 43327–43328, 43332–43338) (75 FR 73338).

CPT Code	Short Descriptor	AMA RUC-recommended work RVU	CMS-adjusted work RVU, pre-BN	CY 2011 interim final work RVU
43283	Lap esoph lengthening	4.00	4.00	2.95
43327	Esoph fundoplasty lap	18.10	18.10	13.35
43328	Esoph fundoplasty thor	27.00	27.00	19.91
43332	Transab esoph hiat hern rpr	26.60	26.60	19.62
43333	Transab esoph hiat hern rpr	30.00	29.10	21.46
43334	Transthor diaphrag hern rpr	30.00	30.00	22.12
43335	Transthor diaphrag hern rpr	33.00	32.50	23.97
43336	Thorabd diaphr hern repair	35.00	35.00	25.81
43337	Thorabd diaphr hern repair	37.50	37.50	27.65
43338	Esoph lengthening	3.00	3.00	2.21

As mentioned previously, and detailed in the CY 2011 PFS final rule with comment period, for CPT codes 43333 (Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; with implantation of mesh or other prosthesis) and 43335 (Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; with implantation of mesh or other prosthesis), we disagreed with the AMA RUC-recommended work RVUs and assigned alternate RVUs prior to the application of work budget neutrality (75 FR 73331). For CPT code 43333 we assigned a pre-budget neutrality work RVU of 29.10 and for CPT code 43335 we assigned a pre-budget neutrality work RVU of 32.50. We arrived at these values by starting with the AMA RUC-recommended values for the repair of papaesophageal hernia without mesh, CPT codes 43332 (Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; without implantation of mesh or other prosthesis) and 43334 (Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; without implantation of mesh or other prosthesis) then adjusted them upward by a work RVU of 2.50 to account for the incremental difference associated with the implantation of mesh or other prosthesis. The AMA RUC recommended a work RVU of 30.00 for CPT code 43333 and a work RVU of 33.00 for CPT 43335 for CY 2011.

Comment: Commenters disagreed with the application of work budget neutrality to this set of services and noted that the specialty societies and AMA RUC agreed that there was compelling evidence that technology has changed the physician work to repair esophageal hernias. Commenters stated that the work described by the deleted CPT codes was intended for patients with acid reflux or blockage and that, with the advent of medical management and less invasive treatments, the patients' currently undergoing surgery are symptomatic, typically with blockage. They stated that the typical patient has more advanced disease and requires more complex repair. Commenters also stated that the CY 2011 interim final values would create rank order anomalies between these CPT codes and other major inpatient surgical procedures.

With regard to CPT codes 43333 and 43335, commenters disagreed with the CMS-assigned pre-budget neutrality work RVU of 29.10 for CPT code 43333 and 32.50 for CPT code 43335, and believe that the AMA RUC-recommended work RVUs of 30.00 for CPT code 43333 and 33.00 for CPT code 43335 are more appropriate for these services. Commenters noted that CMS adjusted the AMA RUC-recommended values for CPT codes 43333 and 43335 by 2.50 work RVUs, an increment established in the AMA RUC's valuation of CPT codes 43336 and 43337. In other words CMS added 2.50 work RVUs to the AMA RUC-recommended work RVUs of 26.60 for CPT code 43332, which resulted in a value of 29.10 for CPT code 43333. Also, CMS added 2.50 work RVUs to the AMA RUC-recommended work RVUs of 30.00 for CPT code 43334, which resulted in a value of 32.50 for CPT code 43335. Commenters disagreed with this method because CMS' interim values were not supported by the survey results or AMA RUC recommendations. Commenters note that the AMA RUC recommendations were based on magnitude estimation rather than the building block methodology, which considers the total work of the service rather than the work of the component parts of the service. Commenters did not agree with adding component parts on to values that were based through magnitude estimation. Commenters asserted that these,services should be valued through magnitude estimation, rather than incremental addition of work RVUs of 2.50 in order to account for both the work related to inserting mesh, as well as other patient factors that in turn make the insertion of mesh necessary. Based on these arguments, commenters stated that work budget neutrality should not be applied to these codes, and urged CMS to accept the AMA RUC-recommended values for these services.

Response: Based on comments received, we referred this set of paraesophageal hernia procedures (CPT codes 43283, 43327–43328, and 43332–43338) to the CY 2011 multi-specialty refinement panel for further review. Though the refinement panel median work RVUs were work RVUs of 30.00 for CPT code 43333 and 33.00 for CPT 43335, which were consistent with the AMA RUC-recommended values for these services. We continue to believe that the application of work budget neutrality is appropriate for this set of clinically related CPT codes. While we understand that the practice of medicine has changed since these codes were originally valued, we do not believe these changes have resulted in more aggregate physician work. As such, we believe that allowing an increase in utilization-weighted RVUs within this set of clinically related CPT codes would be unjustifiably redistributive among PFS services. Additionally, we continue to believe that a work RVU of 2.50, which was based on a differential that was recommended by the AMA RUC between a pair of with/without implantation of mesh codes in this family, appropriately accounts for the incremental difference in work between CPT codes 43332 and 43333, and 43334 and 43335. After consideration of the public comments, refinement panel

results, and our clinical review, we are finalizing the CY 2011 interim final work RVU values for paraesophageal hernia procedures (CPT codes 43283, 43327–43328, and 43332–43338) for CY 2012. The CY 2012 final work RVUs for these services are as follows:

CPT Code	Short Descriptor	CY 2012 Final Work RVU
43283	Lap esoph lengthening	2.95
43327	Esoph fundoplasty lap	13.35
43328	Esoph fundoplasty thor	19.91
43332	Transab esoph hiat hern rpr	19.62
43333	Transab esoph hiat hern rpr	21.46
43334	Transthor diaphrag hern rpr	22.12
43335	Transthor diaphrag hern rpr	23.97
43336	Thorabd diaphr hern repair	25.81
43337	Thorabd diaphr hern repair	27.65
43338	Esoph lengthening	2.21

Additionally, we received no public comments on the Fourth Five-Year Review proposed work RVUs for CPT code 43415. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(16) Digestive: Rectum (CPT code 45331)

As detailed in the Fourth Five-Year Review, for CPT code 45331 (Sigmoidoscopy, flexible; with biopsy, single or multiple) we believed that the current (CY 2011) work RVUs continued to accurately reflect the work of these services and, therefore, proposed a work RVU of 1.15 for CPT code 45331. The AMA RUC recommended maintaining the current work RVUs for this service as well. For CPT code 45331, the AMA RUC recommended a pre-service time of 15 minutes, intra-service time of 15 minutes, and post-service time of 10 minutes. While the AMA RUC recommended pre-service times based on the 75th percentile of the survey results, we believed it was more appropriate to accept the median survey physician times. Accordingly, we proposed to refine the times to the following: 5 minutes for pre-evaluation; 5 minutes for pre-service other, 5 minutes for pre- dress, scrub, and wait; 10 minutes intra-service; and 10 minutes immediate post-service (76 FR 32448).

Comment: In its public comment to CMS on the Fourth Five-Year Review, the AMA RUC wrote that CMS agreed with the AMA RUC recommended work RVU, but noted that CMS disagreed with the AMA RUC recommended time components. The commenters further noted that CMS proposed to use the median survey time for CPT code 45331. The AMA RUC recommends that CMS accept the AMA RUC recommended intra-service time of 15 minutes for CPT code 45331.

Response: In response to comments, we re-reviewed CPT code 45331. After reviewing the descriptions of pre-service work and the recommended pre-service time packages, we disagree with the times recommended by the AMA RUC. For CPT code 45331 we are finalizing a work RVU of 1.15. In addition, we are finalizing the following times for CPT code 45331: 5 minutes for pre-evaluation; 5 minutes for pre-service other, 5 minutes for pre- dress, scrub, and wait; 10 minutes intra-service; and 10 minutes immediate post-service. CMS time refinements can be found in Table 16.

(17) Digestive: Biliary Tract (CPT Codes 47480, 47490, 47563, and 47564)

In the Fourth Five-Year Review, CMS identified CPT code 47563 as potentially misvalued through the Harvard Valued—Utilization > 30,000 screen and site-of-service anomaly screen. The AMA RUC reviewed CPT codes 47564 and 47563.

As detailed in the Fourth Five-Year Review (76 FR 32448), for CPT code 47563 (Laparoscopy, surgical; cholecystectomy with cholangiography), we proposed a work RVU of 11.47 with refinements in time for CPT code 47563 for CY 2012. The survey data show 95 percent (57 out of 60) of survey respondents stated they furnish the procedure ''in the hospital.'' However, of those respondents who stated that they typically furnish the procedure in the hospital, 30 percent (17 out of 57) stated that the patient is ''discharged the same day''; 46 percent (26 out of 57) stated the patient is ''kept overnight (less than 24 hours)''; and 25 percent (14 out of 57) stated the patient is ''admitted (more than 24 hours).'' These responses make no distinction between the patient's status as an inpatient or outpatient of the hospital for stays of longer than 24 hours. Based on the survey data, we valued this service based on our methodology to address 23-hour stay site-of-service anomaly services.

As we discussed in section III.A. of this final rule with comment period, for codes with site-of-service anomalies, our policy is to remove any post-procedure inpatient visits remaining in the values for these codes and adjust physician times accordingly. It is also our policy for codes with site-of-service anomalies to consistently include the value of half of a discharge day management service, adjusting physician times accordingly. The AMA RUC recommended that this service be valued as a service furnished predominately in the facility setting with a work RVU of 12.11 for CPT code 47563 (76 FR 32448).

Comment: Commenters disagreed with the proposed work RVU of 11.47, and supported the AMA RUC-recommended work RVU of 12.11 for CPT code 47563. Commenters disagreed with CMS' methodology to address 23-hour stay site-of-service anomaly services of removing half of a discharge day management service. Commenters noted the change in physician work in the past five years; specifically, a more complex patient population. Commenters also stated that the physician's discharge work remains the same, independent of facility status. Commenters stated that CPT code 47563 is more intense and has a higher intra-service time than the key reference code 47562 (Laparoscopy, surgical; cholecystectomy), and cautioned against a rank order anomaly within the family

with CPT code 47562 (work RVU = 11.76). Commenters requested that CMS accept the AMA RUC-recommended work RVU of 12.11 and include a full day discharge service for CPT code 47563.

Response: Based on the comments we received, we referred CPT code 47563 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 12.11, which was consistent with the AMA RUC recommendation and the current (CY 2011) work RVU. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this 23-hour stay service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. After consideration of the public comments, refinement panel results, and our clinical review, we are finalizing a work RVU of 11.47 to CPT code 47563. CMS time refinements can be found in Table 16.

As detailed in the Fourth Five-Year Review (76 FR 32449), for CPT code 47564 (Laparoscopy, surgical; cholecystectomy with exploration of common duct), we proposed a work RVU of 18.00, the survey low work RVU, for CY 2012. We accepted the AMA RUC-recommended median survey times and believed the work RVU of 18.00 for CPT code 35860 was more appropriate given the significant reduction in recommended physician times in comparison to the current times. The AMA RUC recommended a work RVU of 20.00, the 25th survey percentile, for CPT code 47564.

Comment: Commenters disagreed with the proposed work RVU of 18.00, and supported the AMA RUC-recommended work RVU of 20.00 for CPT code 47564. Commenters disagreed with CMS' acceptance of the survey low, while the AMA RUC recommended the 25th survey percentile. Commenters noted that the physician times for CPT code 47564 were crosswalked in 1994 and were not accurate. Therefore, they state that reducing the work value based on the reduction in physician time is not appropriate.

Response: Based on comments we received, we referred CPT code 47564 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 20.00, which was consistent with the AMA RUC recommendation for this service. We find that the median survey times, recommended by the AMA RUC, do not support the AMA RUC-recommended increase in work RVUs. We believe that the proposed work RVU is more appropriate with the AMA RUC-recommended physician times that we accepted. After consideration of the public comments, refinement panel results, and our clinical review, we are finalizing a work RVU of 18.00 for CPT code 47564. CMS time refinements can be found in Table 16.

For CY 2012, we received no comments on the Fourth Five-Year Review proposed work RVUs for CPT codes 47480 and 47490. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(18) Digestive: Abdomen, Peritoneum, and Omentum (CPT codes 49324–49655)

We discussed CPT codes 49507 (Repair initial inguinal hernia, age 5 years or over; incarcerated or strangulated), 49521 (Repair recurrent inguinal hernia, any age; incarcerated or strangulated), and 49587 (Repair umbilical hernia, age 5 years or over; incarcerated or strangulated) in the Fourth Five-Year Review (76 FR 32449) where we noted these codes were identified as codes with a site-of-service anomaly. Medicare PFS claims data indicated that these codes are typically furnished in an outpatient setting. However, the current and AMA RUC-recommended values for these codes reflected work that is typically associated with an inpatient service. As discussed in section III.A. of this final rule with comment period, our policy is to remove any post-procedure inpatient and subsequent observation care visits remaining in the values for these codes and adjust physician times accordingly. It is also our policy for codes with site-of- service anomalies to consistently include the value of half of a discharge day management service. While the AMA RUC recommended maintaining the current work RVUs, utilizing our methodology, we proposed an alternative work RVU of 9.09 for CPT code 49507, 11.48 for CPT code 49521, and 7.08 for CPT code 49587, with appropriate refinements to the time.

Comment: Commenters disagreed with the CMS-proposed work RVU for CPT codes 49507 49521, and 49587. The commenters noted that for these three hernia repair codes, the AMA RUC survey data show 98–100 percent of survey respondents stated they furnish the procedure ''in the hospital.'' Commenters disagreed with CMS' use of the reverse building block methodology, which removed the subsequent observation care code and reduced the full hospital discharge day management code to a half day, along with the associated work RVUs and times. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time. Commenters requested that CMS reconsider this issue and accept the AMA RUC recommended work RVU as a valid relative measure using magnitude estimation and comparison to codes with similar work and intensity.

Response: Based on comments received, we referred CPT codes 49507, 49521, and 49587 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs were 10.05 for CPT code 49507, 12.44 for CPT code 49521, and 8.04 for CPT code 49587, which was consistent with the AMA RUC recommendation to maintain the current (CY 2011) work RVU for this service. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. While the commenter noted that the survey respondents overwhelmingly indicated that they furnish this procedure ''in the hospital,'' the Medicare claims data show these patients are typically in the hospital as outpatients, not inpatients and we do not believe that maintaining the current

value, which reflects work that is typically associated with an inpatient service, is appropriate. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU for CY 2012 of 9.09 for CPT code 49507, 11.48 for CPT code 49521, and 7.08 for CPT code 49587, with appropriate refinements to the time. CMS time refinements can be found in Table 16.

We discussed CPT code 49652 (Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); reducible), CPT code 49653 (Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated), CPT code 49654 (Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible), and CPT code 49655 (Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed)) in the Fourth Five-Year Review of Work (76 FR 32450–32452) where we noted these codes were identified as codes with a sites-of-services anomaly. Medicare PFS claims data indicated that these codes are typically furnished in an outpatient setting. However, the current and AMA RUC-recommended values for these codes reflected work that is typically associated with an inpatient service. As discussed in section III.A. of this final rule with comment period, our policy is to remove any post-procedure inpatient and subsequent observation care visits remaining in the values for these codes and adjust physician times accordingly. It is also our policy for codes with site-of-service anomalies to consistently include the value of half of a discharge day management service. While the AMA RUC recommended maintaining the current work RVUs, utilizing our methodology, we proposed an alternative work RVU of 11.92 with refinements to the time for CPT code 49652, 14.92 with refinements to the time for CPT code 49653, 13.76 with refinements to the time for CPT code 49654, and 16.84 with refinements to the time for CPT code 49655.

Comment: Commenters disagreed with the CMS-proposed work RVU for CPT codes 49652, 49653, 49654, and 49655. Commenters noted that similar to the three hernia repair codes previously discussed, the AMA RUC survey data show 98–100 percent of survey respondents stated they furnish these laparoscopic hernia repair procedures ''in the hospital.'' Commenters disagreed with CMS' use of the reverse building block methodology, which removed the subsequent observation care codes and reduced the full hospital discharge day management code to a half day, along with the associated work RVUs and times. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time. Commenters also contended the surgeon's post-operative work has not changed and has not become easier because of a change in facility designation. Commenters requested that CMS reconsider this issue and accept the AMA RUC recommended work RVU as a valid relative measure using magnitude estimation and comparison to codes with similar work and intensity.

Response: Based on comments received, we referred CPT codes 49652, 49653, 49654, and 49655 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs were 12.88, 16.21, 15.03, and 18.11 for CPT codes 49652, 49653, 49654, and 49655, respectively, which were consistent with the AMA RUC recommendation to maintain the current work RVUs for this services. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. We note again that while survey respondents overwhelmingly indicated that they furnish these procedures ''in the hospital,'' the Medicare claims data show these patients are typically in the hospital as outpatients, not inpatients and we do not believe that maintaining the current value, which reflects work that is typically associated with an inpatient service, is appropriate. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU for CY 2012 of 11.92 with refinements to the time for CPT code 49652, 14.92 with refinements to the time for CPT code 49653, 13.76 with refinements to the time for CPT code 49654, and 16.84 with refinements to the time for CPT code 49655.

For CY 2012, we received no public comments on the CY 2011 interim final work RVUs for CPT codes 49324, 49327, 49412, 49418, 49419, 49421, and 49422. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(19) Urinary System: Bladder (CPT Codes 51705–53860)

As detailed in the Fourth Five-Year Review, for CPT code 51710 (Change of cystostomy tube; complicated), we agreed with the AMA RUC-recommended work RVU, and proposed a work RVU of 1.35 for CY 2012. The AMA RUC noted that a request was sent to CMS to have the global service period changed from a 10-day global period (010) to a 0-day global period (000), which only includes RVUs for the same day pre- and post-operative period. The AMA RUC indicated that in the standards of care for this procedure, there is no hospital time and there are no follow up visits. The AMA RUC also noted that while the service was surveyed as a 10-day global, the respondents inadvertently included a hospital visit, CPT code 99231 (Subsequent hospital care), and removed the RVUs for that visit.

Consequently, the AMA RUC did not use the survey results to value the code. Rather, comparing the physician work within the family of services, the AMA RUC compared CPT code 51710 to CPT code 51705 (Change of cystostomy tube; simple) and recommended a work RVU of 1.35 for CPT code 51710.

We agreed to change the global period from a 10-day global to 0-day global. However, we noted that while we believed that changing a cystostomy tube in a complicated patient may be more time consuming than in a patient that requires a simple cystostomy tube change, we believed that the prepositioning time is unnecessarily high given the recommended pre-positioning time of 5 minutes for CPT

code 51705, which has an identical pre-positioning work description. Hence, we proposed refinements in time for CPT code 51710 for CY 2012 (76 FR 32452).

Comment: In their public comment to CMS on the Fourth Five-Year Review, the AMA RUC wrote that CMS agreed with the AMA RUC recommended work RVU and the request to change the global period from a 10-day global to 0-day global period. Commenters disagreed with CMS that the pre-service positioning time is identical between codes 51710 and 51705. Commenters also state that the service does require more time for positioning since many times patients must be transferred from a wheelchair to an examination table. Lastly, commenters recommend that CMS accept the AMA RUC-recommended pre-service positioning time of 10 minutes for CPT code 51710.

Response: In response to comments, we re-reviewed CPT code 51710. After reviewing the descriptions of pre-service work and the recommended pre-service time packages, we continue to disagree with the times recommended by the AMA RUC. We believe that the prepositioning time is unnecessarily high given the recommended pre-positioning time of 5 minutes for CPT code 51705, which has an identical pre-positioning work description. For CPT code 51710, we are finalizing a work RVU of 1.35. In addition, we are finalizing the following times for CPT code 51710: 7 minutes for pre-evaluation; 5 minutes for pre-service positioning, 15 minutes for intra-service; and 15 minutes post-service. CMS time refinements can be found in Table 16.

CPT codes 52281 (Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy, with or without injection procedure for cystography, male or female) and 52332 (Cystourethroscopy, with insertion of indwelling ureteral stent (*e.g.,* Gibbons or double-J type)) were identified as a potentially misvalued code through the Five-Year Review Identification Workgroup under the Harvard-Valued potentially misvalued codes screen for services with utilization over 100,000.

As detailed in the CY 2011 final rule with comment period (75 FR 73339), for CPT code 52281, we assigned an interim final work RVU of 2.60. The AMA RUC reviewed the survey results and determined that the physician time of 16 minutes pre-, 20 minutes intra-, and 10 minutes immediate post-service time and maintaining the current work RVUs of 2.80 appropriately accounted for the time and work required to furnish this procedure. We disagreed with the AMA RUC recommendation to maintain the current RVUs for this code because the physician time to furnish this service (a building block of the code) has changed since the original ''Harvard values'' were established, as indicated by the AMA RUC-recommended reduction in pre-service time. Accounting for the reduction in pre-service time, we calculated work RVUs that were close to the survey 25th percentile.

Comment: Commenters disagreed with the interim final work RVU of 2.60. Commenters acknowledged that CPT code 52281 had significant reductions to the pre-service times. However, commenters stated that the work for this service had not changed. Commenters asserted that because this service was valued using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, it is not appropriate to remove RVUs based on time (a building block of the code). For CPT code, commenters requested that CMS accept the AMA RUC-recommended work RVU of 2.80.

Response: Based on the comments received, we referred CPT code 52281 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 2.75. As a result of the refinement panel ratings and clinical review by CMS, we are assigning a work RVU of 2.75 to CPT code 52281 as the final value for CY 2012.

As detailed in the CY 2011 final rule with comment period (75 FR 73339), for CPT code 52332, we assigned an interim final work RVU of 2.60. We disagreed with the AMA RUC's CY 2011 work RVU recommendation to maintain the current value due significant reduction in pre-service time. Based on the same building block rationale we applied to CPT code 52281, the other code within this family, we believed 2.60, which is the survey 25th percentile and maintains rank order, was a more appropriate valuation for 52332.

Comment: Commenters believed that CMS made a mistake on the valuation for code 52332 in the CY 2011 PFS final rule with comment period. The information in the final rule with comment period prior to correction stated that the 25th percentile work RVU was 1.47. The commenters noted that the RUC states that the 25th percentile is 3.20 not 1.47 as stated in the final rule. Additionally, the commenters stated that if CMS maintains the 1.47 work RVU, then 52332 will have less value than cystoscopy (52000) at 2.23 work RVUs. Moreover, commenters stated that the procedure identified as 52332 is a more intense procedure than 52000.

Commenters also acknowledged that CPT code 52332 had significant reductions to the pre-service times. However, commenters stated that the work for this service had not changed. Commenters asserted that because this service was valued using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, it is not appropriate to remove RVUs based on time (a building block of the code). For CPT code, commenters requested that CMS accept the AMA RUC-recommended work RVU of 2.83.

Response: We corrected a typographical error in the CY 2011 PFS final rule with comment period that improperly valued the work RVU for CPT code 52332 at 1.47, instead of the interim final work RVU of 2.60 for CY 2011 (76 FR 1673). Based on the comments received, we referred CPT code 52332 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 2.82. As a result of the refinement panel ratings and clinical review by CMS, we are assigning a work RVU of 2.82 for CPT code 52332 as the final value for CY 2012.

In the Fourth Five-Year Review, we identified CPT codes 51705, 52005 and 52310 as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen. CPT codes 51710, 52007 and 52315 were added as part of the family of services for AMA RUC review. In addition, we identified CPT codes 52630, 52649, 53440 and 57288 as potentially misvalued through the site-of-service anomaly screen. The specialty agreed to add CPT codes 52640 and 57287 as part of the family of services for AMA RUC review.

As detailed in the Fourth Five-Year Review of Work (76 FR 32452), for CPT code 52630 (Transurethral resection; residual or regrowth of obstructive prostate tissue including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internalurethrotomy are included)), we proposed a work RVU of 6.55 for CY 2012. Medicare PFS claims data indicated that CPT code 52630 is typically furnished in an outpatient setting. However, the current AMA RUC-recommended values for this code reflected work that is typically associated with an inpatient service. Therefore, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described

in section III.A. of this final rule with comment period, for CPT code 52630, we removed the post procedure inpatient visit remaining in the AMA RUC-recommended value and adjusted the physician times accordingly. We also reduced the discharge day management service by one-half. The AMA RUC recommended maintaining the current work RVU of 7.73 for CPT code 52630.

Comment: Commenters disagreed with the CMS-proposed work RVU of 6.55 for CPT code 52630 and believe that the AMA RUC-recommended work RVU of 7.73 is more appropriate for this service. The commenters disagreed with CMS' reduction to half of a discharge day management service. Furthermore, commenters stated that one full discharge day management code (either 99238 or 99217 1.28 RVU) should be included in the valuation of 52630. The commenters asserted that there was not appropriate justification for CMS to remove 0.64 work RVUs from the RUC's recommendation to reduce the full day of discharge management services to one-half day. Commenters also stated that the AMA RUC-recommended physician time should be restored.

Response: Based on comments received, we referred CPT code 52630 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 7.14. The AMA RUC recommended maintaining the current (CY 2011) work RVU of 7.73. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not adequately reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU of 6.55 to CPT code 52630 as the final value for CY 2012. Therefore, we are finalizing a pre-service time of 33 minutes, a pre-service positioning time of 5 minutes, a pre-service (dress, scrub, wait) time of 15 minutes, an intra-service time of 60 minutes, and a post-service time of 35 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 52630. CMS time refinements can be found in Table 16.

As detailed in the Fourth Five-Year Review of Work (76 FR 32453), for CPT code 52649 (Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)), we proposed a work RVU of 14.56 for CY 2012. Medicare PFS claims data indicated that CPT code 52649 is typically furnished in an outpatient setting. However, the current AMA RUC-recommended values for this code reflected work that is typically associated with an inpatient service. Therefore, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described in section III.A. of this final rule with comment period, CPT code 52649, we reduced the discharge day management service to one-half and adjusted the physician times accordingly. The AMA RUC recommended a work RVU of 15.20 for CPT code 52649.

Comment: Commenters disagreed with the CMS proposed work RVU of 14.56 for CPT code 52649 and believe that the AMA RUC-recommended work RVU of 15.20 is more appropriate for this service. In addition, the commenters disagreed that a half-day of discharge management services is appropriate for this code. The commenters support the utilization of a full discharge day that takes into account the time the physician spends returning to the hospital later that night or the next morning to review charts, furnish an examination of the patient, check on post-operative status, speak with the patient's family, and provide any subsequent discharge services that usually require more than 30 minutes. Commenters also stated that the AMA RUC physician time should be restored.

Response: Based on comments received, we referred CPT code 52649 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 14.88. The AMA RUC recommendation for this service was a work RVU of 15.20. The AMA RUC-recommended work value for this service included a full discharge day management service, which we do not believe is appropriate for an outpatient service. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. The AMA RUC-recommendation and refinement panel results do not adequately reflect the appropriate decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU of 14.56 to CPT code 52649 as the final value for CY 2012. In addition, we are finalizing a pre-service time of 33 minutes, a pre-service positioning time of 5 minutes, a pre-service (dress, scrub, wait) time of 15 minutes, an intra-service time of 120 minutes, and a post-service time of 25 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 52649. CMS time refinements can be found in Table 16.

As detailed in the Fourth Five-Year Review of Work (76 FR 32453), for CPT code 53440 (Sling operation for correction of male urinary incontinence (*e.g.,* fascia or synthetic)), we proposed a work RVU of 13.36 for CY 2012. Medicare PFS claims data indicated that CPT code 53440 is typically furnished in a hospital setting as an outpatient service. However, the current AMA RUC-recommended values for this code reflected work that is typically associated with an inpatient service. Therefore, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described in section III.A. of this final rule with comment period, for CPT code 53440, we reduced the discharge day management service to one-half. The AMA RUC recommended a work RVU of 14.00 for CPT code 53440.

Comment: Commenters disagreed with the CMS proposed work RVU of 13.36 for CPT code 53440 and believe that the AMA RUC-recommended work RVU of 14.00 is more appropriate for this service. In addition, the commenters disagreed that a half-day of discharge management services is appropriate for this code. The commenters support the utilization of a full discharge day that takes into account the time the physician spends returning to the hospital later that night or the next morning to review charts, furnish an examination of the patient,

check on post-op status, speak with the patient's family, and provide any subsequent discharge services that usually require more than 30 minutes. Commenters also stated that the AMA RUC-recommended physician time should be restored.

Response: Based on comments received, we referred CPT code 53440 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 13.68. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not adequately reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU of 13.36 to CPT code 53440 as the final value for CY 2012. In addition, we are finalizing a pre-service time of 33 minutes, a pre-service positioning time of 7 minutes, a pre-service (dress, scrub, wait) time of 15 minutes, an intra-service time of 90 minutes, and a post-service time of 22 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 53440. CMS time refinements can be found in Table 16.

For CY 2009, CPT code 53445 (Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff) was identified as potentially misvalued through the site-of-service anomaly screen. As detailed in the CY 2012 PFS proposed rule (76 FR 42799), we proposed a work RVU of 13.00 for CY 2012. Medicare PFS claims data indicated that CPT code 53445 is typically furnished in a hospital setting as an outpatient service. Upon clinical review of this service and the time and visits associated with it, we believe that the survey 25th percentile work RVU of 13.00 appropriately accounts for the work required to furnish this service (76 F42800).

Comment: Commenters disagreed with the CMS-proposed work RVU of 13.00 for CPT code 53445 and stated that a work RVU of 15.39 is more appropriate for this service. Some commenters opposed the reduction in RVUs for this service and our utilization of a reverse building block methodology. Additionally, some commenters expressed concerns regarding the use of the 25th percentile in the CMS and whether this methodology accounts for the resources required to furnish this service. However, the AMA RUC clarified that the AMA RUC recommendation was misstated in the proposed rule due to an error, and that the AMA RUC-recommended work RVU is 13.00 for CPT 53445.

Response: We agree with the AMA RUC that the 25th percentile value of 13.00 work RVUs is appropriate for this service. Therefore, we are finalizing a work RVU of 13.00 for CPT code 53445 for CY 2012.

For CY 2012, we received no public comments on the CY 2011 interim final work RVUs for CPT codes 50250, 50542, 51736, 51741, 53860, 55866, and 55876. Also, for CY 2012, we received no public comments on the CY 2012 proposed work RVUs for CPT codes 52341, 52342, 52343, 52344, 52345, 52346, 52400, 52500, 54410, and 54530. Finally, for CY 2012, we received no public comments on the Fourth Five-Year Review proposed work RVUs for CPT codes 51705, 52005, 52007, 52310, 52315, and 52640. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(20) Female Genital System: Vagina (CPT Codes 57155–57288)

We discussed CPT code 57155 (Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy) in the CY 2011 PFS final rule with comment period (75 FR 73330). For CY 2011, the AMA RUC reviewed survey responses, concluded that the survey median work RVU appropriately accounts for the physician work required to furnish this service, and recommended a work RVU of 5.40 for CPT code 57155. We disagreed with the AMA RUC-recommended value for this service because the description of the AMA RUC's methodology was unclear to us. We believed the work RVU of 3.37 was more appropriate for this service, which is the same as the value assigned to CPT code 58823 (Drainage of pelvic abscess, transvaginal or transrectal approach, percutaneous (*e.g.,* ovarian, pericolic)), which we believed was an appropriate crosswalk. Therefore, we assigned an alternative work RVU of 3.37 to CPT code 57155 on an interim final basis for CY 2011.

Comment: Commenters disagreed with this proposed value. Commenters did not believe comparison of CPT code 57155 to CPT code 58823 was acceptable, asserting CPT code 57155 is a much higher intensity procedure that is not clinically parallel in work or intensity to CPT code 58823. Commenters stated that they preferred CMS accept the AMA RUC recommendation.

Response: Based on the comments received, we referred CPT code 57155 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 5.40. As a result of the refinement panel ratings and clinical review by CMS, we are assigning a work RVU of 5.40 to CPT code 57155 as the final value for CY 2012.

We discussed CPT code 57156 (Insertion of a vaginal radiation afterloading apparatus for clinical brachytherapy) in the CY 2011 PFS final rule with comment period (75 FR 73330). For CY 2011, the AMA RUC reviewed survey responses, concluded that the survey 25th work RVU appropriately accounts for the physician work required to furnish this service, and recommended a work RVU of 2.69. We disagreed with the AMA RUC's valuation of the work associated with this service and determined it was more appropriate to crosswalk CPT code 57156 to CPT code 62319 (Injection, including catheter placement, continuous infusion or intermittent bolus, not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or subarachnoid; lumbar, sacral (caudal)) (work RVUs = 1.87), which has the same intra-service time (30 minutes) and overall lower total time than the comparison services referenced by the AMA RUC. We assigned an alternative value of 1.87 work RVUs to CPT code 57156 on an interim final basis for CY 2011.

Comment: The commenters disagreed with interim final value, noting the AMA RUC recommended the survey 25th percentile value which the commenters preferred over CMS' crosswalk. The commenters requested that CMS accept the AMA RUC recommendation.

Response: Based on the comments received, we referred CPT code 57156 to the CY 2011 multi-specialty refinement panel for further review. The refinement

panel median work RVU was 2.69. As a result of the refinement panel ratings and clinical review by CMS, we are assigning a work RVU of 2.69 to CPT code 57156 as the final value for CY 2012.

Additionally, we note there were two other codes in the Female Genital System: Vagina family for which we agreed with the AMA RUC recommendations. We received no public comments on CPT codes 57287 (Revise/remove sling repair) and 57288 (Repair bladder defect). For CY 2012, we received no public comments on the Fourth Five-Year Review of Work proposed work RVUs for CPT codes 57287 and 57288. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(21) Maternity Care and Delivery (CPT Codes 59400–59410, 59510–59515, and 59610–59622)

CPT codes 54900–59622 were identified as potentially misvalued codes ''High IWPUT'' screen. The specialty societies surveyed their members, and the AMA RUC issued recommendations to us for the CY 2011 PFS final rule with comment period.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73338), for CY 2011 the AMA RUC reviewed 17 existing obstetrical care codes as part of the potentially misvalued code initiative. The AMA RUC recommended significant increases in the work RVUs for some of the comprehensive obstetrical care codes, largely to address the management of labor. While we generally agreed with the resulting AMA RUC-recommended rank order of services in this family, we believed that the aggregate increase in work RVUs for the obstetrical services that would result from the adoption of the CMS-adjusted pre-budget neutrality work RVUs was not indicative of a true increase in physician work for the services. Therefore, we believed that it would be appropriate to apply work budget neutrality to this set of CPT codes. After reviewing the AMA RUC-recommended work RVUs, we adjusted the work RVUs for several codes, then applied work budget neutrality to the set of clinically related CPT codes. The work budget neutrality factor for the 17 obstetrical care CPT codes was 0.8922. The AMA RUC-recommended work RVU, CMS-adjusted work RVU prior to the budget neutrality adjustment, and the CY 2011 interim final work RVU for obstetrical care codes (CPT codes 59400–59410, 59510–59515, and 59610–59622) follow.

CPT Code	Short Descriptor	AMA RUC-recommended Work RVU	CMS-adjusted work RVU, pre-BN	CY 2011 interim final work RVU
59400	Obstetrical care	32.69	32.16	28.69
59409	Obstetrical care	14.37	14.37	12.82
59410	Obstetrical care	18.54	18.01	16.07
59412	Antepartum manipulation	1.71	1.71	1.53
59414	Deliver placenta	1.61	1.61	1.44
59425	Antepartum care only	6.31	6.31	5.63
59426	Antepartum care only	11.16	11.16	9.96
59430	Care after delivery	2.47	2.47	2.20
59510	Cesarean delivery	36.17	35.64	31.80
59514	Cesarean delivery only	16.13	16.13	14.39
59515	Cesarean delivery	22.00	21.47	19.15
59610	VBAC delivery	34.40	33.87	30.22
59612	VBAC delivery only	16.09	16.09	14.35
59614	VBAC care after delivery	20.26	19.73	17.60
59618	Attempted VBAC delivery	36.69	36.16	32.26
59620	Attempted VBAC delivery only	16.66	16.66	14.86
59622	Attempted VBAC after care	22.53	22.00	19.63

As mentioned previously, and detailed in the CY 2011 PFS final rule with comment period, we disagreed with the AMA RUC-recommended work RVUs for a subset of the obstetrical care CPT codes, and assigned alternate RVUs prior to the application of work budget neutrality (75 FR 73340). For obstetrical care services that include postpartum care with delivery, the AMA RUC included one CPT code 99214 visit (Level 4 established patient office or other outpatient visit). We believed that one CPT code 99213 visit (Level 3 established patient office or other outpatient visit) more accurately reflected the services furnished at this postpartum care visit. Therefore, for the obstetrical care services that include postpartum care following delivery, we converted the CPT code 99214 visit to a 99213 visit and revised the work RVUs accordingly. This includes the following CPT codes: 59400 (Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care), 59410 (Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care), 59510 (Routine obstetric care including antepartum care, cesarean delivery, and postpartum care), 59515 (Cesarean delivery only; including postpartum care), 59610 (Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery), 59614 (Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care), 59618 (Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery), and 59622 (Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care).

Comment: Commenters disagreed with the application of work budget neutrality to this set of services and noted that the specialty societies and AMA RUC agreed that there was compelling evidence that the work RVUs for these services should be increased. Commenters stated that the original work RVUs for the obstetrical care codes were established using a flawed building block methodology, and that discharge day management was not accounted for. Commenters also stated that the original building blocks that were used to develop RVUs for the obstetrical care codes included evaluation and management codes, and that the RVUs for these obstetrical care codes had not been increased though the evaluation and management codes have had significant RVU increases in the past 17 years. Based on these arguments, commenters stated that work budget neutrality should not be applied to these codes, and urged CMS to accept the AMA RUC-recommended values for these services.

Additionally, commenters disagreed with the CMS decision to change the post-partum visit building block from a CPT code 99214 office visit to a CPT code 99213 office visit. Commenters noted that the post-partum visit includes not only a post-procedure physical exam, but also counseling and screening. They reiterated that they believe the CPT code 99214 office visit best reflects the amount of services provided by the physician at this visit. Therefore, commenters requested that CMS accept the AMA RUC-recommended values for all of the obstetrical care services.

Response: We appreciate the specialty society's comprehensive application of the building block methodology to value the obstetrical care services and the detailed rationale they provided. After clinical review, we continue to believe that CPT code 99213, rather than CPT code 99214, accurately reflects the work associated with the provision of the post-partum office visit, and are maintaining the CMS-adjusted pre-budget neutrality RVUs for these services. After reviewing public comments and the history of the valuation of the obstetrical care CPT codes, we agree with commenters that the increase in work RVUs reflects a true increase in aggregate work for this set of service, and not just a structural coding change. As such, we are not applying the budget neutrality scaling factor of 0.8922 discussed in the CY 2011 PFS final rule with comment period for these obstetrical care services. After consideration of the public comments, refinement panel results, and our clinical review, we are finalizing the following values for obstetrical care services (CPT codes 59400–59410, 59510–59515, and 59610–59622) for CY 2012:

CPT code	Short Descriptor	CY 2012 Final Work RVU
59400	Obstetrical care	32.16
59409	Obstetrical care	14.37
59410	Obstetrical care	18.01
59412	Antepartum manipulation	1.71
59414	Deliver placenta	1.61
59425	Antepartum care only	6.31
59426	Antepartum care only	11.16
59430	Care after delivery	2.47
59510	Cesarean delivery	35.64
59514	Cesarean delivery only	16.13
59515	Cesarean delivery	21.47
59610	VBAC delivery	33.87
59612	VBAC delivery only	16.09
59614	VBAC care after delivery	19.73
59618	Attempted VBAC delivery	36.16
59620	Attempted VBAC delivery only	16.66
59622	Attempted VBAC after care	22.00

(22) Endocrine System: Thyroid Gland (CPT Codes 60220–60240)

In the Fourth Five-Year Review, we identified CPT codes 60220, 60240, and 60500 as potentially misvalued through the sites-of-service anomaly screen. The related specialty societies surveyed these codes and the AMA RUC issued recommendations to CMS for the Fourth Five-Year Review of Work.

As detailed in the Fourth Five-Year Review of Work (76 FR 32453), for CPT code 60220 (Total thyroid lobectomy, unilateral; with or without isthmusectomy), we proposed a work RVU of 11.19 for CY 2012. Medicare PFS claims data indicated that CPT code 60220 is typically furnished as an outpatient rather than inpatient service. However, the AMA RUC recommended that this service be valued as a service furnished predominately in the facility setting. The AMA RUC indicated that since the typical patient is kept overnight, the AMA RUC believes that one inpatient hospital visit as well as one discharge day management service should be maintained in the post operative visits for this service. Using magnitude estimation, the AMA RUC recommended the current work RVU of 12.37 for CPT code 60220. In accordance with our methodology to address 23-hour stay and site-of-service anomalies described in III.A. of this final rule with comment period, for CPT code 60220, we removed the hospital visit, reduced the discharge day management service by one-half, and adjusted times.

Comment: Commenters disagreed with the CMS-proposed work RVU of 11.19 for CPT code 60220 and believe that that AMA RUC recommended work RVU is more appropriate for this service. Commenters noted that the CMS value was derived from the reverse building block methodology, which removed the subsequent hospital care code and reduced the full hospital

discharge day management code to a half day. Commenters also stated that our reverse building block methodology is incorrect because Harvard did not use RVU's for E/M codes to build the values-minutes were used. Commenters recommended maintaining the current work RVU of 12.37 for CPT code 60220. Commenters also stated that the AMA RUC-recommended physician time should be restored.

Response: Based on the public comments received, we referred CPT 60220 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 12.37, which is consistent with the AMA RUC recommendation to maintain the current (CY 2011) work RVU for CPT code 60220. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this now outpatient service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. Therefore, we are finalizing a work RVU for CPT code 60220 of 11.19. In addition, after reviewing the descriptions of the AMA RUC-recommended time packages, we disagree with the post-service time recommended by the AMA RUC. Therefore, we are finalizing a pre-service time of 40 minutes, a pre-service positioning time of 12 minutes, a pre-service (dress, scrub, wait) time of 20 minutes, an intra-service time of 90 minutes, and a post-service time of 40 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 60220. CMS time refinements can be found in Table 16.

As detailed in the Fourth Five-Year Review of Work (76 FR 32454), for CPT code 60240 (Thyroidectomy, total or complete), we proposed a work RVU of 15.04 for CY 2012. Medicare PFS claims data indicated that CPT code 60240 is typically furnished as an outpatient rather than inpatient service. Using magnitude estimation, the AMA RUC believed the current work RVU of 16.22 for CPT code 60240 was appropriate. However, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described in section III.A. of this final rule with comment period, for CPT code 60240, we removed the post-procedure inpatient visit and reduced the discharge day management service to one-half. The AMA RUC recommended maintaining the current work RVU of 16.22 for CPT code 60240.

Comment: Commenters disagreed with the CMS-proposed work RVU of 15.04 of CPT code 60240 and believe that the AMA RUC-recommended work RVU of 16.22 is more appropriate. Additionally, commenters noted that the CMS value was derived from the reverse building block methodology, which removed the post-procedure inpatient visit and reduced the discharge day management service to one-half. Commenters also stated that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, and requested that CMS accept the AMA RUC-recommended work RVU of 16.22 for CPT code 60420. Commenters also stated that the AMA RUC-recommended physician time should be restored.

Response: Based on the public comments received, we referred CPT 60240 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 16.22, which was consistent with the AMA RUC recommendation to maintain the current (CY 2011) work RVU for CPT code 60240. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this service, which is typically furnished on an outpatient basis, to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies finalized in the CY 2011 PFS final rule with comment period (75 FR 73220). Therefore, we are finalizing a work RVU for CPT code 60240 of 15.04. In addition, after reviewing the descriptions of the AMA RUC-recommended time packages, we disagree with the post-service time recommended by the AMA RUC. Therefore, we are finalizing a pre-service time of 40 minutes, a pre-service positioning time of 12 minutes, a pre-service (dress, scrub, wait) time of 20 minutes, an intra-service time of 150 minutes, and a post-service time of 40 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 60240. CMS time refinements can be found in Table 16.

(23) Endocrine System: Parathyroid, Thymus, Adrenal Glands, Pancreas, and Cartoid Body (CPT Code 60500)

As detailed in the Fourth Five-Year Review of Work (76 FR 32454), for CPT code 60500 (Parathyroidectomy or exploration of parathyroid(s)), we proposed a work RVU of 15.60 for CY 2012. Medicare PFS claims data indicated that CPT code 60500 is typically furnished as an outpatient rather than inpatient service. Using magnitude estimation, the AMA RUC believed the current work RVU of 16.78 for CPT code 60500 was appropriate. Therefore, in accordance with our methodology to address 23-hour stay and site-of-service anomalies described in section III.A. of this final rule with comment period, for CPT code 60500, we removed the hospital visit, reduced the discharge day management service by one-half, and adjusted times. The AMA RUC recommended maintaining the current work RVU of 16.78 for CPT code 60500.

Comment: Commenters disagreed with the CMS-proposed work RVU of 15.60 for CPT code 60500 and believe that the AMA RUC-recommended work RVU of 16.78 is more appropriate. Additionally, commenters noted that the CMS value was derived from the reverse building block methodology, which removed the hospital visit and reduced the discharge day management service to one-half. Commenters also stated that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, and requested that CMS accept the AMA RUC recommended work RVU of 16.78 for CPT code 60500. Commenters also stated that the AMA RUC recommended physician time should be restored.

Response: Based on the public comments received, we referred CPT 60500 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 16.78, which was consistent with the AMA RUC recommendation to maintain

the current (CY 2011) work RVU for CPT code 60500. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not reflect a decrease in physician work. We do not believe it is appropriate for this service, which is typically furnished on an outpatient basis, to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. Therefore, we are finalizing a work RVU for CPT code 60500 of 15.60. In addition, after reviewing the descriptions of the AMA RUC-recommended time packages, we disagree with the post-service time recommended by the AMA RUC. Therefore, we are finalizing a pre-service time of 40 minutes, a pre-service positioning time of 12 minutes, a pre-service (dress, scrub, wait) time of 20 minutes, an intra-service time of 120 minutes, and a post-service time of 40 minutes. We are also reducing the hospital discharge day by 0.5 for CPT code 60500. CMS time refinements can be found in Table 16.

(24) Nervous System: Skull, Meninges, Brain and Extracranial Peripheral Nerves, and Autonomic Nervous System (CPT Codes 61781–61885, 64405–64831)

We discussed CPT code 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array) in the CY 2011 final rule with comment period (75 FR 73332) where we noted that this code was identified as a site-of-service anomaly code in September 2007. After reviewing the vagal nerve stimulator family of services, the specialty societies agreed that the family lacked clarity and the CPT Editorial Panel created three new codes to accurately describe revision of a vagal nerve stimulator lead, the placement of the pulse generator and replacement or revision of the vagus nerve electrode. For CY 2011, the AMA RUC recommended a work RVU of 6.44 for CPT code 61885. Although the AMA RUC compared this service to the key reference service, CPT code 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling) (work RVUs = 6.05) and other relative services and noted the similarities in times, the AMA RUC elected not to recommend this value of 6.05 for CPT code 61885. We believed the AMA RUC-recommended work RVUs did not adequately account for the elimination of two inpatient visits and the reduction in outpatient visits for this service. We disagreed with the AMA RUC recommended value and believed 6.05 work RVUs, the survey 25th percentile, was appropriate for this service. Therefore, we assigned an alternative value of 6.05 work RVUs to CPT code 61885 on an interim final basis for CY 2011.

Comment: Commenters stated that assumptions by CMS that the RUC recommendations did not adequately account for the elimination of two inpatient visits and the reduction in outpatient visits for this service is flawed. Furthermore, the commenters asserted that the rationale in the RUC database indicates that the initial RUC recommended value for this code included a reduction in value due to an adjustment of the post-operative E/M visits. Commenters recommended we accept the AMA RUC-recommended work RVU of 6.44 for CPT code 61885.

Response: Based on the comments received, we referred CPT code 61885 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 6.44, which was consistent with the AMA RUC-recommendation to maintain the current work RVU for this service. We believe that the AMA RUC-recommended work RVUs did not adequately account for the elimination of two inpatient visits and the reduction in outpatient visits for this service. We believe that 6.05 work RVUs, the survey 25th percentile, is appropriate for this service. Therefore, we are finalizing a work RVU of 6.05 for CPT code 61885 in CY 2012.

In the Fourth Five-Year Review (76 FR 32455), CMS identified CPT code 64405 as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen. As detailed in the Fourth Five-Year Review of Work, for CPT code 64405 ((Injection, anesthetic agent; greater occipital nerve), we proposed a work RVU of 0.94 for CY 2012. The AMA RUC reviewed the survey results and recommended the median survey work RVU of 1.00 for CPT code 64405. We disagreed with the AMA RUC-recommended work RVU for CPT code 64405. Upon clinical review and a consideration of physician time and intensity, we believed this code is comparable to the key reference CPT code 20526 (Injection, therapeutic (*e.g.,* local anesthetic, corticosteroid), carpal tunnel) (work RVU = 0.94).

Comment: Commenters disagreed with the CMS-proposed work RVU of 0.94 of CPT code 64405 and believe that the AMA RUC-recommended work RVU of 1.00 is more appropriate. The commenters noted survey findings stating that 97 percent of the respondents agreed that the vignette described the typical patient for this service. Furthermore, the commenters stated that CMS does not provide any rationale explaining use of CPT code 20526 as a comparison over the AMA RUC vignette and survey results. Commenters believed that CMS should give more consideration to the survey results when valuing an occipital nerve block.

Response: Based on the public comments received, we referred CPT 64405 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU supported the AMA RUC-recommended work RVU of 1.00 for CPT code 64405. We believe that the comparison to CPT code 20526 is appropriate for this service and related work RVUs. Therefore, we are finalizing a work RVU of 0.94 for CPT code 64405.

For CPT code 64568 (Incision for implantation of cranial nerve (*e.g.,* vagus nerve) neurostimulator electrode array and pulse generator), the AMA RUC recommended 11.19 work RVUs; however, the methodology was unclear. As with CPT code 61885 discussed previously, to which this code is related, we conducted a clinical review and compared the physician intensity and time associated with providing this service and determined that the survey 25th percentile, 9.00 work RVUs, was appropriate. Therefore, we assigned an alternative value of 9.00 work RVUs to CPT code 64568 on an interim final basis for CY 2011 (75 FR 73332).

In the CY 2011 PFS final rule with comment period (75 FR 73332), for CPT codes 64569 (Revision or replacement of cranial nerve (*e.g.,* vagus nerve) neurostimulator electrode array, including connection to existing pulse generator) and 64570 (Removal of cranial nerve (*e.g.,* vagus nerve) neurostimulator electrode array and pulse generator), we assigned interim final work RVUs of 11.00 and 9.10, respectively, for CY 2011. In section II.B.3. of this final rule with comment period, we described maintaining relativity for the codes in families as a

priority in the review of misvalued codes. Based on the reduction in work RVUs for CPT codes 61885 and 64568 that we adopted on an interim final basis for CY 2011, we believed work RVUs of 11.00, the survey 25th percentile, were appropriate for CPT code 64569 and work RVUs of 9.10, the survey 25th percentile, were appropriate for CPT code 64570. Therefore, we assigned alternative work RVUs of 11.00 to CPT code 64569 and 9.10 to CPT code 64570 on an interim final basis for CY 2011.

Comment: Commenters noted that CMS makes its interim recommendations based on the selection of a reference code which has similar time and intensity. Additionally, commenters asserted that CMS does not offer any reference codes to support the proposed interim values for any of these services. Moreover, the commenters disagreed with CMS's interim final values for 64568, 64569, and 64570, which were based on CMS' rationale to support the valuation of 61885, a site-of-service anomaly code. The commenters requested that CMS accept the AMA RUC-recommended values of 11.19 for CPT code 64568.

Response: Based on the comments received, we referred CPT code 64568, 64569, and 64570 to the CY 2011 multi-specialty refinement panel for further review. Although the refinement panel median work RVUs were 11.47 for CPT code 64568, 15.00 for CPT code 64569, and 13.00 for 64570, we believe it is imperative to maintain appropriate relativity within the code family as well as across code families in order to ensure accuracy in the entire PFS system. Accordingly, to maintain appropriate relativity with CPT code 61885, we are finalizing the following work RVUs for CY 2012: 9.00 for CPT code 64568, 11.00 for CPT code 64569 and 9.10 for CPT code 64570.

For CY 2012, we received no public comments on the CY 2011 interim final work RVUs for CPT codes 61781, 61782, 61783, 64415, 64445, 64447, 64479, 64480, 64484, 64566, 64581, 64611, 64708, 64712, 64713, and 64714. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

Finally, we received no public comments on the CY 2012 proposed work RVUs for CPT codes 64831 and 64708. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(25) Nervous System: Spine and Spinal Cord (CPT Codes 62263–63685)

As we discussed in the CY 2012 PFS proposed rule (76 FR 42800), CPT code 62263 (Percutaneous lysis of epidural adhesions using solution injection (*e.g.,* hypertonic saline, enzyme) or mechanical means (*e.g.,* catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days), was identified for CY 2009 as potentially misvalued through the site-of-service anomaly screen. We referred this code back to the AMA RUC for review because of our ongoing concern that the AMA RUC did not believe the AMA RUC appropriately accounted for the change in site-of-service when providing the recommendation for work RVUs. That is, for CY 2009, the AMA reviewed survey data, compared this code to other services, and concluded that while it was appropriate to remove the inpatient subsequent hospital care visits to reflect the current outpatient place of service, the AMA RUC recommended maintaining the CY 2008 work RVU for this service. We disagreed with the AMA RUC's methodology because we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. Accordingly, while we accepted the AMA RUC-recommended work RVU for this code on an interim basis for CYs 2009 and 2010 (with a slight adjustment in CY 2010 due to the consultation code policy (74 FR 61775)), we referred the code back to the AMA RUC to be reexamined.

Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and recommended that the current work RVU of 6.54 for CPT code 62263 be maintained. In the CY 2012 PFS proposed rule (76 FR 42800), we indicated that we continue to disagreed with the AMA RUC recommended work RVU for this service because we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. We noted also that the AMA RUC disregarded survey results that indicated the respondents believed this service should be valued lower. In fact, the median survey work RVU was 5.00. After CMS clinical review of this service where we considered this code in comparison to other codes in the PFS and accounted for the change in the site-of-service, we believed that the survey median work RVU of 5.00 appropriately accounted for the removal of the inpatient visits. Therefore, we proposed a work RVU of 5.00 for CPT code 62263 for CY 2012.

Comment: Commenters disagreed with CMS' proposed work RVU, stating that they remained concerned that CMS still assumes that the starting values for these services were correct. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 62263 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 6.02. We do not believe that either the AMA RUC recommended work RVU or the refinement panel result adequately accounts for the removal of all the inpatient visits for this service which was originally identified as having a site-of-service anomaly. As we specified previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails both removing the inpatient visits and modifying the work RVU to adequately account for the removal of all the inpatient visits originally included. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology to address codes with site-of-service anomalies as discussed in detail in section III.A. of this final rule with comment period. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU for CY 2012 of 5.00 for CPT code 62263 with refinements to time. CMS time refinements can be found in Table 16.

As we discussed in the CY 2012 PFS proposed rule (76 FR 42800), CPT code 62355 (Removal of previously implanted intrathecal or epidural catheter) was identified as potentially misvalued through the site-of-service anomaly screen for CY 2009. The AMA RUC reviewed this service and recommended a work RVU of 4.30, approximately midway between the survey median and 75th percentile. The AMA RUC also recommended removing the inpatient building blocks to reflect the outpatient site-of-service, removing all but 1 of the post-procedure office visits to reflect the shift in global period from 90 days to 10 days, and reducing the physician time associated with this service. While we accepted the AMA RUC-recommended work RVU for this

code on an interim basis for CYs 2009 and 2010 (with a slight adjustment in CY 2010 due to the consultation code policy (74 FR 61775)), we referred the code back to the AMA RUC to be reexamined because we did not believe the AMA RUC-recommended work RVU fully accounted for the reduction in inpatient building blocks to reflect the shift to the outpatient setting.

Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and ultimately recommended that the current work RVU of 4.35 for CPT code 62355 be maintained. We disagreed with the AMA RUC-recommended work RVU for CPT code 62355. As stated previously, we believed the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. We did not believe that the reduction from the CY 2008 work RVU of 6.60 to the CY 2009 work RVU of 4.30 adequately accounted for the removal of 3 subsequent hospital care visits and half a discharge management day, which together represent a work RVU of 5.40. Also, the time required to furnish this service dropped significantly, even after considering the global period change. Upon clinical review, we believed that the survey median work RVU of 3.55 appropriately accounted for the removal of the inpatient visits and decreased time for this service. Therefore, proposed a work RVU of 3.55 for CPT code 62355 for CY 2012.

Comment: Commenters disagreed with CMS' proposed work RVU, stating that they remained concerned that CMS still assumes that the starting values for these services were correct. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 62355 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 4.18. The AMA RUC recommended maintain the current (CY 2011) work RVU of 4.35 for CPT code 62355. While the AMA RUC reduced the RVUs for CY 2009, we do not believe the AMA RUC-recommended value adequately accounted for the shift from inpatient to outpatient and the reduction in office/outpatient visits. That is, we do not believe that either the AMA RUC recommended work RVU or the refinement panel result adequately accounts for the removal of all the inpatient visits for this service which was originally identified as having a site-of-service anomaly. As we specified previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails both removing the inpatient visits and modifying the work RVU to adequately account for the removal of all the inpatient visits originally included. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology to address codes with site-of-service anomalies as discussed in detail in section III.A. of this final rule with comment period. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU for CY 2012 of 3.55 for CPT code 62355.

As we discussed in the CY 2012 PFS proposed rule (76 FR 42800), CPT code 62361 (Implantation or replacement of device for intrathecal or epidural drug infusion; nonprogrammable pump) was identified for CY 2009 as potentially misvalued through the site-of-service anomaly screen. The AMA RUC reviewed this code and recommended a work RVU of 5.60, approximately midway between the survey median and 75th percentile. The AMA RUC also recommended removing the inpatient visits to reflect the outpatient site-of-service, removing all but 1 of the post procedure office visits to reflect the shift in global period from 90 days to 10 days, and reducing the physician time associated with this service. While we accepted the AMA RUC's recommended work RVU for this code on an interim basis for CYs 2009 and 2010 (with a slight adjustment to 5.65 work RVUs in CY 2010 due to the consultation code policy (74 FR 61775)), we referred the code back to the AMA RUC to be reexamined because we did not believe the AMA RUC recommended work RVU fully accounted for the reduction in inpatient building blocks to reflect the shift to the outpatient setting.

Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and ultimately recommended that the work RVU of 5.65 for CPT code 62361 be maintained. We disagreed with the AMA RUC-recommended work RVU for CPT code 62361. As stated previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. We did not believe that the reduction from the CY 2008 work RVU of 6.59 to the CY 2009 work RVU of 5.60 adequately accounted for the removal of 3 subsequent hospital care visits and half a discharge management day, which together represent a work RVU of 5.40. Also, the time required to furnish this service dropped significantly, even after considering the global period change. Upon clinical review, we believed that the survey 25th percentile work RVU of 5.00 appropriately accounted for the removal of the inpatient visits and decreased time for this service. Therefore, we proposed a work RVU of 5.00 for CPT code 62361 for CY 2012.

Comment: Commenters disagreed with CMS' proposed work RVU, stating that they remained concerned that CMS still assumes that the starting values for these services were correct. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 62361 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 5.48. The AMA RUC recommended maintaining the current work RVU of 5.65 for CPT code 62361. We do not believe that either the AMA RUC recommended work RVU or the refinement panel result adequately accounts for the removal of all the inpatient visits for this service which was originally identified as having a site-of-service anomaly. As we specified previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails both removing the inpatient visits and modifying the work RVU to adequately account for the removal of all the inpatient visits originally included. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology to address codes with site-of-service anomalies as discussed in detail in section III.A. of this final rule with comment period. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU for CY 2012 of 5.00 for CPT code 62361.

As we discussed in the CY 2012 PFS proposed rule (76 FR 42800), CPT code 62362 (Implantation or replacement of device for intrathecal or epidural drug

infusion; programmable pump, including preparation of pump, with or without programming) was identified for CY 2009 as potentially misvalued through the site-of-service anomaly screen. The AMA RUC reviewed the code and recommended a work RVU of 6.05, approximately midway between the survey median and 75th percentile. The AMA RUC also recommended removing the inpatient visits to reflect the outpatient site-of-service, removing all but 1 of the post procedure office visits to reflect the shift in global period from 90 days to 10 days, and reducing the physician time associated with this service. While we accepted the AMA RUC's recommended work RVU for this code on an interim basis for CYs 2009 and 2010 (with a slight adjustment to 6.10 work RVUs in CY 2010 due to the consultation code policy (74 FR 61775)), we referred the code back to the AMA RUC to be reexamined because we did not believe the AMA RUC-recommended work RVU fully accounted for the reduction in inpatient building blocks to reflect the shift to the outpatient setting. Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and ultimately recommended that the current work RVU of 6.10 for CPT code 62362 be maintained. We disagree with the AMA RUC-recommended work RVU for CPT code 62362. As stated previously, we believed the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. We do not believe that the reduction from the CY 2008 work RVU of 8.58 to the CY 2009 work RVU of 6.05 adequately accounts for the removal of 3 subsequent hospital care visits and half a discharge management day, which together represent a work RVU of 5.40. Also, the time required to furnish this service dropped significantly, even after considering the global period change. Upon clinical review, we believed that the survey median work RVU of 5.60 appropriately accounted for the removal of the inpatient visits and decreased time for this service. Therefore, we proposed a work RVU of 5.60 for CPT code 62362 for CY 2012.

Comment: Commenters disagreed with CMS' proposed work RVU, stating that they remained concerned that CMS still assumes that the starting values for these services were correct. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 62362 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 5.95. The AMA RUC recommended maintaining the current work RVU of 6.10 for CPT code 62362. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not adequately reflect a decrease in physician work. We do not believe that either the AMA RUC recommended work RVU or the refinement panel result adequately accounts for the removal of all the inpatient visits for this service which was originally identified as having a site-of-service anomaly. As we specified previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails both removing the inpatient visits and modifying the work RVU to adequately account for the removal of all the inpatient visits originally included. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology to address codes with site-of-service anomalies as discussed in detail in section III.A. of this final rule with comment period. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU for CY 2012 of 5.60 for CPT code 62362.

As we discussed in the CY 2012 PFS proposed rule (76 FR 42801), CPT code 62365 (Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion) was identified for CY 2009 as potentially misvalued through the site-of-service anomaly screen. The AMA RUC reviewed this service and recommended a work RVU of 4.60, the survey median. Additionally, the AMA RUC recommended removing the inpatient visits to reflect the outpatient site-of-service, removing all but 1 of the post-procedure office visits to reflect the shift in global period from 90 days to 10 days, and reducing the physician time associated with this service. While we accepted the AMA RUC's recommended work RVU for this code on an interim basis for CYs 2009 and 2010 (with a slight adjustment to 4.65 work RVUs in CY 2010 due to the consultation code policy (74 FR 61775)), we referred the code back to the AMA RUC to be reexamined because we did not believe the AMA RUC-recommended work RVU fully accounted for the reduction in inpatient building blocks to reflect the shift to the outpatient setting.

Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and ultimately recommended that the current work RVU of 4.65 for CPT code 62365 be maintained. We disagreed with the AMA RUC recommended work RVU for CPT code 62365. As stated previously, we believed the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. We did not believe that the reduction from the CY 2008 work RVU of 6.57 to the CY 2009 work RVU of 4.60 adequately accounted for the removal of 3 subsequent hospital care visits and half a discharge management day, which together represent a work RVU of 5.40. Also, the time required to furnish this service dropped significantly, even after considering the global period change. We believed that this service is similar in terms of time intensity to that of CPT code 33241 (Subcutaneous removal of single or dual chamber pacing cardioverter-defibrillator pulse generator) which has a work RVU of 3.29 but does not include a half day of discharge management service. Upon clinical review, we believed that a work RVU of 3.93, that is a work RVU of 3.29 plus a work RVU of 0.64 to account for the half day of discharge management service, appropriately accounted for the removal of the inpatient visits and decreased time for this service. Therefore, we proposed a work RVU of 3.93 for CPT code 62365 for CY 2012.

Comment: Commenters disagreed with CMS' proposed work RVU, stating that they remained concerned that CMS still assumes that the starting values for these services were correct. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 62365 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 4.40. The AMA RUC recommended maintaining the current work RVU of 4.65 for CPT code 62365. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not adequately reflect a decrease in physician work. We do not believe that either the AMA RUC recommended work RVU or the refinement panel result adequately accounts for the removal of all the inpatient visits for this service which was originally identified as having a site-of-service anomaly. As we specified previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails both removing the inpatient visits and modifying the work RVU to adequately account for the removal of all the inpatient visits originally included. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology to address codes with site-of-service anomalies as discussed in detail in section III.A. of this final rule with comment period. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU for CY 2012 of 3.93 for CPT code 62365.

As we discussed in the CY 2012 PFS proposed rule (76 FR 42802), CPT code 63650 (Percutaneous implantation of neurostimulator electrode array, epidural) or mechanical means (such as, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days, was identified for CY 2009 as potentially misvalued through the site-of-service anomaly screen. The AMA RUC reviewed this service and recommended the survey median work RVU of 7.15 as well as removing the inpatient subsequent hospital care visits to reflect the current outpatient place of service. While we accepted the AMA RUC's recommended work RVU for this code on an interim basis for CYs 2009 and 2010 (with a slight adjustment to 7.20 work RVUs in CY 2010 due to the consultation code policy (74 FR 61775)), we referred the code back to the AMA RUC to be reexamined because we did not believe the AMA RUC-recommended work RVU fully accounted for the reduction in inpatient building blocks to reflect the shift to the outpatient setting.

Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and ultimately recommended that the current work RVU of 7.20 for CPT code 63650 be maintained. We disagreed with the AMA RUC-recommended work RVU of 7.20 for CPT code 63650. As stated previously, we believed the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. Upon clinical review, we believed that the survey median work RVU of 7.15 appropriately accounted for the removal of the inpatient visits, as well as the physician time and post-operative office visit changes. Therefore, we proposed a work RVU of 7.15 for CPT code 63650 for CY 2012.

Comment: Commenters disagreed with CMS' proposed work RVU, stating that they remained concerned that CMS still assumes that the starting values for these services were correct. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 63650 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 7.18. The AMA RUC recommended maintaining the current work RVU of 7.20 for CPT code 63650. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not adequately reflect a decrease in physician work. That is, we do not believe that either the AMA RUC recommended work RVU or the refinement panel result adequately accounts for the removal of all the inpatient visits for this service which was originally identified as having a site-of-service anomaly. As we specified previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails both removing the inpatient visits and modifying the work RVU to adequately account for the removal of all the inpatient visits originally included. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology to address codes with site-of-service anomalies as discussed in detail in section III.A. of this final rule with comment period. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU for CY 2012 of 7.15 for CPT code 63650.

As discussed in the Fourth Five-Year Review of Work (76 FR 32454), CMS identified CPT code 63655 (Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural) as potentially misvalued through the Site-of-Service Anomaly screen. The AMA RUC recommended maintaining the current work RVU of 11.56, as well as the current physician time components. We disagreed with the AMA RUC-recommended work RVU for CPT code 63655. We noted that according to the survey data provided by the AMA RUC, of the 90 percent of respondents that stated they furnish the procedure ''in the hospital,'' 18 percent stated that the patient is ''discharged the same day'' and 55 percent stated that the patient was ''kept overnight (less than 24 hours).'' Given that the most recently available Medicare PFS claims data continue to show the typical case is not an inpatient, and that the survey data for this code suggested the typical case is a 23-hour stay service, we believed it was appropriate to apply our established policy and reduce the discharge day management service to one-half. Accordingly, we proposed an alternative work RVU of 10.92 with refinements in time for CPT code 63655 for CY 2012.

Comment: Commenters disagreed with the CMS proposed work RVU of 10.92 for CPT code 63655 and believed that the AMA RUC recommended work RVU of 11.56 was more appropriate. Commenters believed that there was no evidence that the work of this procedure, which includes a full laminectomy, has changed since April 2009. In addition, commenters noted that complete 2008 Medicare utilization data shows that 63655 was billed 51.2 percent in the inpatient hospital setting,

questioning whether it was appropriate for this service to be on the ''site of service'' change list at all since it was so close to 50 percent, the threshold which defines ''typical.''

Response: Based on the public comments received, we referred CPT 63655 to the CY 2011 Multi-Specialty Refinement Panel for further review. The refinement panel median work RVU was 11.56, which was consistent with the the AMA RUC recommendation to maintain the current work RVU for CPT code 63655. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not adequately reflect a decrease in physician work. We do not believe it is appropriate for this service, which is typically furnished on an outpatient basis, to continue to reflect work that is typically associated with an inpatient service. We note that 50 percent defines ''typical'' for purposes of valuing services under the PFS. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology described previously to address 23-hour stay site-of-service anomalies. Therefore, we are finalizing a work RVU for CPT code 63655 of 10.92 for CY 2012. We are also finalizing the proposed refinements to time. CMS time refinements can be found in Table 16.

As we discussed in the CY 2012 PFS proposed rule (76 FR 42802), CPT code 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling) was identified for CY 2009 as potentially misvalued through the site-of-service anomaly screen. The AMA RUC reviewed this service and recommended the survey median work RVU of 6.00. The AMA RUC also recommended removing the inpatient subsequent hospital care visits to reflect the current outpatient place of service. While we accepted the AMA RUC's recommended work RVU for this code on an interim basis for CYs 2009 and 2010 (with a slight adjustment to the work RVUs in CY 2010 due to the consultation code policy (74 FR 61775)), we referred the code back to the AMA RUC to be reexamined because we did not believe the AMA RUC-recommended work RVU fully accounted for the reduction in inpatient building blocks to reflect the shift to the outpatient setting.

Upon re-review for CY 2012, the AMA RUC affirmed its previous recommendation and ultimately recommended that the current work RVU for CPT code 63685 be maintained. We disagreed with the AMA RUC-recommended work RVU of 6.05 for CPT code 63685. As stated previously, we believed the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. Upon clinical review, we believed that the survey 25th percentile work RVU of 5.19 appropriately accounted for the removal of the inpatient visits, as well as the physician time and post-operative office visit changes. Therefore, we proposed a work RVU of 5.19 for CPT code 63685 for CY 2012.

Comment: Commenters disagreed with CMS' proposed work RVU, stating that they remained concerned that CMS still assumes that the starting values for these services were correct. Commenters noted that the AMA RUC originally valued this service using magnitude estimation based on comparison reference codes, which considers the total work of the service rather than the work of the component parts of the service, and requested CMS accept the AMA RUC-recommended work RVU and physician time.

Response: Based on comments received, we referred CPT code 63685 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 5.78. The AMA RUC recommended maintaining the current work RVU of 6.05 for CPT code 63685. The current (CY 2011) work RVU for this service was developed when this service was typically furnished in the inpatient setting. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, the AMA RUC-recommendation and refinement panel results do not adequately reflect a decrease in physician work. That is, we do not believe that either the AMA RUC recommended work RVU or the refinement panel result adequately accounts for the removal of all the inpatient visits for this service which was originally identified as having a site-of-service anomaly. As we specified previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails both removing the inpatient visits and modifying the work RVU to adequately account for the removal of all the inpatient visits originally included. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology to address codes with site-of-service anomalies as discussed in detail in section III.A. of this final rule with comment period. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU for CY 2012 of 5.19 for CPT code 63685.

We received no public comments on the CY 2011 final rule with comment period interim work RVUs for CPT codes 63075 and 63076. We received no public comments on the Fourth Five-Year Review of Work proposed work RVUs for CPT code 62284. Finally, we also received no public comments on the CY 2012 PFS proposed rule proposed work RVUs for CPT codes 62360 and 62350. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(26) Eye and Ocular Adnexa: Eyeball (CPT Codes 65285)

As detailed in the CY 2012 PFS proposed rule (76 FR 42802), we identified CPT code 65285 (Repair of laceration; cornea and/orsclera, perforating, with reposition or resection of uveal tissue) as a potentially misvalued code through the site-of-service anomaly screen in 2009. The AMA RUC recommended removing the CPT code from the site-of-service anomaly list and maintaining the CY 2008 work RVUs (14.43), physician times, and visits. In the CY 2010 PFS final rule with comment period, while we adopted the AMA RUC-recommended work value on an interim final basis and referred the service back to the AMA RUC to be reexamined, the work RVU for CPT code 65285 used under the PFS was increased to 14.71 based on the redistribution of RVUs that resulted from the our policy to no longer recognize the CPT consultation codes (74 FR 61775).

In the CY 2012 PFS proposed rule (76 FR 42802), we proposed to apply the 23-hour stay methodology described in section III.A. of this final rule with comment period. That is, we reduced the one day of discharge management service to one-half day, and adjusted physician work RVUs and times accordingly. As a result, we proposed a work RVU of 15.36 with refinements to

the time for CPT code 65285 for CY 2012. CMS time refinements can be found in Table 16. The AMA RUC recommended a work RVU of 16.00 for CPT code 65285 for CY 2012.

Comment: Commenters disagreed with the CMS proposed work RVU of 15.36, and requested that CMS accept the AMA RUC-recommended work RVU of 16.00 for CPT code 65285. Commenters stated that the AMA RUC-recommended RVU was more appropriate because the intensity of and complexity of the procedure has increased due to enhanced microsurgical technology, improvements in suture and graft materials and new pharmaceuticals that control post operative complications. Commenters also disagreed with applying the site-of-service methodology of reducing the discharge management service to one-half day when the AMA RUC's valuation was not based on a building block methodology.

Response: Based on the comments we received, we referred CPT code 65285 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 16.00, which was consistent with the AMA RUC recommendation. The AMA RUC-recommended work value for this service included a full discharge day management service, which we do not believe is appropriate for an outpatient service. As this service is now typically furnished in the outpatient setting, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. However, we do not believe the AMA RUC-recommendation and refinement panel results adequately reflect a decrease in physician work. We do not believe it is appropriate for this service to continue to reflect work that is typically associated with an inpatient service. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology to address site-of-service anomalies as discussed in section III.A. of this final rule with comment period. After consideration of the public comments, refinement panel results, and our clinical review, we are finalizing a work RVU of 15.36, with time refinements, for CPT code 65285.

For CY 2012, we receive no public comments on the CY 2011 interim final work RVUs for CPT codes 65778 through 65780, 66174, 66175, and 66761. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(27) Eye and Ocular Adnexa: Posterior Segment (CPT Code 67028)

CPT code 67028 (Intravitreal injection of a pharmacologic agent (separate procedure) was identified for review by the Five-Year Identification Workgroup through the High Volume CMS Fastest Growing Screen. For CY 2011, the AMA RUC reviewed the survey results, compared the code to other services, and concluded that CPT code 67028 was similar in both physician time and intensity to another eye injection code, CPT code 67500 (retrobulbar injection: Medication). Accordingly, the AMA RUC recommended accepting the specialty society recommended time and directly crosswalking the work RVUs of CPT code 67500 of 1.44 to CPT code 67028. Upon clinical review, we agreed that these two services are similar and therefore assigned a CY 2011 interim final work RVU of 1.44 to CPT code 67028 (75 FR 73732).

Comment: Commenters strongly disputed the AMA RUC-recommended work RVU for CPT code 67028 that CMS accepted as the interim final value for CY 2011. Commenters asserted that a comparison of CPT code 67028 to CPT code 67500 shows that the AMA RUC significantly underestimated the physician work of CPT code 67028. Commenters believed that injecting medication directly into the vitreous of the eye is more intense, carries more risk, requires more training and is inherently more stressful than injecting medication around the external areas of the eye and that this difference should be recognized in a relative value system with a higher physician work value. The commenters requested this code be discussed at the CY 2011 refinement panel and recommended a value of 2.12 work RVUs be finalized for CPT code 67028, instead of the interim final value of 1.44.

Response: Based on comments received, we referred CPT code 67028 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 1.96. Upon clinical review, we believe that the physician work of CPT code 67028 is similar to that of CPT code 67500. We find it compelling that the specialty-recommended time for this code is similar to the reference code and that the AMA RUC has also concluded that the services are similar in both time and intensity. Accordingly, we are assigning final work RVU of 1.44 to CPT code 67028 for CPT code 67028.

(28) Diagnostic Radiology: Chest, Spine, and Pelvis (CPT Codes 71250, 72100, 72110, 72120, 72125, 72128, 72131, 72144, and 72170)

As we discussed in the CY 2011 final rule with comment period (75 FR 73340), CPT Code 71250 (Computed tomography, thorax; without contrast material) was identified as a potentially misvalued code by the Five-Year Review Identification Workgroup under the ''CMS Fastest Growing'' potentially misvalued codes screen. While the AMA RUC recommended the survey results for physician times, the AMA RUC believed maintaining the code's current value of 1.16 work RVUs was more appropriate, noting that this recommended value is slightly lower than the survey 25th percentile of 1.20. We disagreed with the AMA RUC's CY 2011 work RVU recommendation to maintain the current value for CPT code 71250 and similar codes. As we noted in the CY 2011 final rule with comment period (75 FR 73340), we were increasingly concerned over the validity of accepting work valuations based upon surveys conducted on existing codes as we have noticed a pattern of predictable survey results. Increasingly, rather than recommending the median survey value that has historically been most commonly used, the AMA RUC has been choosing to recommend the 25th percentile value, potentially responding to the same concern we have identified. Therefore, based on our concern that CT codes would continue to be misvalued if we were to accept the AMA RUC recommendation to maintain the current value, we assigned an alternative value of 1.00 work RVUs (the survey low value) to CPT code 71250 on an interim final basis for CY 2011.

Also in the CY 2011 final rule with comment period (75 FR 73341), we noted CPT codes 72125 (Computed tomography, cervical spine; without contrast material), 72128 (Computed tomography, thoracic spine; without contrast material), and 72131 (Computed tomography, lumbar spine; without contrast material) were also identified as potentially misvalued codes by the Five-Year Review Workgroup under the ''CMS Fastest Growing'' screen for potentially misvalued codes. For CPT code 72125, the AMA RUC concurred with the specialty-recommended times but concluded that it was appropriate to maintain the current work RVUs of 1.16. Similarly, for CPT codes 72128 and 72131, the AMA RUC accepted the survey physician times, but also disregarded the median survey work RVU results in favor of recommending

maintaining the current values. Upon clinical review of these codes in this family, we were concerned over the validity of the survey results since the survey 25th percentile values are very close to the current value of 1.16 RVUs for the code. As we stated previously, we were concerned that this pattern may indicate a bias in the survey results. Therefore, based on our concern that the CT codes would continue to be misvalued if we were to accept the AMA RUC recommendation to maintain the current values, we assigned alternative work RVUs of 1.00 (the survey low value) to CPT codes 72125, 72128, and 72131 on an interim final basis for CY 2011.

Comment: Commenters acknowledged that the existing RVUs are available within the public domain and are accessible on the CMS Web site, however, the commenters doubted this influenced the RVU choices among the respondents. The commenters noted that the survey respondents are provided with reference codes to which they may compare services in order to maintain relativity within the system. Furthermore, some commenters noted that ''other data used by the RUC to validate the RVUs chosen by most respondents, such as the existing service period times and those of the reference services, are not readily available to the respondents and the RUC methodology of evaluating survey results is even less accessible.'' Thus, commenters ''believe CMS' conclusion that bias was interjected into the survey process is unwarranted.'' The commenters requested CMS accept the AMA RUC recommended work RVU instead.

Response: Based on comments received, we referred CPT codes 71250, 72125, 72128, and 72131 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs were 1.02 for CPT code 71250, 1.07 for CPT code 72125, 1.00 for CPT code 72128, and 1.00 for CPT code 72131. As a result of the refinement panel ratings and clinical review by CMS, we are assigning CY 2012 final work RVU of 1.02 to CPT code 71250, 1.07 to CPT code 72125, 1.00 to CPT code 72128, and 1.00 to 72131.

(29) Diagnostic Radiology: Upper and Lower Extremities (CPT Codes 73030–73700)

As discussed in the CY 2011 final rule with comment period (75 FR 73341), CPT codes 73200 (Computed tomography, upper extremity; without contrast material) and 73700 (Computed tomography, lower extremity; without contrast material) were identified as potentially misvalued codes by the Five-Year Review Workgroup under the ''CMS Fastest Growing'' screen for potentially misvalued codes. Our clinical review of CPT codes 73200 and 73700, as with the other CT codes previously discussed, concluded that maintaining the current values would result in an overvaluing of this type of service. Similar to the other CT codes previously discussed, the AMA RUC reviewed the survey results and accepted the survey physician times but recommended maintaining the current work RVUs of 1.09 for both of these services. We remain concerned over the validity of the survey results. Therefore, based on our concern that CT codes would continue to be misvalued if we were to accept the AMA RUC recommendation to maintain the current values, we assigned alternative work RVUs of 1.00 (the survey low RVU value) to CPT codes 73200 and 73700 on an interim final basis for CY 2011.

Comment: Commenters believed the surveys were valid and noted the high response rate relative to other specialty societies' surveys conducted on codes with known current values. The commenters asserted the AMA RUC's review was rigorous and urged CMS to accept the AMA RUC recommended work RVUs for CT codes.

Response: Based on comments received, we referred CPT codes 73200 and 73700 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 1.00 for CPT code 73200 and 1.00 for CPT code 73700. As a result of the refinement panel ratings and clinical review by CMS, we are assigning CY 2012 final work RVU of 1.00 to CPT code 73200 and 1.00 to CPT code 73700.

Furthermore, for CY 2012, we received no public comments on the CY 2011 interim final work RVUs for CPT codes 73080, 73510, 73610, and 73630. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(30) Diagnostic Ultrasound: Extremities (CPT Codes 76881–76882)

As discussed in the CY 2011 final rule with comment period (75 FR 73332), in October 2008, CPT code 76880 (Ultrasound, extremity, nonvascular, real time with image documentation) was identified by the Five-Year Review Identification Workgroup through its ''CMS Fastest Growing'' screen for potentially misvalued codes. In February 2009, the CPT Editorial Panel deleted CPT code 76880 and created two new codes, CPT codes 76881 (Ultrasound, extremity, nonvascular, real-time with image documentation; complete) and 76882 (Ultrasound, extremity, nonvascular, real-time with image documentation; limited anatomic specific) to distinguish between the comprehensive diagnostic ultrasound and the focused anatomic-specific ultrasound. For CPT code 76881, the AMA RUC recommended work RVUs of 0.72. For CPT code 76882, the AMA RUC recommended 0.50 work RVUs. We noted the predecessor CPT code 76880 (Ultrasound, extremity, nonvascular, real time with image documentation) described a nonvascular ultrasound of the entire extremity and was assigned work RVUs of 0.59. In contrast, the new CPT codes describe a complete service, CPT code 76881, and a limited service, CPT code 76882 (defined as examination of a specific anatomic structure, such as a tendon or muscle). As such, for CPT code 76881, we did not believe an increase in work RVUs was justified given that this service will be reported for the evaluation of the extremity, as was CPT code 76800 which is being deleted for CY 2011. Therefore, we assigned a CY 2011 interim work RVU of 0.59 for this service, which is consistent with the value of the predecessor code. For CPT code 76882, we assigned a CY 2011 interim work RVU of 0.41 to maintain appropriate relativity with CPT code 76800.

Comment: The commenters clarified that based on Medicare claims data, podiatry was the dominant provider of the predecessor code 76880 and their specialty acknowledged that they more commonly furnish a limited ultrasound examination, which will now be reported as CPT code 76882. CPT code 76881 will now be used for the more complete examination. The commenters maintained that the AMA RUC-recommended values for these two codes were more appropriate than CMS' CY 2011 interim final values.

Response: Based on comments received, we referred CPT codes 76881 and 76882 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 0.63 for CPT code 76881 and 0.49 for CPT code 76882. As a result of the refinement panel ratings and our clinical review, we are assigning CY 2012 final work RVU of 0.63 to CPT code 76881 and 0.49 to CPT code 76882.

Furthermore, for CY 2012, we received no public comments on the CY 2011 interim final work RVUs for CPT code 74962. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(31) Radiation Oncology: Radiation Treatment Management (CPT Codes 77427–77469)

CPT code 77427 (Radiation treatment management, 5 treatments) was identified as a potentially misvalued code by the Five-Year Identification Workgroup's ''Site-of-Service Anomalies'' screen for potentially misvalued codes in 2007.

As detailed in the CY 2011 PFS final rule with comment period (75 FR73341), we assigned a work RVU of 3.37 for CPT code 77427 on an interim final basis for CY 2011. We agreed with the AMA RUC's use of the building block approach to value the treatment visits associated with CPT code 77427. The AMA RUC averaged the number of weekly E/M visits, that is, 4 of CPT code 99214 (Level 4 established patient office or other outpatient visit) and 2 of CPT code 99213 (Level 3 established patient office or other outpatient visit) over 6 weeks to calculate an E/M building block of 1.32 RVUs. Similarly, to value the post-operative office visits associated with this code, the AMA RUC calculated a building block of 0.57 to account for the average over 6 weeks of ''E/M visits after treatment planning.'' The AMA RUC then crosswalked the physician times for CPT code 77427 to CPT code 77315 (Teletherapy, isodose plan (whether hand or computer calculated); complex (mantle or inverted Y, tangential ports, the use of wedges, compensators, complex blocking, rotational beam, or special beam considerations)) and used the value of CPT code 77315 as the remaining building block for CPT code 77427.

Upon clinical review, we modified one of the building blocks that the AMA RUC used to calculate the work RVUs associated with the treatment E/M office visits. We believed instead of the average based upon 4 units of CPT code 99214 and 2 units of CPT code 99213, a more appropriate estimation was an average of 3 units of CPT code 99214 and 3 units of CPT code 99213. Accordingly, we assigned a work RVU of 3.37 on an interim final basis for CY 2011 for CPT code 77427 (75 FR73341, corrected in 76 FR 1670). The AMA RUC recommended a work RVU of 3.45 for CPT code 77427 based on the use of 4 units of CPT code 99214 and 2 units of CPT code 99213 (75 FR 73341).

Comment: Commenters disagreed with the interim final work RVU of 3.37, and supported the AMA RUC-recommended work RVU of 3.45 for CPT code 77427. Commenters agreed with the AMA RUC building block of 4 units of 99214 and 2 units of 99213, and supported this conclusion with comparison to other services, CPT codes 95953 (work RVU = 3.30), 77263 (work RVU = 3.14), and 90962 (work RVU = 3.15). Commenters requested that CMS accept the AMA–RUC building block of 4 units of 99214 and 2 units of 99213 and a final work RVU of 3.45 for CPT code 77427.

Response: We appreciate commenters' support for the building block method utilized for CPT code 77427. While commenters agree with the AMA RUC-recommended E/M building blocks, we continue to believe 3 units of CPT code 99214 and 3 units of CPT code 99213 is a more appropriate building block for CPT code 77427. Therefore, we are finalizing a work RVU of 3.37 for CPT code 77427 in CY 2012.

(32) Nuclear Medicine: Diagnostic (CPT Codes 78264)

In the Fourth Five-Year Review (76 FR 32455), we identified CPT code 78264 as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen.

As detailed in the Fourth Five-Year Review, for CPT code 78264 (Gastric emptying study), we proposed a work RVU of 0.80 for CPT code 78264 for CY 2012. We believed the 25th percentile survey value was appropriate based on its similarity in physician work to other diagnostic tests. The AMA RUC reviewed the survey results and recommended the survey median work RVU of 0.95 for CPT code 78264 (76 FR 32455).

Comments: Commenters disagreed with the proposed work RVU of 0.80 for CPT code 78264. Commenters noted that the work and time required to furnish the gastric emptying study has substantially changed since its last valuation 20 years ago when it was Harvard valued. Commenters supported the AMA RUC-recommended work RVU of 0.95 for CPT code 78264, the AMA survey median, which they state is supported by comparison to the key reference service, CPT code 78707 (work RVU = 0.96, total time = 22 minutes). Commenters also compared this service to CPT code 78453 (work RVU=1.00, total time = 20 minutes), which they stated compared favorably to CPT code 78264 and had similar physician time. Commenters noted that a work RVU of 0.95 better maintains relativity among other services, and requested that CMS accept the AMA RUC-recommended work RVU of 0.95.

Response: Based on comments we received, we referred CPT code 78264 to the CY 2011 multi-specialty refinement panel for further review. Although commenters requested that we accept the AMA RUC-recommended work RVU of 0.95, the refinement panel ratings supported our proposed work RVU of 0.80. We also continue to believe that the 25th percentile survey value is more appropriate based on its similarity to other diagnostic test. Therefore, we are finalizing the proposed work RVU of 0.80 for CPT code 78264 in CY 2012. We also finalized the proposed refinements to time, which can be found on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

(33) Pathology and Laboratory: Urinalysis (CPT Codes 88120, 88121, 88172, 88173, and 88177)

For CY 2011, the AMA's CPT Editorial Panel created two new cytopathology codes that describe in situ hybridization testing using urine samples: CPT code 88120 (Cytopathology, in situ hybridization (*e.g.,* FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; manual) and CPT code 88121 (Cytopathology, in situ hybridization (*e.g.,* FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; using computer-assisted technology). In the CY 2011 PFS final rule with comment period (75 FR 73170), we assigned a work RVU of 1.20 for CPT code 88120 and a work RVU of 1.00 for CPT code 88121 on an interim basis for CY 2011. However, as detailed in the CY 2012 PFS proposed rule (76 FR 42796), we asked the AMA RUC to review the both the direct PE inputs and work values of the following codes in accordance with the consolidated approach to reviewing potentially misvlaued codes. Therefore, we are maintaining RVUs of 1.20 for CPT code 88120 and 1.00 for CPT code 88121 on an interim final basis for CY 2012, pending the AMA RUC review of these services. For more information on CPT codes 88120 and 88121, see section II.B.5.b.1 of this final rule with comment period.

In February 2010, the CPT Editorial Panel revised the descriptor for CPT code 88172 (Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy of specimen(s)) and created a new code, CPT code 88177 (Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, each separate additional evaluation episode, same site), to report the first evaluation episode and each additional episode of cytopathology evaluation of fine needle aspirate. As detailed in the CY 2011 PFS final rule with comment period (75 FR 73333), we maintained the CY 2010

work RVU of 0.60 on an interim final basis for CY 2011 because we did not believe that the work had changed. While CPT code 88172 was revised by the CPT Editorial Panel, the AMA RUC explanation did not adequately demonstrate increased work. The AMA RUC recommended work RVUs of 0.69 based on comparing this code to several other services, which we did not find to be an appropriate methodology for valuing CPT code 88172 (75 FR 73333).

Comment: Commenters disagreed with the interim final work RVU of 0.60 assigned to CPT code 88172. Commenters reiterated that CPT code 88177 was added to differentiate reporting between the first episode and each additional episode of cytopathology evaluation of fine needle aspirate. Commenters stated that the first episode was more intense than the subsequent episodes, and requested that CMS accept the AMA RUC-recommended work RVU of 0.69.

Response: Based on the comments we received, we referred CPT code 88172 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 0.69. As a result of the refinement panel and our clinical review, we are assigning a work RVU of 0.69 to CPT code 88172 as a final value.

For CY 2012, we received no public comments on the CY 2011 interim final work RVUs for CPT codes 88173 and 88177. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(34) Immunization Administration for Vaccines/Toxoids (CPT Codes 90460–90461)

As detailed in the CY 2011 PFS final rule with comment period (75 FR 73333), the CPT Editorial Panel revised the reporting of immunization administration in the pediatric population in order to better align the service with the evolving best practice model of delivering combination vaccines. In addition, effective January 1, 2011, reporting and payment for these services is to be structured on a per toxoid basis rather than a per vaccine (combination of toxoids) basis as it was in prior years. We maintained the CY 2010 work RVUs for the related predecessor codes since these codes would be billed on a per toxoid basis in CY 2011. We assigned a work RVU of 0.17 for CPT code 90460 (Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care profession; first vaccine/toxoid component) and a work RVU of 0.15 for CPT code 90461 (Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health profession; each additional vaccine/toxoid component (List separately in addition to code for primary procedure)) on an interim final basis for CY 2011. The AMA RUC recommended a work RVU of 0.20 for CPT code 90460 and 0.16 for CPT code 90461 (75 FR 73333).

Comment: Commenters disagreed with the CMS-proposed work RVUs of 0.17 for CPT code 90460 and 0.15 for CPT code 90461, and stated that the AMA RUC-recommended work RVUs of 0.20 for CPT code 90460 and 0.16 for CPT code 90461 are more appropriate. Commenters noted that the immunization administration codes were revised to allow physicians to accurately report the work involved in counseling for vaccines with more than one component. Commenters stressed that it is inappropriate to crosswalk CPT codes 90460 and 90461 to their respective predecessor codes, 90471 and 90472, given the differences in work involved in patient counseling with CPT codes 90460 and 90461.

Response: Based on comments we received, we referred CPT codes 90460 and 90461 to the multi-specialty refinement panel for further review. The refinement panel median work RVUs were 0.23 for CPT code 90460 and 0.17 for CPT code 90461, which were higher than the AMA RUC-recommended values. However, we believe it is appropriate to value these services at the same rate as their predecessor codes. We do not agree with commenters that the addition of counseling in the code descriptor supports increasing the work RVUs because CPT codes 90460 and 90461 were restructured to be reported on a per toxoid basis, rather than a per vaccine (combination of toxoids) basis as it was in prior years. After consideration of public comments, refinement panel results, and our clinical review, we are finalizing work RVUs of 0.17 for CPT 90460 and 0.15 for CPT code 90461.

(35) Gastroenterology (CPT Codes 91010–91117)

For CY 2011 the CPT Editorial Panel restructured a set of CPT codes used to describe esophageal motility and high resolution esophageal pressure topography services. The specialty societies surveyed their members, and the AMA RUC issued recommendations to us for the CY 2011 PFS final rule with comment period.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73338), in the esophageal motility and high resolution esophageal pressure topography set of services, for CY 2011 two CPT codes were deleted and the services are now reported under a revalued existing CPT code 91010 (Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report; 2-dimensional data) and a new add-on CPT code 91013 (Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report; with stimulation or perfusion during 2-dimensional data study (*e.g.,* stimulant, acid or alkali perfusion) (List separately in addition to code for primary procedure)). We agreed with the AMA RUC that there was compelling evidence to change the work RVUs for the existing CPT code to account for the inclusion of procedures with higher work RVUs that would previously have been reported under the deleted code. We also agreed with the AMA RUC-recommended work RVUs for the add-on code. However, we did not believe that this structural coding change should result in an increase in aggregate physician work for the same services. Therefore, we believed it would be appropriate to apply work budget neutrality to this set of CPT codes. The work budget neutrality factor for these 2 CPT codes was 0.8500. The AMA RUC-recommended work RVU, CMS-adjusted work RVU prior to the budget neutrality adjustment, and the CY 2011 interim final work RVU for these esophageal motility and high resolution esophageal pressure topography procedure codes (CPT codes 91010 and 91013) follow.

CPT Code	Short Descriptor	AMA RUC-recommended Work RVU	CMS-adjusted Work RVU, pre-BN	CY 2011 Interim Final Work RVU
91010	Esophagus motility study	1.50	1.50	1.28
91013	Esophgl motil w/stim/perfus	0.21	0.21	0.18

Comment: Commenters disagreed with the application of work budget neutrality to this set of services and noted that the specialty societies and AMA RUC agreed that there was compelling evidence to change the work RVUs associated with these services. Specifically, commenters wrote that they believed that the current value for CPT code 91010 was based on an incorrect assumption; and that advancements in technology have had an impact on physician work since the code was originally valued. They went on to state that esophageal manometry is a more comprehensive and complex study than it was years ago. Based on these arguments, commenters stated that work budget neutrality should not be applied to these codes, and urged CMS to accept the AMA RUC-recommended values for these services.

Response: Based on comments we received, we referred this set of esophageal motility and high resolution esophageal pressure topography procedures (CPT codes 91010 and 91013) to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs were 1.50 for CPT code 91010 and 0.21 for CPT code 91013, which were consistent with the AMA RUC-recommended values for these services. We continue to believe that the application of work budget neutrality is appropriate for this set of clinically related CPT codes. While we understand that technology has advanced since these codes were originally valued, we do not believe that these advancements have resulted in more aggregate physician work. As such, we believe that allowing an increase in utilization-weighted RVUs within this set of clinically related CPT codes would be unjustifiably redistributive among PFS services. After consideration of the public comments, refinement panel results, and our clinical review, we are finalizing a work RVU of 1.28 for CPT code 91010, and a work RVU of 0.18 for CPT code 91013 for CY 2012.

We received no public comments on the CY 2011 final rule with comment period interim work RVUs for CPT codes 91038 and 91117. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(36) Opthalmology: Special Opthalmological Services (CPT Codes 92081–92285)

In February, 2010 the CPT Editorial Panel established two codes for reporting remote imaging for screening retinal disease and management of active retinal disease. As detailed in the CY 2011 PFS proposed rule (75 FR 73333), for CPT code 92228 (Remote imaging for monitoring and management of active retinal disease (*e.g.,* diabetic retinopathy) with physician review, interpretation and report, unilateral or bilateral), we assigned a work RVU of 0.30 to on an interim final basis for CY 2011. We compared this code to another diagnostic service, CPT code 92135 (Scanning computerized ophthalmic diagnostic imaging, posterior segment, (*e.g.,* canning laser) with interpretation and report, unilateral) (Work RVUs = 0.35), which we believed was more equivalent than CPT code 92250 (Fundus photography with interpretation and report) (Work RVU = 0.44), the AMA RUC reference service, but had more pre- and intra-service time. Upon further review of CPT code 92228 and the time and intensity needed to furnish this service, we assigned a work RVU of 0.30, the survey low value, on an interim final basis for CY 2011. The AMA RUC recommended a work RVU of 0.44 for CPT code 92228 for CY 2011 (75 FR 73333).

Comment: Commenters disagreed with the CMS interim final work RVU of 0.030, and requested that CMS accept the AMA RUC-recommended RVU of 0.44. Commenters disagreed with CMS' use CPT code 92135 as a comparison service for the valuation of CPT code 92228. Commenters stated that CPT code 92250 more accurately reflects the service involved in CPT code 92228. Furthermore, commenters raised concerns regarding a rank order anomaly with CPT code 92250, which they stated represents the same physician work as CPT code 92228, if CMS finalizes the interim final work RVU of 0.30 for CPT code 92228.

Response: Based on the comments we received, we referred CPT code 92228 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVU was 0.37. As a result of the refinement panel ratings and our clinical review, we are finalizing a work RVU of 0.37 for CPT code 92228.

For CY 2012, we received no public comment on the CY 2011 interim final work RVUs for CPT codes 92132 through 92134 and 9222. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(37) Special Otorhinolaryngologic Services (CPT Codes 92504–92511)

Section 143 of the MIPPA specifies that speech-language pathologists may independently report services they provide to Medicare patients. Starting in July 2009, speech-language pathologists were able to bill Medicare as independent practitioners. As a result, the American Speech-Language-Hearing Association (ASHA) requested that CMS ask the AMA RUC to review the speech-language pathology codes to newly value the professionals' services in the work and not the practice expense. ASHA indicated that it would survey the 12 speech-language pathology codes over the course of the CPT 2010 and CPT 2011 cycles. Four of these services were reviewed by the HCPAC or the AMA RUC and were included in the CY 2010 PFS final rule with comment period (74 FR 61784 and 62146). For CY 2011, the HCPAC submitted work recommendations for the remaining eight codes.

As detailed in the CY 2011 PFS final rule with comment period (75 FR 7333), for CPT code 92508 (Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals), we assigned a work RVU of 0.33 on an interim final basis for CY 2011. We derived the work RVU of 0.33 by dividing the value for CPT code 92507 (Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual) (work RVU = 1.30) by 4 participants based on our understanding from practitioners that 4 accurately represented the typical number of participants in a group. Additionally, the work RVU of 0.33 was appropriate for this group treatment service relative to the work RVU of 0.27 for CPT code 97150 (Therapeutic procedure(s), group (2 or more individuals)), which is furnished to a similar patient population, namely patients who have had a stroke. The

HCPAC recommended a work RVU of 0.43 for CPT code 92508 for CY 2011 (75 FR 7333).

Comment: Commenters disagreed with the interim final work RVU of 0.33 for CPT code 92508, and asserted that the HCPAC recommendation of a work RVU of 0.43 was more appropriate. Commenters disagreed with using 4 participants to value CPT code 92508, requesting that CMS assume 3 as the typical number of participants in a group. Commenters also disagreed with CMS' comparison with CPT code 97150, asserting that this service is furnished to a dissimilar patient population by other professional groups. Commenters requested that we accept the HCPAC-recommended work RVU of 0.43 for CPT code 92508.

Response: Based on comments we received, we referred CPT code 92508 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel supported that HCPAC-recommended value of 0.43. As stated previously based on our understanding of this service, we believe that dividing the value for CPT code 92507 by 4 participants more appropriately values CPT code 92508. Furthermore, as stated in CY 2012 PFS final rule with comment period (75 FR 7333), CPT code 97150 (work RVU = 0.27) is furnished to a similar patient population. We believe a work RVU of 0.33 for CPT code 92508 creates appropriate relativity to CPT code 97150. After consideration of the public comments, refinement panel results, and our clinical review, we are finalizing a work RVU of 0.33 for CPT code 92508.

As detailed in the Fourth Five-Year Review, for CPT code 92511 (Nasopharyngoscopy with endoscope (separate procedure)) we proposed a work RVU of 0.61 for CY 2012. The AMA RUC recommended a work RVU of 0.61 for this service as well. For CPT code 92511, the AMA RUC recommended the following times: pre-service evaluation time of 6 minutes; pre-service (dress, scrub, wait) of 5 minutes; an intra-service time of 5 minutes; and a post-service time of 5 minutes. We proposed a pre-service evaluation time for CPT code 92511 of 4 minutes, pre-service (dress, scrub, wait) of 5 minutes, an intra-service time of 5 minutes, and a post-service time of 3 minutes to account for the E/M service begin provided on the same day (76 FR 32455).

Comment: In its public comment to CMS on the Fourth Five-Year Review, the AMA RUC wrote that CMS agreed with the AMA RUC-recommended work RVU, but noted that CMS disagreed with the AMA RUC recommended pre-service and post-service time components due to an E/M service typically being provided on the same day of service. The AMA RUC recommends that CMS accept the AMA RUC-recommended pre-service evaluation time of 6 minutes and immediate post-service time of 5 minutes for CPT code 92511.

Response: In response to comments, we re-reviewed the descriptions of pre-service work and the recommended pre-service time packages for CPT code 92511. We disagree with the times recommended by the AMA RUC, and we do not believe the recommended times account for the overlap with an E/M service typically billed on the same day of service. We continue to believe our proposal to reduce the pre- and post-service time by 2 minutes is appropriate for this service. For CPT code 92511, we are finalizing a work RVU of 0.61. In addition, we are finalizing a pre-service evaluation time of 4 minutes, pre-service (dress, scrub, wait) time of 5 minutes, an intra-service time of 5 minutes, and a post-service time of 3 minutes for CPT code 92511. CMS time refinements can be found in Table 16.

For CY 2012, we received no public comments on the CY 2011 interim final work RVUs for CPT Codes 92504, 92507, and 92508. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(38) Special Otorhinolaryngologic Services: Evaluative and Therapeutic Services (CPT Codes 92605–92618)

As detailed in the CY 2011 PFS final rule with comment period (75 FR 7333), for CPT code 92606 (Therapeutic service(s) for the use of non-speech generating device, including programming and modification), we published the AMA RUC-recommended work RVU of 1.40 in Addendum B to the final rule with comment period in accordance with our usual practice for bundled services. This service is currently bundled under the PFS and we maintained the bundled status for CY 2011.

Comment: Commenters requested that CMS consider applying an active Medicare status to this service to be covered by Medicare.

Response: As stated previously, CPT code 92606 is currently bundled and paid as a part of other services on the PFS. We do not pay separately for services that are included in other paid services, as this would amount to double payments for those services. We are maintaining the bundled status for CPT code 92606 for CY 2012.

For CY 2012, we received no public comments on the CY 2011 interim final work RVUs for CPT codes 92607 through 92609. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(39) Cardiovascular: Therapeutic Services and Procedures (CPT Codes 92950)

In the Fourth Five-Year Review, CMS identified CPT code 92950 (Cardiopulmonary resuscitation (*e.g.,* in cardiac arrest)) as potentially misvalued through the Harvard-Valued—Utilization >30,000 screen. As detailed in the Fourth Five-Year Review of Work, for CPT code 92950 (Cardiopulmonary resuscitation (*e.g.,* in cardiac arrest)), we proposed a work RVU of 4.00 for CY 2012. The AMA RUC reviewed the survey results and recommended the median survey work RVU of 4.50 for CPT code 92950. We recognized that patients that undergo this service are very ill; however, we did not believe that the typical patient met all the criteria for the critical care codes. Furthermore, the most currently available Medicare PFS claims data showed that CPT code 92950 is typically furnished on the same day as an E/M visit. We believed some of the pre- and post- service time should not be counted in developing this procedure's work value. As described in section III.A., to account for this overlap, we reduced the pre-service evaluation and post service time by one-third. We believed that 1 minute pre-service evaluation time and 20 minutes post-service time accurately reflect the time required to conduct the work associated with this service.

Comment: Commenters disagreed with the CMS-proposed work RVU of 4.00 of CPT code 92950 and believe that the AMA RUC recommended work RVU of 4.50 is more appropriate. Additionally, commenters asserted that a patient requiring cardiopulmonary resuscitation is clearly as intense as critical care definition having a high probability of imminent life threatening deterioration. Furthermore, commenters note that utilization data show that CPR is not typically reported with an E/M code.

Response: Based on the comments received, we referred CPT code 92950 to the CY 2011 multi-specialty refinement panel for further review. Although the refinement panel median work RVU was 4.50, which was consistent with the AMA RUC-recommendation for this service. The Medicare PFS claims data show that there is an E/M visit billed on the same day as CPT code 92950 more

than 50 percent of the time. We do not believe it is appropriate for this service to reflect the aforementioned E/M visit overlap, which would result in duplicate recognition of activities associated with pre- and post- service times. In order to ensure consistent and appropriate valuation of physician work, we believe it is appropriate to apply our methodology to address services for which there is typically a same-day E/M service. Therefore, we are finalizing a work RVU for CPT code 92950 of 4.00 in CY 2012 with refinements to time. A complete list of CMS time refinements can be found in Table 16.

(40) Neurology and Neuromuscular Procedures: Sleep Testing (CPT Codes 95800–95811)

Sleep testing CPT codes were identified by the Five-Year Review Identification Workgroup as potentially misvalued codes through the ''CMS Fastest Growing'' potentially misvalued codes screen. The CPT Editorial Panel created separate Category I CPT codes to report for unattended sleep studies. The AMA RUC recommended concurrent review of the family of sleep codes.

As detailed in the CY 2011 PFS final rule with comment period (75 FR 73334), we assigned a work RVU of 1.25 for CPT codes 95806 (Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (*e.g.,* thoracoabdominal movement)) and a work RVU of 1.28 for CPT code 95807 (Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist) on an interim basis for CY 2011. The AMA RUC recommended work RVUs of 1.28 for CPT code 95806 and 1.25 for CPT code 95807. Although the AMA RUC-recommended values for these codes reflect the survey 25th percentile, we disagreed with the values and believed the values should be reversed because of the characteristics of the services. CPT code 95807 has 5 minutes more pre-service time but a lower AMA RUC-recommended value. We did not receive any public comments that disagreed with the interim final work values. Therefore, we are finalizing work RVUs of 1.25 for CPT code 95806 and 1.28 for CPT code 95807.

For CY 2012, we received no public comments on the CY 2011 interim final work RVUs for CPT codes 95800, 95801, 95803, 95805, 95808, 95810, and 95811. We believe these values continue to be appropriate and are finalizing them without modification (Table 15).

(41) Osteopathic Manipulative Treatment (CPT Codes 98925–98929)

In the Fourth Five-Year Review (76 FR 32456 through 32458), we identified CPT codes 98925, 98928 and 98929 as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen. Additionally, the American Osteopathic Association identified CPT codes 98926 and 98927 to be reviewed as part of this family since these were also identified to be reviewed by the AMA RUC Relativity Assessment Workgroup because these codes were identified through the Harvard-Valued—Utilization > 100,000 screen.

We reviewed CPT codes 98925 through 98929 and published proposed work RVUs in the Fourth Five-Year Review of Work (76 FR 32456 through 32458). Based on comments we received during the public comment period, we referred CPT codes 98925 through 98929 to the CY 2011 multi-specialty refinement panel for further review.

For CPT code 98925 (Osteopathic manipulative treatment (OMT); 1–2 body regions involved), we proposed a work RVU of 0.46 in the Fourth Five-Year Review (76 FR 32456). We also refined the time associated with CPT code 98925. Recent PFS claims data showed that this service is typically furnished on the same day as an E/M visit. While we understand that there are differences between these services, we believed some of the activities conducted during the pre- and post-service times of the osteopathic manipulative treatment code and the E/M visit overlapped and should not be counted in developing the work RVUs for this service. As described earlier in section III.A. of this final rule with comment period, we reduced the pre-service evaluation and post-service time by 1x3 to account for the overlap. We believed that 1 minute of pre-service evaluation time and 2 minutes post-service time accurately reflected the time required to conduct the work associated with this service.

As detailed in the Fourth Five-Year Review (76 FR 32456), we calculated the value of the extracted time and subtracted it from the AMA RUC-recommended work RVU of 0.50. For CPT code 98925, we removed a total of 2 minutes from the AMA RUC-recommended pre- and post-service times, which amounts to the removal of .04 of a work RVU, resulting in a work RVU of 0.46. We noted that 70 percent of the survey respondents indicated that the work of furnishing this service has not changed in the past 5 years (current RVU = 0.45). We proposed a work RVU of 0.46, with refinement in time for CPT code 98925 for CY 2012. CMS time refinements can be found in Table 16. The AMA RUC recommended a work RVU of 0.50 for CPT code 98925.

For CPT code 98926 (Osteopathic manipulative treatment (OMT); 3–4 body regions involved), we proposed a work RVU of 0.71 in the Fourth Five-Year Review (76 FR 32456). We also refined the time associated with CPT code 98926. Recent PFS claims data showed that this service is typically furnished on the same day as an E/M visit. While we understand that there are differences between these services, we believed some of the activities conducted during the pre- and post-service times of the osteopathic manipulative treatment code and the E/M visit overlapped and should not be counted in developing the work RVUs for this service. As described earlier in section III.A. of this final rule with comment period, we reduced the pre-service evaluation and post-service time by one-third to account for the overlap. We believed that 1 minute of pre-service evaluation time and 2 minutes post-service time accurately reflected the time required to conduct the work associated with this service.

As detailed in the Fourth Five-Year Review (76 FR 32456), we calculated the value of the extracted time and subtracted it from the AMA RUC-recommended work RVU of 0.75. For CPT code 98926, we removed a total of 2 minutes from the AMA RUC-recommended pre- and post-service times, which amounts to the removal of .04 of a work RVU, resulting in a work RVU of 0.71. We noted that 81 percent of the survey respondents indicated that the work of furnishing this service has not changed in the past 5 years (current RVU = 0.65). We proposed an alternative work RVU of 0.71, with refinement in time for CPT code 98926 for CY 2012. CMS time refinements can be found in Table 16. The AMA RUC recommended a work RVU of 0.75 for CPT code 98926.

For CPT code 98927 (Osteopathic manipulative treatment (OMT); 5–6 body regions involved), we proposed a work RVU of 0.96 in the Fourth Five-Year Review (76 FR 32457). We also refined the time associated with CPT code 98927. Recent PFS claims data showed that this service is typically furnished on the same day as an E/M visit. While we understand that there are differences between these services, we believed some of the activities conducted during the pre- and post-service times of the osteopathic manipulative treatment code and the E/M visit overlapped and should not be counted in developing the work RVUs

for this service. As described earlier in section III.A. of this final rule with comment period, we reduced the pre-service evaluation and post-service time by one-third to account for the overlap. We believed that 1 minute of pre-service evaluation time and 2 minutes post-service time accurately reflected the time required to conduct the work associated with this service.

As detailed in the Fourth Five-Year Review (76 FR 32457), we calculated the value of the extracted time and subtracted it from the AMA RUC-recommended work RVU of 1.00. For CPT code 98927, we removed a total of 2 minutes from the AMA RUC-recommended pre- and post-service times, which amounts to the removal of 0.04 of a work RVU, resulting in a work RVU of 0.96. We noted that 77 percent of the survey respondents indicated that the work of furnishing this service has not changed in the past 5 years (current RVU = 0.87). We proposed a work RVU of 0.96, with refinement in time for CPT code 98927 for CY 2012. CMS time refinements can be found in Table 16. The AMA RUC recommended a work RVU of 1.00 for CPT code 98927.

For CPT code 98928 (Osteopathic manipulative treatment (OMT); 7–8 body regions involved), we proposed a work RVU of 1.21 in the Fourth Five-Year Review (76 FR 32457). We also refined the time associated with CPT code 98928. Recent PFS claims data showed that this service is typically furnished on the same day as an E/M visit. While we understand that there are differences between these services, we believed some of the activities conducted during the pre- and post-service times of the osteopathic manipulative treatment code and the E/M visit overlapped and should not be counted in developing the work RVUs for this service. As described earlier in section III.A. of this final rule with comment period, we reduced the pre-service evaluation and post-service time by one-third to account for the overlap. We believed that 1 minute of pre-service evaluation time and 2 minutes post-service time accurately reflected the time required to conduct the work associated with this service.

As detailed in the Fourth Five-Year Review (76 FR 32457), we calculated the value of the extracted time and subtracted it from the AMA RUC-recommended work RVU of 1.25. For CPT code 98928, we removed a total of 2 minutes from the AMA RUC-recommended pre- and post-service times, which amounts to the removal of 0.04 of a work RVU, resulting in a work RVU of 1.21. We noted that 67 percent of the survey respondents indicated that the work of furnishing this service has not changed in the past 5 years (current RVU = 1.03). We proposed a work RVU of 1.21, with refinement in time for CPT code 98928 for CY 2012. CMS time refinements can be found in Table 16. The AMA RUC recommended a work RVU of 1.25 for CPT code 98928.

For CPT code 98929 (Osteopathic manipulative treatment (OMT); 9–10 body regions involved), we proposed a work RVU of 1.46 in the Fourth Five-Year Review (76 FR 32457). We also refined the time associated with CPT code 98929. Recent PFS claims data showed that this service is typically furnished on the same day as an E/M visit. While we understand that there are differences between these services, we believed some of the activities conducted during the pre- and post-service times of the osteopathic manipulative treatment code and the E/M visit overlapped and should not be counted in developing the work RVUs for this service. As described earlier in section III.A. of this final rule with comment period, we reduced the pre-service evaluation and post-service time by 1x3 to account for the overlap. We believed that 1 minute of pre-service evaluation time and 2 minutes post-service time accurately reflected the time required to conduct the work associated with this service.

As detailed in the Fourth Five-Year Review (76 FR 32457), we calculated the value of the extracted time and subtracted it from the AMA RUC-recommended work RVU of 1.50. For CPT code 98929, we removed a total of 2 minutes from the AMA RUC-recommended pre- and post-service times, which amounts to the removal of .04 of a work RVU, resulting in a work RVU of 1.46. We noted that 63 percent of the survey respondents indicated that the work of furnishing this service has not changed in the past 5 years (current RVU = 1.19). We proposed a work RVU of 1.46, with refinement in time for CPT code 98928 for CY 2012. CMS time refinements can be found in Table 16. The AMA RUC recommended a work RVU of 1.50 for CPT code 98929.

Comment: Commenters disagreed with the CMS-proposed work RVUs for these osteopathic manipulative treatment services, and state that the AMA RUC-recommended RVUs of 0.50 for CPT code 98925, 0.75 for CPT code 98926, 1.00 for CPT code 98927, 1.25 for CPT code 98928, 1.50 for CPT code 98929 are more appropriate. Commenters reminded CMS that the AMA RUC incorporated reductions in the pre- and post-service times recommended in the specialty's survey of the codes. Commenters noted that the proposed work RVUs were derived from the reverse building block methodology, which removed 0.04 from the AMA RUC-recommended RVUs for CPT codes 98925 through 98929 to account for the overlap with the E/M services.

Commenters also found that the survey responses indicating that the work of furnishing these services had not changed in the past 5 years were irrelevant to valuing these services because there was compelling evidence that the methodology was flawed in the original valuation of these codes. Commenters requested that CMS accept the AMA RUC-recommended work RVUs and physician time.

Response: Based on the comments we received, we referred CPT codes 98925, 98926, 98927, 98928, and 98929 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs were 0.49, 0.74, 0.99, 1.24, 1.49 for CPT codes 98925, 98926, 98927, 98928, and 98929, respectively. While the AMA RUC asserts that it reduced physician times to account for the E/M service on the same day, we do not believe the recommended physician times adequately account for the overlap in services with an E/M visit on the same day. We continue to believe that some of the activities in the pre- and post-service times of the osteopathic manipulative treatment codes and the E/M visit overlap, and that our proposal to remove 1 minute of pre- and 1 minute of post-service time appropriately accounts for this overlap. As detailed earlier in section III.A. of this final rule with comment period, we do not believe the overlap in activities should be counted in developing these procedures' work values. In order to ensure consistent and appropriate valuation of physician work, we are continuing with the application of our methodology, explained in the Fourth Five-Year Review (76 FR 32422), to address the overlapping activities when a service is typically billed on the same day as an E/M service. After consideration of the public comments, refinement panel results, survey responses, and our clinical review, we are finalizing the proposed work RVUs and refined times associated with these codes. CMS time refinements can be found in Table 16. We are finalizing work RVUs of 0.46 for CPT code 98925, 0.71 for CPT code 98926, 0.96 for CPT code 98927, 1.21 for CPT code 98928, 1.46 for CPT code 98929.

(42) Evaluation and Management: Initial Observation Care (CPT Codes 99218–99220)

In the Fourth Five-Year Review (76 FR 32458), we identified CPT codes 99218 through 99220 as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen. The American College of Emergency Physicians (ACEP) submitted a public comment identifying CPT codes 99218 through 99220 to be reviewed in the Fourth Five-Year Review. ACEP also identified CPT codes 99234 through 99236 as part of the family of services for AMA RUC review. For CPT codes 99218 (Level 1 initial observation care, per day), 99219 (Level 2 initial observation care, per day), and 99220 (Level 3 initial observation care, per day), we stated that we believed there were differences in physician work in the outpatient and inpatient settings, and proposed work RVUs of 1.28 for CPT code 99218, 2.14 for CPT code 99219, and 2.99 for CPT code 99220.

We agreed with the AMA RUC that appropriate relativity must be maintained within and between the families of similar codes. However, we believed that while the work RVUs of the initial observation care codes (99218, 99219, and 99220) should be greater than those of the subsequent observation care codes (99224, 99225, and 99226), we did not believe the work RVUs of the initial observation care codes (99218, 99219, and 99220) should be equivalent (or close) to the initial hospital care codes (99221, 99222, and 99223). We noted that we believed the acuity level of the typical patient receiving outpatient observation services would generally be lower than that of the inpatient level. We believed the work RVUs of the initial observation care codes should reflect the modest differences in patient acuity between the outpatient and inpatient settings. We compared the CY 2011 work RVUs of the initial observation care codes to the CY 2011 interim final work RVUs of the subsequent observation care codes and found that the relativity existing between these codes was acceptable. We also believed that the CY 2011 work RVUs of the initial observation care codes maintained the proper rank order with the initial hospital care services. Therefore, we proposed to maintain the CY 2011 work RVUs for CPT codes 99218, 99219, and 99220. We accepted the survey median physician times for these codes, as recommended by the AMA RUC. CMS time refinements can be found in Table 16. The AMA RUC asserted that a rank order anomaly existed within this family of codes as the observation care codes have an analogous relationship to the initial hospital care codes (99221 through 99223), and recommended work RVUs of 1.92 for CPT code 99218, 2.60 for CPT code 99219, and 3.56 for CPT code 99220.

Comment: Commenters disagreed with the proposed RVUs for CPT codes 99218, 99219, and 99220. Commenters stressed that the physician work is the same whether the patient is in observation status or admitted to the hospital. Commenters stated that these initial observation care codes should be valued consistently with initial hospital care codes (99221, 99222, and 99223). Commenters stated that a patient's classification by a hospital as inpatient or outpatient does not necessarily equate to patient acuity relevance for a physician. Furthermore, commenters noted that hospital classification of patients as inpatient or outpatient may be in response to hospital policies, facility resource utilization, or other factors, while physician work is described within CPT guidelines for the E/M codes. Commenters requested that CMS accept the AMA RUC-recommended work RVUs of 1.92 for CPT code 99218, 2.60 for CPT code 99219, and 3.56 for CPT code 99220 with the AMA RUC-recommended physician times.

Response: Based on comments we received, we referred CPT codes 99218, 99219, and 99220 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs were 1.92 for CPT code 99218, 2.60 for CPT code 99219, and 3.56 for CPT code 99220. As a result of the refinement panel ratings and our clinical review, we are finalizing work RVUs of 1.92 for CPT code 99218, 2.60 for CPT code 99219, and 3.56 for CPT code 99220. We are also finalizing the AMA RUC-recommended physician times. CMS time refinements can be found in Table 16.

(43) Evaluation and Management: Subsequent Observation Care (CPT Codes 99224–99226)

At the June 2009 CPT Editorial Panel meeting, three new codes were approved to report subsequent observation services in a facility setting. These codes are CPT code 99224 (Level 1 subsequent observation care, per day); CPT code 99225 (Level 2 subsequent observation care, per day); and CPT code 99226 (Level 3 subsequent observation care, per day). Observation services are outpatient services ordered by a patient's treating practitioner. In the CY 2011 PFS final rule with comment period (75 FR 73334), we assigned interim final work RVUs of 0.54 to CPT code 99224, 0.96 to CPT code 99225, and 1.44 to CPT code 99226 for CY 2011. As detailed in the CY 2011 PFS final rule with comment period, we stated that there are generally differences in patient acuity between the inpatient and outpatient settings. To account for these differences, we removed the pre- and post-services times from the AMA RUC-recommended values for subsequent observation care, reducing the values to approximately 75 percent of the values for the subsequent hospital care codes. The AMA RUC recommended work RVUs of 0.76 for CPT code 99224, 1.39 for CPT code 99225, and 2.00 for CPT 99226.

Comment: Commenters disagreed with the interim final RVUs for the CPT codes 99224, 99225, and 99226. Commenters stressed that the physician work is the same whether the patient is admitted to the hospital or in observation status, and should be valued consistently with subsequent hospital care codes (99231, 99232, and 99233). Commenters also disagreed with CMS removing the pre- and post-service time for valuation of these codes. Commenters stated that subsequent observation care involves physician time and work before and after the patient encounter. Commenters requested that CMS accept the AMA RUC-recommended RVUs of 0.76 for 99224, 1.39 for 99225, and 2.00 for 99226, which correlate to the subsequent hospital care codes (99231, 99232, and 99233).

Response: Based on the comments we received, we referred CPT codes 99224, 99225, and 99226 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs were 0.76 for 99224, 1.39 for 99225, and 2.00 for 99226. As a result of the refinement panel ratings and our clinical review, we are finalizing work RVUs of 0.76 for 99224, 1.39 for 99225, and 2.00 for 99226. We are also finalizing the AMA RUC-recommended pre- and post-service times. CMS time refinements can be found in Table 16.

(44) Evaluation and Management: Subsequent Hospital Care (CPT Codes 99234–99236)

In the Fourth Five-Year Review (76 FR 32458), for CPT codes 99234 (Level 1, observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date); 99235 (Level 2, observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same

date); and 99236 (Level 3 observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date), we proposed a work RVUs of 1.92 for CPT code 99234, 2.78 for CPT code 99235, and 3.63 for CPT code 99236. We followed the same approach to valuing these observation same day admit/discharge services as the AMA RUC—taking the corresponding initial observation care code of the same level, plus half the value of a hospital discharge day management service. However, we incorporated the Fourth Five-Year Review proposed values for CPT codes 99218, 99219, and 99220 discussed previously. We also made corresponding physician time changes. CMS time refinements can be found in Table 16. The AMA RUC recommended 2.56 for CPT code 99234, 3.24 for CPT code 99235, and 4.20 for CPT code 99236 based on the same methodology, but incorporated the AMA RUC-recommended RVUs for 99218, 99219, and 99220, respectively.

Comment: Commenters disagreed with the proposed RVUs for CPT codes 99234, 99235, and 99236. Commenters supported the methodology CMS and the AMA RUC used to value these services of taking the corresponding initial observation care code of the same level, plus half the value of a hospital discharge day management service, but commenters disagreed with the underlying initial observation care code RVUs. Commenters requested that CMS continue to apply the same methodology from the Fourth Five-Year Review. However, commenters requested that CMS use the AMA RUC-recommended RVUs, rather than the CMS proposed values for the initial observation care codes in the calculation of RVUs for CPT codes 99234, 99235, and 99236. Commenters requested that CMS accept the AMA RUC-recommended RVUs of 2.56 for CPT code 99234, 3.24 for CPT code 99235, and 4.20 for CPT code 99236 with the AMA RUC-recommended physician times.

Response: Based on the comments we received, we referred CPT codes 99224, 99225, and 99226 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs were 2.56 for CPT code 99234, 3.24 for CPT code 99235, and 4.20 for CPT code 99236. As a result of the refinement panel ratings and our clinical review, we are finalizing work RVUs of 2.56 for CPT code 99234, 3.24 for CPT code 99235, and 4.20 for CPT code 99236. We are also finalizing the AMA RUC-recommended physician times. CMS time refinements can be found in Table 16.

As noted previously, for all CY 2011 new, revised, or potentially misvalued codes with CY 2011 interim final work RVUs that are not specifically discussed in this final rule with comment period, we are finalizing, without modification, the interim final direct PE inputs that we initially adopted for CY 2011. Table 15 provides a comprehensive list of all final values.

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TABLE 15: CY 2012 Work RVUs for Services Reviewed in the CY 2011 PFS Final Rule with Comment Period, the Fourth-Five Year Review, and the CY 2012 PFS Proposed Rule

CPT Code	Short Descriptor	CMS WRVU Review*	AMA RUC/ HCPAC Recommended Work RVU	2011 Refinement Panel Rating	CY 2012 WRVU	CMS Refinement to AMA RUC/HCPAC Rec'd Time
10140	Drainage of hematoma/fluid	5Y	1.58		1.58	
10160	Puncture drainage of lesion	5Y	1.25		1.25	
11010	Debride skin at fx site	FR	4.19		4.19	
11011	Debride skin musc at fx site	FR	4.94		4.94	
11012	Deb skin bone at fx site	FR	6.87		6.87	
11042	Deb subq tissue 20 sq cm/<	FR	1.12	1.01	1.01	
11043	Deb musc/fascia 20 sq cm/<	FR	3.00	2.70	2.70	
11044	Deb bone 20 sq cm/<	FR	4.56	4.10	4.10	
11045	Deb subq tissue add-on	FR	0.69	0.50	0.50	
11046	Deb musc/fascia add-on	FR	1.29	1.03	1.03	
11047	Deb bone add-on	FR	2.00	1.80	1.80	
11732	Remove nail plate, add-on	5Y	0.48		0.44	Yes
11765	Excision of nail fold, toe	5Y	1.48		1.22	Yes
11900	Injection into skin lesions	FR	0.52		0.52	
11901	Added skin lesions injection	FR	0.80		0.80	
12001	Repair superficial wound(s)	FR	0.84		0.84	
12002	Repair superficial wound(s)	FR	1.14		1.14	
12004	Repair superficial wound(s)	FR	1.44		1.44	
12005	Repair superficial wound(s)	FR	1.97		1.97	
12006	Repair superficial wound(s)	FR	2.39		2.39	
12007	Repair superficial wound(s)	FR	2.90		2.90	
12011	Repair superficial wound(s)	FR	1.07		1.07	
12013	Repair superficial wound(s)	FR	1.22		1.22	
12014	Repair superficial wound(s)	FR	1.57		1.57	
12015	Repair superficial wound(s)	FR	1.98		1.98	
12016	Repair superficial wound(s)	FR	2.68		2.68	
12017	Repair superficial wound(s)	FR	3.18		3.18	
12018	Repair superficial wound(s)	FR	3.61		3.61	
12031	Intmd wnd repair s/tr/ext	5Y	2.00		2.00	
12032	Intmd wnd repair s/tr/ext	5Y	2.52		2.52	
12034	Intmd wnd repair s/tr/ext	5Y	2.97		2.97	
12035	Intmd wnd repair s/tr/ext	5Y	3.60	3.55	3.50	
12036	Intmd wnd repair s/tr/ext	5Y	4.50	4.23	4.23	Yes
12037	Intmd wnd repair s/tr/ext	5Y	5.25	5.00	5.00	
12041	Intmd wnd repair n-hf/genit	5Y	2.10		2.10	
12042	Intmd wnd repair n-hg/genit	5Y	2.79		2.79	
12044	Intmd wnd repair n-hg/genit	5Y	3.19		3.19	
12045	Intmd wnd repair n-hg/genit	5Y	3.90	3.83	3.75	
12046	Intmd wnd repair n-hg/genit	5Y	4.60	4.45	4.30	Yes
12047	Intmd wnd repair n-hg/genit	5Y	5.50	5.23	4.95	Yes
12051	Intmd wnd repair face/mm	5Y	2.33		2.33	
12052	Intmd wnd repair face/mm	5Y	2.87		2.87	
12053	Intmd wnd repair face/mm	5Y	3.17		3.17	
12054	Intmd wnd repair, face/mm	5Y	3.50		3.50	
12055	Intmd wnd repair face/mm	5Y	4.65	4.65	4.50	Yes
12056	Intmd wnd repair face/mm	5Y	5.50	5.50	5.30	Yes
12057	Intmd wnd repair face/mm	5Y	6.28	6.28	6.00	Yes
13100	Repair of wound or lesion	5Y	3.17		3.17	Yes
13101	Repair of wound or lesion	5Y	3.96		3.96	Yes

CPT Code	Short Descriptor	CMS WRVU Review*	AMA RUC/ HCPAC Recommended Work RVU	2011 Refinement Panel Rating	CY 2012 WRVU	CMS Refinement to AMA RUC/HCPAC Rec'd Time
15120	Skn splt a-grft fac/nck/hf/g	5Y	10.15		10.15	Yes
15121	Skn splt a-grft f/n/hf/g add	5Y	2.00		2.00	
15260	Skin full graft een & lips	5Y	11.64		11.64	
15732	Muscle-skin graft, head/neck	5Y	19.83	17.38	16.38	Yes
15823	Revision of upper eyelid	FR	6.81		6.81	
17250	Chemical cautery, tissue	5Y	0.50		0.50	
17260	Destruction of skin lesions	5Y	0.96		0.96	
17261	Destruction of skin lesions	5Y	1.22		1.22	
17262	Destruction of skin lesions	5Y	1.63		1.63	
17263	Destruction of skin lesions	5Y	1.84		1.84	
17264	Destruction of skin lesions	5Y	1.99		1.99	
17266	Destruction of skin lesions	5Y	2.39		2.39	
17270	Destruction of skin lesions	5Y	1.37		1.37	
17271	Destruction of skin lesions	5Y	1.54		1.54	
17272	Destruction of skin lesions	5Y	1.82		1.82	
17273	Destruction of skin lesions	5Y	2.10		2.10	
17274	Destruction of skin lesions	5Y	2.64		2.64	
17276	Destruction of skin lesions	5Y	3.25		3.25	
17280	Destruction of skin lesions	5Y	1.22		1.22	
17281	Destruction of skin lesions	5Y	1.77		1.77	
17282	Destruction of skin lesions	5Y	2.09		2.09	
17283	Destruction of skin lesions	5Y	2.69		2.69	
17284	Destruction of skin lesions	5Y	3.20		3.20	
17286	Destruction of skin lesions	5Y	4.48		4.48	
19302	P-mastectomy w/ln removal	5Y	13.99	13.99	13.99	
19357	Breast reconstruction	FR	18.50		18.50	
20005	I&d abscess subfascial	FR	3.58		3.58	
20664	Application of halo	FR	10.06		10.06	
20930	Sp bone algrft morsel add-on	FR	0.00		0.00	
20931	Sp bone algrft struct add-on	FR	1.81		1.81	
21025	Excision of bone, lower jaw	NPRM	10.03		10.03	
22315	Treat spine fracture	FR	10.11		10.11	
22520	Percut vertebroplasty thor	5Y	9.22		9.22	
22521	Percut vertebroplasty lumb	5Y	8.65	8.65	8.65	
22522	Percut vertebroplasty addl	5Y	4.30		4.30	
22523	Percut kyphoplasty, thor	5Y	9.26	9.04	9.04	
22524	Percut kyphoplasty, lumbar	5Y	8.86	8.54	8.54	
22525	Percut kyphoplasty, add-on	5Y	4.47		4.47	
22551	Neck spine fuse&remove addl	FR	24.50		25.00	
22552	Addl neck spine fusion	FR	6.50		6.50	
22554	Neck spine fusion	FR	17.69		17.69	
22585	Additional spinal fusion	FR	5.52		5.52	
22851	Apply spine prosth device	FR	6.70		6.70	
23415	Release of shoulder ligament	NPRM	9.23		9.23	
23430	Repair biceps tendon	FR	10.17		10.17	
25116	Remove wrist/forearm lesion	NPRM	7.56		7.56	
25600	Treat fracture radius/ulna	5Y	2.78	2.78	2.78	Yes
25605	Treat fracture radius/ulna	5Y	6.50	6.25	6.25	Yes
27065	Remove hip bone les super	FR	6.55		6.55	
27066	Remove hip bone les deep	FR	11.20		11.20	
27067	Remove/graft hip bone lesion	FR	14.72		14.72	
27070	Part remove hip bone super	FR	11.56		11.56	
27071	Part removal hip bone deep	FR	12.39		12.39	
27385	Repair of thigh muscle	5Y	8.11	7.77	6.93	Yes

CPT Code	Short Descriptor	CMS WRVU Review*	AMA RUC/ HCPAC Recommended Work RVU	2011 Refinement Panel Rating	CY 2012 WRVU	CMS Refinement to AMA RUC/HCPAC Rec'd Time
27530	Treat knee fracture	5Y	2.81	2.76	2.65	Yes
27792	Treatment of ankle fracture	5Y	9.71	9.71	8.75	Yes
28002	Treatment of foot infection	5Y	5.34	5.34	5.34	
28003	Treatment of foot infection	5Y	9.06		9.06	
28120	Part removal of ankle/heel	5Y	8.27	8.27	7.31	Yes
28122	Partial removal of foot bone	5Y	7.72	7.72	6.76	Yes
28285	Repair of hammertoe	5Y	5.62	5.62	5.62	
28715	Fusion of foot bones	5Y	14.60	14.60	13.42	Yes
28725	Fusion of foot bones	NPRM	12.18	12.18	11.22	Yes
28730	Fusion of foot bones	NPRM	12.42	12.42	10.70	Yes
28820	Amputation of toe	5Y	7.00	7.00	5.82	Yes
28825	Partial amputation of toe	5Y	6.01	6.01	5.37	Yes
29125	Apply forearm splint	5Y	0.59	0.50	0.50	Yes
29126	Apply forearm splint	5Y	0.77	0.77	0.68	Yes
29405	Apply short leg cast	5Y	0.80		0.80	
29425	Apply short leg cast	5Y	0.80		0.80	
29515	Application lower leg splint	5Y	0.73		0.73	Yes
29540	Strapping of ankle and/or ft	FR	0.39	0.39	0.39	
29550	Strapping of toes	FR	0.25	0.25	0.25	Yes
29914	Hip arthro w/femoroplasty	FR	14.67		14.67	
29915	Hip arthro acetabuloplasty	FR	15.00		15.00	
29916	Hip arthro w/labral repair	FR	15.00		15.00	
30901	Control of nosebleed	FR	1.21		1.10	
31256	Exploration maxillary sinus	FR	3.29		3.29	
31267	Endoscopy maxillary sinus	FR	5.45		5.45	
31276	Sinus endoscopy surgical	FR	8.84		8.84	
31287	Nasal/sinus endoscopy surg	FR	3.91		3.91	
31288	Nasal/sinus endoscopy surg	FR	4.57		4.57	
31295	Sinus endo w/balloon dil	FR	2.70		2.70	
31296	Sinus endo w/balloon dil	FR	3.29		3.29	
31297	Sinus endo w/balloon dil	FR	2.64		2.64	
31634	Bronch w/balloon occlusion	FR	4.00		4.00	
32405	Biopsy, lung or mediastinum	5Y	1.93		1.93	
32851	Lung transplant, single	5Y	63.00	63.00	59.64	
32852	Lung transplant with bypass	5Y	74.37	74.37	65.50	
32853	Lung transplant, double	5Y	90.00	85.00	84.48	
32854	Lung transplant with bypass	5Y	95.00	95.00	90.00	
33030	Partial removal of heart sac	5Y	39.50	37.10	36.00	
33031	Partial removal of heart sac	5Y	45.00		45.00	
33120	Removal of heart lesion	5Y	42.88	42.88	38.45	
33315	Exploratory heart surgery	5Y	35.00		35.00	
33411	Replacement of aortic valve	FR 5Y	62.07		62.07	
33412	Replacement of aortic valve	5Y	60.00	59.00	59.00	
33468	Revision of tricuspid valve	5Y	50.00	46.00	45.13	
33620	Apply r&l pulm art bands	FR	30.00		30.00	
33621	Transthor cath for stent	FR	16.18		16.18	
33622	Redo compl cardiac anomaly	FR	64.00		64.00	
33645	Revision of heart veins	5Y	33.00	31.50	31.30	
33647	Repair heart septum defects	5Y	35.00	33.00	33.00	
33692	Repair of heart defects	5Y	38.75	38.75	36.15	
33710	Repair of heart defects	5Y	43.00	43.00	37.50	
33860	Ascending aortic graft	FR	59.46		59.46	
33863	Ascending aortic graft	FR	58.79		58.79	
33864	Ascending aortic graft	FR	60.08		60.08	

CPT Code	Short Descriptor	CMS WRVU Review*	AMA RUC/ HCPAC Recommended Work RVU	2011 Refinement Panel Rating	CY 2012 WRVU	CMS Refinement to AMA RUC/HCPAC Rec'd Time
33875	Thoracic aortic graft	5Y	56.83	56.83	50.72	
33910	Remove lung artery emboli	5Y	52.33	52.33	48.21	
33916	Surgery of great vessel	5Y	78.00		78.00	
33935	Transplantation, heart/lung	5Y	100.00	100.00	91.78	
33975	Implant ventricular device	5Y	25.00		25.00	
33976	Implant ventricular device	5Y	30.75		30.75	
33977	Remove ventricular device	5Y	20.86		20.86	
33978	Remove ventricular device	5Y	25.00		25.00	
33979	Insert intracorporeal device	5Y	37.50		37.50	
33980	Remove intracorporeal device	5Y	40.00	40.00	33.50	
33981	Replace vad pump ext	5Y	16.11		16.11	
33982	Replace vad intra w/o bp	5Y	37.86		37.86	
33983	Replace vad intra w/bp	5Y	44.54		44.54	
34900	Endovasc iliac repr w/graft	FR	16.85		16.85	
35188	Repair blood vessel lesion	5Y	18.50	18.50	18.00	
35471	Repair arterial blockage	FR	10.05		10.05	
35612	Artery bypass graft	5Y	22.00	22.00	20.35	
35800	Explore neck vessels	5Y	13.89	13.89	12.00	
35840	Explore abdominal vessels	5Y	21.19	21.19	20.75	
35860	Explore limb vessels	5Y	16.89	16.89	15.25	
36200	Place catheter in aorta	5Y	3.02		3.02	
36246	Place catheter in artery	5Y	5.27		5.27	
36247	Place catheter in artery	5Y	7.00	7.00	6.29	
36410	Non-routine bl draw > 3 yrs	FR	0.18		0.18	
36470	Injection therapy of vein	5Y	1.10		1.10	
36471	Injection therapy of veins	5Y	1.65		1.65	
36600	Withdrawal of arterial blood	5Y	0.32		0.32	Yes
36819	Av fuse, uppr arm, basilic	5Y	14.47	14.47	13.29	Yes
36821	Av fusion direct any site	5Y	12.11		12.11	
36825	Artery-vein autograft	5Y	15.13	15.13	14.17	Yes
37140	Revision of circulation	5Y	40.00		40.00	
37145	Revision of circulation	5Y	37.00		37.00	
37160	Revision of circulation	5Y	38.00		38.00	
37180	Revision of circulation	5Y	36.50		36.50	
37181	Splice spleen/kidney veins	5Y	40.00		40.00	
37205	Transcath iv stent percut	FR	8.27		8.27	
37206	Transcath iv stent/perc addl	FR	4.12		4.12	
37207	Transcath iv stent open	FR	8.27		8.27	
37208	Transcath iv stent/open addl	FR	4.12		4.12	
37220	Iliac revasc	FR	8.15		8.15	
37221	Iliac revasc w/stent	FR	10.00		10.00	
37222	Iliac revasc add-on	FR	3.73		3.73	
37223	Iliac revasc w/stent add-on	FR	4.25		4.25	
37224	Fem/popl revas w/tla	FR	9.00		9.00	
37225	Fem/popl revas w/ather	FR	12.00		12.00	
37226	Fem/popl revasc w/stent	FR	10.49		10.49	
37227	Fem/popl revasc stnt & ather	FR	14.50		14.50	
37228	Tib/per revasc w/tla	FR	11.00		11.00	
37229	Tib/per revasc w/ather	FR	14.05		14.05	
37230	Tib/per revasc w/stent	FR	13.80		13.80	
37231	Tib/per revasc stent & ather	FR	15.00		15.00	
37232	Tib/per revasc add-on	FR	4.00		4.00	
37233	Tibper revasc w/ather add-on	FR	6.50		6.50	
37234	Revsc opn/prq tib/pero stent	FR	5.50		5.50	

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37235	Tib/per revasc stnt & ather	FR	7.80		7.80	
37765	Stab phleb veins xtr 10-20	FR	7.71		7.71	
37766	Phleb veins - extrem 20+	FR	9.66		9.66	
38900	Io map of sent lymph node	FR	2.50		2.50	
42415	Excise parotid gland/lesion	5Y	18.12	18.12	17.16	Yes
42420	Excise parotid gland/lesion	5Y	21.00	21.00	19.53	Yes
42440	Excise submaxillary gland	NPRM	7.13	7.13	6.14	Yes
43262	Endo cholangiopancreatograph	5Y	7.38		7.38	Yes
43283	Lap esoph lengthening	FR	4.00	4.00	2.95	
43327	Esoph fundoplasty lap	FR	18.10	18.10	13.35	
43328	Esoph fundoplasty thor	FR	27.00	27.00	19.91	
43332	Transab esoph hiat hern rpr	FR	26.60	26.60	19.62	
43333	Transab esoph hiat hern rpr	FR	30.00	30.00	21.46	
43334	Transthor diaphrag hern rpr	FR	30.00	30.00	22.12	
43335	Transthor diaphrag hern rpr	FR	33.00	33.00	23.97	
43336	Thorabd diaphr hern repair	FR	35.00	35.00	25.81	
43337	Thorabd diaphr hern repair	FR	37.50	37.50	27.65	
43338	Esoph lengthening	FR	3.00	3.00	2.21	
43415	Repair esophagus wound	5Y	44.88		44.88	
43605	Biopsy of stomach	FR	13.72		13.72	
43753	Tx gastro intub w/asp	FR	0.45		0.45	
43754	Dx gastr intub w/asp spec	FR	0.45		0.45	
43755	Dx gastr intub w/asp specs	FR	0.94		0.94	
43756	Dx duod intub w/asp spec	FR	0.77		0.77	
43757	Dx duod intub w/asp specs	FR	1.26		1.26	
45331	Sigmoidoscopy and biopsy	5Y	1.15		1.15	Yes
47480	Incision of gallbladder	FR	13.25		13.25	
47490	Incision of gallbladder	FR	4.76		4.76	
47563	Laparo cholecystectomy/graph	5Y	12.11	12.11	11.47	Yes
47564	Laparo cholecystectomy/explr	5Y	20.00	20.00	18.00	
49324	Lap insert tunnel ip cath	FR	6.32		6.32	
49327	Lap ins device for rt	FR	2.38		2.38	
49412	Ins device for rt guide open	FR	1.50		1.50	
49418	Insert tun ip cath perc	FR	4.21		4.21	
49419	Insert tun ip cath w/port	FR	7.08		7.08	
49421	Ins tun ip cath for dial opn	FR	4.21		4.21	
49422	Remove tunneled ip cath	FR	6.29		6.29	
49507	Prp i/hern init block >5 yr	5Y	10.05	10.05	9.09	Yes
49521	Rerepair ing hernia, blocked	5Y	12.44	12.44	11.48	Yes
49587	Rpr umbil hern, block > 5 yr	5Y	8.04	8.04	7.08	Yes
49652	Lap vent/abd hernia repair	5Y	12.88	12.88	11.92	Yes
49653	Lap vent/abd hern proc comp	5Y	16.21	16.21	14.94	Yes
49654	Lap inc hernia repair	5Y	15.03	15.03	13.76	Yes
49655	Lap inc hern repair comp	5Y	18.11	18.11	16.84	Yes
50250	Cryoablate renal mass open	FR	22.22		22.22	
50542	Laparo ablate renal mass	FR	21.36		21.36	
51705	Change of bladder tube	5Y	0.90		0.90	
51710	Change of bladder tube	5Y	1.35		1.35	Yes
51736	Urine flow measurement	FR	0.17		0.17	
51741	Electro-uroflowmetry first	FR	0.17		0.17	
52005	Cystoscopy & ureter catheter	5Y	2.37		2.37	
52007	Cystoscopy and biopsy	5Y	3.02		3.02	
52281	Cystoscopy and treatment	FR	2.80	2.75	2.75	
52310	Cystoscopy and treatment	5Y	2.81		2.81	

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52315	Cystoscopy and treatment	5Y	5.20		5.20	
52332	Cystoscopy and treatment	FR	2.83	2.82	2.82	
52341	Cysto w/ureter stricture tx	NPRM	5.35		5.35	
52342	Cysto w/up stricture tx	NPRM	5.85		5.85	
52343	Cysto w/renal stricture tx	NPRM	6.55		6.55	
52344	Cysto/uretero, stricture tx	NPRM	7.05		7.05	
52345	Cysto/uretero w/up stricture	NPRM	7.55		7.55	
52346	Cystouretero w/renal strict	NPRM	8.58		8.58	
52400	Cystouretero w/congen repr	NPRM	8.69		8.69	
52500	Revision of bladder neck	NPRM	8.14		8.14	
52630	Remove prostate regrowth	5Y	7.73	7.14	6.55	Yes
52640	Relieve bladder contracture	5Y	4.79		4.79	
52649	Prostate laser enucleation	5Y	15.20	14.88	14.56	Yes
53440	Male sling procedure	5Y	14.00	13.68	13.36	Yes
53445	Insert uro/ves nck sphincter	NPRM	13.00		13.00	
53860	Transurethral rf treatment	FR	3.97		3.97	
54410	Remove/replace penis prosth	NPRM	15.18		15.18	Yes
54530	Removal of testis	NPRM	8.46		8.46	
55866	Laparo radical prostatectomy	FR	32.06		32.06	
55876	Place rt device/marker pros	FR	1.73		1.73	
57155	Insert uteri tandems/ovoids	FR	5.40	5.40	5.40	
57156	Ins vag brachytx device	FR	2.69	2.69	2.69	
57287	Revise/remove sling repair	5Y	11.15		11.15	
57288	Repair bladder defect	5Y	12.13		12.13	
59400	Obstetrical care	FR	32.69		32.16	
59409	Obstetrical care	FR	14.37		14.37	
59410	Obstetrical care	FR	18.54		18.01	
59412	Antepartum manipulation	FR	1.71		1.71	
59414	Deliver placenta	FR	1.61		1.61	
59425	Antepartum care only	FR	6.31		6.31	
59426	Antepartum care only	FR	11.16		11.16	
59430	Care after delivery	FR	2.47		2.47	
59510	Cesarean delivery	FR	36.17		35.64	
59514	Cesarean delivery only	FR	16.13		16.13	
59515	Cesarean delivery	FR	22.00		21.47	
59610	Vbac delivery	FR	34.40		33.87	
59612	Vbac delivery only	FR	16.09		16.09	
59614	Vbac care after delivery	FR	20.26		19.73	
59618	Attempted vbac delivery	FR	36.69		36.16	
59620	Attempted vbac delivery only	FR	16.66		16.66	
59622	Attempted vbac after care	FR	22.53		22.00	
60220	Partial removal of thyroid	5Y	12.37	12.37	11.19	Yes
60240	Removal of thyroid	5Y	16.22	16.22	15.04	Yes
60500	Explore parathyroid glands	5Y	16.78	16.78	15.60	Yes
61781	Scan proc cranial intra	FR	3.75		3.75	
61782	Scan proc cranial extra	FR	3.18		3.18	
61783	Scan proc spinal	FR	3.75		3.75	
61885	Insrt/redo neurostim 1 array	NPRM/ FR	6.44	6.44	6.05	
62263	Epidural lysis mult sessions	NPRM	6.54	6.02	5.00	Yes
62284	Injection for myelogram	5Y	1.54		1.54	
62350	Implant spinal canal cath	NPRM	6.05		6.05	
62355	Remove spinal canal catheter	NPRM	4.35	4.18	3.55	
62360	Insert spine infusion device	NPRM	4.33		4.33	
62361	Implant spine infusion pump	NPRM	5.65	5.48	5.00	

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62362	Implant spine infusion pump	NPRM	6.10	5.95	5.60	
62365	Remove spine infusion device	NPRM	4.65	4.40	3.93	
63075	Neck spine disk surgery	FR	19.60		19.60	
63076	Neck spine disk surgery	FR	4.04		4.04	
63650	Implant neuroelectrodes	NPRM	7.20	7.18	7.15	
63655	Implant neuroelectrodes	5Y	11.56	11.56	10.92	Yes
63685	Insrt/redo spine n generator	NPRM	6.05	5.78	5.19	
64405	N block inj, occipital	5Y	1.00	1.00	0.94	
64415	N block inj brachial plexus	FR	1.48		1.48	
64445	N block inj sciatic sng	FR	1.48		1.48	
64447	N block inj fem single	FR	1.50		1.50	
64479	Inj foramen epidural c/t	FR	2.29		2.29	
64480	Inj foramen epidural add-on	FR	1.20		1.20	
64483	Inj foramen epidural l/s	FR	1.90	1.90	1.90	
64484	Inj foramen epidural add-on	FR	1.00		1.00	
64566	Neuroeltrd stim post tibial	FR	0.60		0.60	
64568	Inc for vagus n elect impl	FR	11.19	11.47	9.00	
64569	Revise/repl vagus n eltrd	FR	15.00	15.00	11.00	
64570	Remove vagus n eltrd	FR	13.00	13.00	9.10	
64581	Implant neuroelectrodes	FR	12.20		12.20	
64611	Chemodenerv saliv glands	FR	1.03		1.03	
64708	Revise arm/leg nerve	FR	6.36		6.36	
64708	Revise arm/leg nerve	NPRM	6.36		6.36	
64712	Revision of sciatic nerve	FR	8.07		8.07	
64713	Revision of arm nerve(s)	FR	11.40		11.40	
64714	Revise low back nerve(s)	FR	10.55		10.55	
64831	Repair of digit nerve	NPRM	9.16		9.16	
65285	Repair of eye wound	NPRM	16.00	16.00	15.36	Yes
65778	Cover eye w/membrane	FR	1.19		1.19	
65779	Cover eye w/membrane stent	FR	3.92		3.92	
65780	Ocular reconst transplant	FR	10.73		10.73	
66174	Translum dil eye canal	FR	12.85		12.85	
66175	Trnslum dil eye canal w/stnt	FR	13.60		13.60	
66761	Revision of iris	FR	3.00		3.00	
67028	Injection eye drug	FR	1.44	1.96	1.44	
69220	Clean out mastoid cavity	5Y	0.83		0.83	
69801	Incise inner ear	FR	2.06		2.06	
69802	Incise inner ear	FR	13.50		13.50	
71250	Ct thorax w/o dye	FR	1.16	1.02	1.02	
72125	Ct neck spine w/o dye	FR	1.16	1.07	1.07	
72128	Ct chest spine w/o dye	FR	1.16	1.00	1.00	
72131	Ct lumbar spine w/o dye	FR	1.16	1.00	1.00	
73080	X-ray exam of elbow	FR	0.17		0.17	
73200	Ct upper extremity w/o dye	FR	1.09	1.00	1.00	
73510	X-ray exam of hip	FR	0.21		0.21	
73610	X-ray exam of ankle	FR	0.17		0.17	
73630	X-ray exam of foot	FR	0.17		0.17	
73700	Ct lower extremity w/o dye	FR	1.09	1.00	1.00	
74176	Ct abd & pelvis w/o contrast	FR	1.74		1.74	
74177	Ct abdomen&pelvis w/contrast	FR	1.82		1.82	
74178	Ct abd&pelv 1+ section/regns	FR	2.01		2.01	
75954	Iliac aneurysm endovas rpr	FR	0.00		0.00	
75960	Transcath iv stent rs&i	FR	0.82		0.82	
75962	Repair arterial blockage	FR	0.54		0.54	

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75964	Repair artery blockage each	FR	0.36		0.36	
76881	Us xtr non-vasc complete	FR	0.72	0.63	0.63	
76882	Us xtr non-vasc lmtd	FR	0.50	0.49	0.49	
76942	Echo guide for biopsy	FR	0.67		0.67	
77003	Fluoroguide for spine inject	FR	0.60		0.60	
77012	Ct scan for needle biopsy	FR	1.16		1.16	
77427	Radiation tx management x5	FR	3.45		3.37	
78264	Gastric emptying study	5Y	0.95	0.80	0.80	Yes
88120	Cytp urne 3-5 probes ea spec	FR	1.20		1.20	
88121	Cytp urine 3-5 probes cmptr	FR	1.00		1.00	
88172	Cytp dx eval fna 1st ea site	FR	0.69	0.69	0.69	
88173	Cytopath eval fna report	FR	1.39		1.39	
88177	Cytp c/v auto thin lyr addl	FR	0.42		0.42	
88300	Surgical path gross	FR	0.08		0.08	
88302	Tissue exam by pathologist	FR	0.13		0.13	
88304	Tissue exam by pathologist	FR	0.22		0.22	
88305	Tissue exam by pathologist	FR	0.75		0.75	
88307	Tissue exam by pathologist	FR	1.59		1.59	
88309	Tissue exam by pathologist	FR	2.80		2.80	
88363	Xm archive tissue molec anal	FR	0.37		0.37	
88367	Insitu hybridization auto	FR	1.30		1.30	
88368	Insitu hybridization manual	FR	1.40		1.40	
90460	Imadm any route 1st vac/tox	FR	0.20	0.23	0.17	
90461	Inadm any route addl vac/tox	FR	0.16	0.17	0.15	
90870	Electroconvulsive therapy	FR	2.50		2.50	
90935	Hemodialysis one evaluation	FR	1.48		1.48	
90937	Hemodialysis repeated eval	FR	2.11		2.11	
90945	Dialysis one evaluation	FR	1.56		1.56	
90947	Dialysis repeated eval	FR	2.52		2.52	
91010	Esophagus motility study	FR	1.50	1.50	1.28	
91013	Esophgl motil w/stim/perfus	FR	0.21	0.21	0.18	
91038	Esoph imped funct test > 1h	FR	1.10		1.10	
91117	Colon motility 6 hr study	FR	2.45		2.45	
91132	Electrogastrography	FR	0.52		0.52	
91133	Electrogastrography w/test	FR	0.66		0.66	
92081	Visual field examination(s)	FR	0.30		0.30	
92082	Visual field examination(s)	FR	0.40		0.40	
92132	Cmptr ophth dx img ant segmt	FR	0.35		0.35	
92133	Cmptr ophth img optic nerve	FR	0.50		0.50	
92134	Cptr ophth dx img post segmt	FR	0.50		0.50	
92227	Remote dx retinal imaging	FR	0.00		0.00	
92228	Remote retinal imaging mgmt	FR	0.44	0.37	0.37	
92285	Eye photography	FR	0.05		0.05	
92504	Ear microscopy examination	FR	0.18		0.18	
92507	Speech/hearing therapy	FR	1.30		1.30	
92508	Speech/hearing therapy	FR	0.43	0.43	0.33	
92511	Nasopharyngoscopy	5Y	0.61		0.61	Yes
92606	Non-speech device service	FR	1.40		1.40	
92607	Ex for speech device rx 1hr	FR	1.85		1.85	
92608	Ex for speech device rx addl	FR	0.70		0.70	
92609	Use of speech device service	FR	1.50		1.50	
92950	Heart/lung resuscitation cpr	5Y	4.50	4.50	4.00	Yes
93040	Rhythm ecg with report	FR	0.15		0.15	
93042	Rhythm ecg report	FR	0.15		0.15	

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93224	Ecg monit/reprt up to 48 hrs	FR	0.52		0.52	
93227	Ecg monit/reprt up to 48 hrs	FR	0.52		0.52	
93228	Remote 30 day ecg rev/report	FR	0.52		0.52	
93268	Ecg record/review	FR	0.52		0.52	
93272	Ecg/review interpret only	FR	0.52		0.52	
93321	Doppler echo exam, heart	5Y	0.15		0.15	
93563	Inject congenital card cath	FR	2.00		1.11	
93564	Inject hrt congntl art/grft	FR	2.10		1.13	
93565	Inject l ventr/atrial angio	FR	1.90		0.86	
93652	Ablate heart dysrhythm focus	FR	17.65		17.65	
93922	Upr/l xtremity art 2 levels	FR	0.25		0.25	
93923	Upr/lxtr art stdy 3+ lvls	FR	0.45		0.45	
93924	Lwr xtr vasc stdy bilat	FR	0.50		0.50	
94660	Pos airway pressure, cpap	5Y	0.76		0.76	
95800	Slp stdy unattended	FR	1.05		1.05	
95801	Slp stdy unatnd w/anal	FR	1.00		1.00	
95803	Actigraphy testing	FR	0.90		0.90	
95805	Multiple sleep latency test	FR	1.20		1.20	
95806	Sleep study unatt&resp efft	FR	1.28		1.25	
95807	Sleep study attended	FR	1.25		1.28	
95808	Polysomnography 1-3	FR	1.74		1.74	
95810	Polysomnography 4 or more	FR	2.50		2.50	
95811	Polysomnography w/cpap	FR	2.60		2.60	
95857	Cholinesterase challenge	FR	0.53		0.53	
95950	Ambulatory eeg monitoring	FR	1.51		1.51	
95953	Eeg monitoring/computer	FR	3.08		3.08	
95956	Eeg monitor technol attended	FR	3.61		3.61	
96105	Assessment of aphasia	FR	1.75		1.75	
96446	Chemotx admn prtl cavity	FR	0.37		0.37	
97597	Rmvl devital tis 20 cm/<	FR	0.54	0.54	0.51	
97598	Rmvl devital tis addl 20 cm<	FR	0.40	0.24	0.24	
98925	Osteopathic manipulation	5Y	0.50	0.49	0.46	Yes
98926	Osteopathic manipulation	5Y	0.75	0.74	0.71	Yes
98927	Osteopathic manipulation	5Y	1.00	0.99	0.96	Yes
98928	Osteopathic manipulation	5Y	1.25	1.24	1.21	Yes
98929	Osteopathic manipulation	5Y	1.50	1.49	1.46	Yes
99218	Observation care	5Y	1.92	1.92	1.92	
99219	Observation care	5Y	2.60	2.60	2.60	
99220	Observation care	5Y	3.56	3.56	3.56	
99224	Subsequent observation care	FR	0.76	0.76	0.76	
99225	Subsequent observation care	FR	1.39	1.39	1.39	
99226	Subsequent observation care	FR	2.00	2.00	2.00	
99234	Observ/hosp same date	5Y	2.56	2.56	2.56	
99235	Observ/hosp same date	5Y	3.24	3.24	3.24	
99236	Observ/hosp same date	5Y	4.20	4.20	4.20	
99315	Nursing fac discharge day	5Y	1.28		1.28	
99316	Nursing fac discharge day	5Y	1.90		1.90	
99460	Init nb em per day, hosp	5Y	1.92		1.92	
99462	Sbsq nb em per day, hosp	5Y	0.84		0.84	
99463	Same day nb discharge	5Y	2.13		2.13	

* FR = 2011 PFS final rule with comment period (75 FR 73170)
5Y = Fourth Five-Year Review (76 FR 32410)
NPRM = CY 2012 PFS proposed rule (76 FR 42772)

Table 16: CY 2011 and AMA RUC-Recommended Physician Time and Work Values for CY 2012

HCPCS Code	Short Descriptor	Year	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Critical Care, First Hour- 99291	Critical Care, Addl 30 Mins- 99292	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day-99238	Hospital Discharge Day-99239	Subsequent Observation Care- 99224	Subsequent Observation Care- 99225	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213	Office/Outpatient Visit, Est- 99214	Office/Outpatient Visit, Est- 99215
10140	Drainage of hematoma/fluid	CY 2011	1.58	7.0	0.0	0.0	16.0	7.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
10140	Drainage of hematoma/fluid	RUC Rec	1.58	17.0	3.0	5.0	15.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
10140	**Drainage of hematoma/fluid**	**CY 2012**	**1.58**	**17.0**	**3.0**	**5.0**	**15.0**	**10.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**
11732	Remove nail plate add-on	CY 2011	0.57	0.0	0.0	0.0	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
11732	Remove nail plate add-on	RUC Rec	0.48	0.0	1.0	1.0	10.0	3.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
11732	**Remove nail plate add-on**	**CY 2012**	**0.44**	**0.0**	**1.0**	**1.0**	**10.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
11765	Excision of nail fold toe	CY 2011	0.74	7.0	0.0	0.0	24.0	7.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
11765	Excision of nail fold toe	RUC Rec	1.48	17.0	1.0	5.0	15.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
11765	**Excision of nail fold toe**	**CY 2012**	**1.22**	**11.0**	**1.0**	**5.0**	**15.0**	**3.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**
12035	Intmd wnd repair s/tr/ext	CY 2011	3.47	9.0	0.0	0.0	68.0	9.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12035	Intmd wnd repair s/tr/ext	RUC Rec	3.60	11.0	3.0	5.0	60.0	10.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12035	**Intmd wnd repair s/tr/ext**	**CY 2012**	**3.50**	**11.0**	**3.0**	**5.0**	**60.0**	**10.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**
12036	Intmd wnd repair s/tr/ext	CY 2011	4.09	12.0	0.0	0.0	84.0	11.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12036	Intmd wnd repair s/tr/ext	RUC Rec	4.50	13.0	3.0	5.0	75.0	12.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12036	**Intmd wnd repair s/tr/ext**	**CY 2012**	**4.23**	**13.0**	**3.0**	**5.0**	**70.0**	**12.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**
12037	Intmd wnd repair s/tr/ext	CY 2011	4.71	13.0	0.0	0.0	102.0	11.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12037	Intmd wnd repair s/tr/ext	RUC Rec	5.25	13.0	3.0	5.0	90.0	12.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12037	**Intmd wnd repair s/tr/ext**	**CY 2012**	**5.00**	**13.0**	**3.0**	**5.0**	**90.0**	**12.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**
12045	Intmd wnd repair n-hg/genit	CY 2011	3.68	10.0	0.0	0.0	75.0	10.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12045	Intmd wnd repair n-hg/genit	RUC Rec	3.90	10.0	3.0	5.0	60.0	11.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
12045	**Intmd wnd repair n-hg/genit**	**CY 2012**	**3.75**	**10.0**	**3.0**	**5.0**	**60.0**	**11.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**
12046	Intmd wnd repair n-hg/genit	CY 2011	4.29	12.0	0.0	0.0	90.0	11.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12046	Intmd wnd repair n-hg/genit	RUC Rec	4.60	13.0	3.0	5.0	80.0	13.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
12046	**Intmd wnd repair n-hg/genit**	**CY 2012**	**4.30**	**9.0**	**3.0**	**5.0**	**80.0**	**9.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**
12047	Intmd wnd repair n-hg/genit	CY 2011	4.69	13.0	0.0	0.0	111.0	12.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12047	Intmd wnd repair n-hg/genit	RUC Rec	5.50	13.0	3.0	5.0	100.0	15.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
12047	**Intmd wnd repair n-hg/genit**	**CY 2012**	**4.95**	**9.0**	**3.0**	**5.0**	**100.0**	**10.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**
12055	Intmd wnd repair face/mm	CY 2011	4.47	13.0	0.0	0.0	89.0	12.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12055	Intmd wnd repair face/mm	RUC Rec	4.65	13.0	3.0	5.0	70.0	13.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
12055	**Intmd wnd repair face/mm**	**CY 2012**	**4.50**	**13.0**	**3.0**	**5.0**	**60.0**	**13.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**
12056	Intmd wnd repair face/mm	CY 2011	5.28	14.0	0.0	0.0	106.0	12.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12056	Intmd wnd repair face/mm	RUC Rec	5.50	13.0	3.0	5.0	85.0	13.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0

HCPCS Code	Short Descriptor	Year	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Critical Care, First Hour- 99291	Critical Care, Addl 30 Mins- 99292	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day-99238	Hospital Discharge Day-99239	Subsequent Observation Care- 99224	Subsequent Observation Care- 99225	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213	Office/Outpatient Visit, Est- 99214	Office/Outpatient Visit, Est- 99215
12056	**Intmd wnd repair face/mm**	**CY 2012**	**5.30**	**13.0**	**3.0**	**5.0**	**70.0**	**13.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**
12057	Intmd wnd repair face/mm	CY 2011	6.00	15.0	0.0	0.0	131.0	13.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
12057	Intmd wnd repair face/mm	RUC Rec	6.28	13.0	3.0	5.0	100.0	15.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
12057	**Intmd wnd repair face/mm**	**CY 2012**	**6.00**	**13.0**	**3.0**	**5.0**	**90.0**	**15.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**
13100	Repair of wound or lesion	CY 2011	3.17	21.0	0.0	0.0	33.0	21.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
13100	Repair of wound or lesion	RUC Rec	3.17	17.0	1.0	5.0	35.0	16.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
13100	**Repair of wound or lesion**	**CY 2012**	**3.17**	**21.0**	**0.0**	**0.0**	**33.0**	**21.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**
13101	Repair of wound or lesion	CY 2011	3.96	21.0	0.0	0.0	53.0	21.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
13101	Repair of wound or lesion	RUC Rec	3.96	17.0	1.0	5.0	56.0	18.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
13101	**Repair of wound or lesion**	**CY 2012**	**3.96**	**21.0**	**0.0**	**0.0**	**53.0**	**21.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**0.0**
15120	Skn splt a-grft fac/nck/hf/g	CY 2011	11.16	31	0	25	102	25	0.0	0.0	0.5	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0	0.0
15120	Skn splt a-grft fac/nck/hf/g	RUC Rec	10.15	40	12	20	75	25	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0
15120	**Skn splt a-grft fac/nck/hf/g**	**CY 2012**	**10.15**	**40**	**12**	**20**	**75**	**30**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**0.0**
15732	Muscle-skin graft, head/neck	CY 2011	19.90	60.0	0.0	0.0	150.0	30.0	0.0	0.0	4.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0	0.0
15732	Muscle-skin graft, head/neck	RUC Rec	19.83	40.0	12.0	20.0	150.0	30.0	0.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	1.0	0.0
15732	**Muscle-skin graft, head/neck**	**CY 2012**	**16.38**	**40.0**	**12.0**	**20.0**	**150.0**	**60.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**2.0**	**1.0**	**0.0**
17270	Destruction of skin lesions	CY 2011	1.37	4.0	0.0	0.0	15.0	4.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
17270	Destruction of skin lesions	RUC Rec	1.37	7.0	0.0	2.0	15.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
17270	**Destruction of skin lesions**	**CY 2012**	**1.37**	**7.0**	**0.0**	**2.0**	**15.0**	**5.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**
17271	Destruction of skin lesions	CY 2011	1.54	6.0	0.0	0.0	18.0	6.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
17271	Destruction of skin lesions	RUC Rec	1.54	7.0	0.0	2.0	19.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
17271	**Destruction of skin lesions**	**CY 2012**	**1.54**	**7.0**	**0.0**	**2.0**	**19.0**	**5.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**
17274	Destruction of skin lesions	CY 2011	2.64	8.0	0.0	0.0	32.0	8.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
17274	Destruction of skin lesions	RUC Rec	2.64	7.0	0.0	2.0	32.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
17274	**Destruction of skin lesions**	**CY 2012**	**2.64**	**7.0**	**0.0**	**2.0**	**32.0**	**5.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**
19302	P-mastectomy w/ln removal	CY 2011	13.99	41	0	25	109	25	0.0	0.0	2.5	0.0	0.0	1.0	0.0	0.0	0.0	0.0	3.5	0.0	0.0	0.0
19302	P-mastectomy w/ln removal	RUC Rec	13.99	40	3	15	100	20	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	1.0	1.0	1.0	0.0
19302	**P-mastectomy w/ln removal**	**CY 2012**	**13.99**	**40**	**3**	**15**	**100**	**20**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**1.0**	**0.0**
21025	Excision of bone, lower jaw	CY 2011	10.03	60	10	15	90	30	0	0	0	0	0	0	0	0	0	0	2	2	0	0
21025	Excision of bone, lower jaw	RUC Rec	10.03	60	10	15	90	30	0	0	0	0	0	0	0	0	0	0	2	2	0	0
21025	**Excision of bone, lower jaw**	**CY 2012**	**10.03**	**60**	**10**	**15**	**90**	**30**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**2**	**0**	**0**
22521	Percut vertebroplasty lumb	CY 2011	8.65	30	0	0	75	30	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0
22521	Percut vertebroplasty lumb	RUC Rec	8.65	30	0	0	75	30	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0
22521	**Percut vertebroplasty lumb**	**CY 2012**	**8.65**	**30**	**0**	**0**	**75**	**30**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**
22523	Percut kyphoplasty thor	CY 2011	9.26	30	15	15	58	20	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0

HCPCS Code	Short Descriptor	Year	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Critical Care, First Hour- 99291	Critical Care, Addl 30 Mins- 99292	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day-99238	Hospital Discharge Day-99239	Subsequent Observation Care- 99224	Subsequent Observation Care- 99225	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213	Office/Outpatient Visit, Est- 99214	Office/Outpatient Visit, Est- 99215
22523	Percut kyphoplasty thor	RUC Rec	9.26	30	15	15	58	20	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0
22523	**Percut kyphoplasty thor**	**CY 2012**	**9.04**	**30**	**15**	**15**	**58**	**20**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**
22524	Percut kyphoplasty lumbar	CY 2011	8.86	30	15	15	55	20	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0
22524	Percut kyphoplasty lumbar	RUC Rec	8.86	30	15	15	55	20	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0
22524	**Percut kyphoplasty lumbar**	**CY 2012**	**8.54**	**30**	**15**	**15**	**55**	**20**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**	**0.0**
23415	Release of shoulder ligament	CY 2011	9.23	40	15	15	60	20	0	0	0	0	0	0.5	0	0	0	0	2	2	0	0
23415	Release of shoulder ligament	RUC Rec	9.23	40	15	15	60	20	0	0	0	0	0	0.5	0	0	0	0	2	2	0	0
23415	**Release of shoulder ligament**	**CY 2012**	**9.23**	**40**	**15**	**15**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
25116	Remove wrist/forearm lesion	CY 2011	7.56	40	10	15	60	20	0	0	0	0	0	0.5	0	0	0	0	1	3	0	0
25116	Remove wrist/forearm lesion	RUC Rec	7.56	40	10	15	60	20	0	0	0	0	0	0.5	0	0	0	0	1	3	0	0
25116	**Remove wrist/forearm lesion**	**CY 2012**	**7.56**	**40**	**10**	**15**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**1**	**3**	**0**	**0**
25600	Treat fracture radius/ulna	CY 2011	2.78	13.0	0.0	0.0	25.0	12.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0	0.0	0.0	0.0
25600	Treat fracture radius/ulna	RUC Rec	2.78	7.0	0.0	0.0	15.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.0	0.0	0.0	0.0
25600	**Treat fracture radius/ulna**	**CY 2012**	**2.78**	**5.0**	**0.0**	**0.0**	**15.0**	**7.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**5.0**	**0.0**	**0.0**	**0.0**
25605	Treat fracture radius/ulna	CY 2011	7.25	22.0	0.0	15.0	35.0	23.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.5	0.0	0.0
25605	Treat fracture radius/ulna	RUC Rec	6.50	14.0	1.0	5.0	30.0	20.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	4.0	1.0	0.0	0.0
25605	**Treat fracture radius/ulna**	**CY 2012**	**6.25**	**14.0**	**1.0**	**5.0**	**30.0**	**13.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**4.0**	**1.0**	**0.0**	**0.0**
27385	Repair of thigh muscle	CY 2011	8.11	22.0	0.0	25.0	66.0	19.0	0.0	0.0	1.5	0.0	0.0	1.0	0.0	0.0	0.0	0.0	3.5	0.0	0.0	0.0
27385	Repair of thigh muscle	RUC Rec	8.11	33.0	9.0	15.0	60.0	20.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	3.0	1.0	0.0	0.0
27385	**Repair of thigh muscle**	**CY 2012**	**6.93**	**33.0**	**9.0**	**15.0**	**60.0**	**30.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**3.0**	**1.0**	**0.0**	**0.0**
27530	Treat knee fracture	CY 2011	4.09	17.0	0.0	15.0	33.0	8.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	4.0	0.0	0.0	0.0
27530	Treat knee fracture	RUC Rec	2.81	7.0	2.0	0.0	15.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0	0.0	0.0
27530	**Treat knee fracture**	**CY 2012**	**2.65**	**5.0**	**0.0**	**0.0**	**15.0**	**7.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**4.0**	**0.0**	**0.0**	**0.0**
27792	Treatment of ankle fracture	CY 2011	9.71	40.0	10.0	15.0	60.0	20.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	2.0	2.0	0.0	0.0
27792	Treatment of ankle fracture	RUC Rec	9.71	33.0	10.0	15.0	60.0	20.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	2.0	2.0	0.0	0.0
27792	**Treatment of ankle fracture**	**CY 2012**	**8.75**	**33.0**	**10.0**	**15.0**	**60.0**	**30.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**2.0**	**0.0**	**0.0**
28002	Treatment of foot infection	CY 2011	5.93	50	0	0	60	30	0.0	0.0	3.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	3.0	0.0	0.0
28002	Treatment of foot infection	RUC Rec	5.34	30	3	15	30	20	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0
28002	**Treatment of foot infection**	**CY 2012**	**4.00**	**30**	**3**	**15**	**30**	**20**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**0.0**	**0.0**
28120	Part removal of ankle/heel	CY 2011	8.27	33.0	10.0	15.0	50.0	20.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	3.0	2.0	0.0	0.0
28120	Part removal of ankle/heel	RUC Rec	8.27	33.0	10.0	15.0	50.0	20.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	3.0	2.0	0.0	0.0
28120	**Part removal of ankle/heel**	**CY 2012**	**7.31**	**33.0**	**10.0**	**15.0**	**50.0**	**30.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**3.0**	**2.0**	**0.0**	**0.0**
28122	Partial removal of foot bone	CY 2011	7.72	33.0	10.0	15.0	50.0	20.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	2.0	2.0	0.0	0.0
28122	Partial removal of foot bone	RUC Rec	7.72	33.0	10.0	15.0	45.0	20.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	2.0	2.0	0.0	0.0
28122	**Partial removal of foot bone**	**CY 2012**	**6.76**	**33.0**	**10.0**	**15.0**	**45.0**	**30.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**2.0**	**0.0**	**0.0**

HCPCS Code	Short Descriptor	Year	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Critical Care, First Hour- 99291	Critical Care, Addl 30 Mins- 99292	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day-99238	Hospital Discharge Day-99239	Subsequent Observation Care- 99224	Subsequent Observation Care- 99225	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213	Office/Outpatient Visit, Est- 99214	Office/Outpatient Visit, Est- 99215
28285	Repair of hammertoe	CY 2011	4.76	18	0	15	31	21	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.5	0.0	0.0	0.0
28285	Repair of hammertoe	RUC Rec	5.62	30	3	15	30	15	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	2.0	2.0	0.0	0.0
28285	**Repair of hammertoe**	**CY 2012**	**5.62**	**30**	**3**	**15**	**30**	**15**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**2.0**	**0.0**	**0.0**
28715	Fusion of foot bones	CY 2011	14.60	60.0	0.0	0.0	130.0	30.0	0.0	0.0	2.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0	0.0
28715	Fusion of foot bones	RUC Rec	14.60	40.0	3.0	15.0	125.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	2.0	4.0	0.0	0.0
28715	**Fusion of foot bones**	**CY 2012**	**13.42**	**40.0**	**3.0**	**15.0**	**125.0**	**40.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**4.0**	**0.0**	**0.0**
28725	Fusion of foot bones	CY 2011	12.18	45	10	15	90	20	0	0	1	0	0	1	0	0	0	0	2	3	0	0
28725	Fusion of foot bones	RUC Rec	12.18	33	10	15	90	20	0	0	0	0	0	1	0	1	0	0	2	3	0	0
28725	**Fusion of foot bones**	**CY 2012**	**11.22**	**33**	**10**	**15**	**90**	**30**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**2**	**0**	**0**	**0**
28730	Fusion of foot bones	CY 2011	12.42	45	10	15	100	20	0	0	1	0	0	1	0	0	0	0	2	3	0	0
28730	Fusion of foot bones	RUC Rec	12.42	33	10	15	100	20	0	0	0	0	0	1	0	1	0	0	2	3	0	0
28730	**Fusion of foot bones**	**CY 2012**	**10.70**	**33**	**10**	**15**	**100**	**30**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**2**	**3**	**0**	**0**
28820	Amputation of toe	CY 2011	5.00	22.0	0.0	25.0	42.0	16.0	0.0	0.0	3.5	0.0	0.0	1.0	0.0	0.0	0.0	0.0	3.5	0.0	0.0	0.0
28820	Amputation of toe	RUC Rec	7.00	33.0	10.0	15.0	30.0	20.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	2.0	2.0	0.0	0.0
28820	**Amputation of toe**	**CY 2012**	**5.82**	**33.0**	**10.0**	**15.0**	**30.0**	**30.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**2.0**	**0.0**	**0.0**
28825	Partial amputation of toe	CY 2011	6.01	33.0	10.0	15.0	30.0	20.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	2.0	2.0	0.0	0.0
28825	Partial amputation of toe	RUC Rec	6.01	33.0	10.0	15.0	30.0	20.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	2.0	2.0	0.0	0.0
28825	**Partial amputation of toe**	**CY 2012**	**5.37**	**33.0**	**10.0**	**15.0**	**30.0**	**20.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**2.0**	**0.0**	**0.0**
29125	Apply forearm splint	CY 2011	0.59	6.0	0.0	0.0	21.0	7.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
29125	Apply forearm splint	RUC Rec	0.59	7.0	0.0	0.0	15.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
29125	**Apply forearm splint**	**CY 2012**	**0.50**	**5.0**	**0.0**	**0.0**	**15.0**	**3.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
29126	Apply forearm splint	CY 2011	0.77	8.0	0.0	0.0	25.0	8.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
29126	Apply forearm splint	RUC Rec	0.77	7.0	0.0	0.0	30.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
29126	**Apply forearm splint**	**CY 2012**	**0.68**	**5.0**	**0.0**	**0.0**	**30.0**	**3.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
29515	Application lower leg splint	CY 2011	0.73	9.0	0.0	0.0	22.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
29515	Application lower leg splint	RUC Rec	0.73	7.0	0.0	0.0	15.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
29515	**Application lower leg splint**	**CY 2012**	**0.73**	**5.0**	**0.0**	**0.0**	**15.0**	**3.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
29540	Strapping of ankle and/or ft	CY2011	0.32	7.0	0.0	0.0	9.0	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
29540	Strapping of ankle and/or ft	RUC Rec	0.39	7.0	0.0	0.0	9.0	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
29540	**Strapping of ankle and/or ft**	**CY2012**	**0.39**	**7.0**	**0.0**	**0.0**	**9.0**	**2.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
29550	Strapping of toes	CY2011	0.15	5.0	0.0	0.0	5.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
29550	Strapping of toes	RUC Rec	0.25	7.0	0.0	0.0	5.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
29550	**Strapping of toes**	**CY2012**	**0.25**	**5.0**	**0.0**	**0.0**	**5.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
32851	Lung transplant single	CY 2011	41.61	240	0	0	360	840	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	3.0	3.0
32851	Lung transplant single	RUC Rec	63.00	80	30	30	240	90	3.0	1.0	1.0	3.0	3.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0

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32851	**Lung transplant single**	**CY 2012**	**59.64**	**80**	**30**	**30**	**240**	**90**	**3.0**	**1.0**	**1.0**	**3.0**	**3.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**
32852	Lung transplant with bypass	CY 2011	45.48	240	0	0	390	840	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0	3.0	4.0
32852	Lung transplant with bypass	RUC Rec	74.37	80	30	30	300	90	3.0	1.0	1.0	4.0	4.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0
32852	**Lung transplant with bypass**	**CY 2012**	**65.50**	**80**	**30**	**30**	**300**	**90**	**3.0**	**1.0**	**1.0**	**4.0**	**4.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**
32853	Lung transplant double	CY 2011	50.78	240	0	0	480	840	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	3.0	3.0
32853	Lung transplant double	RUC Rec	90.00	80	20	30	375	90	3.0	1.0	1.0	4.0	5.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0
32853	**Lung transplant double**	**CY 2012**	**84.48**	**80**	**20**	**30**	**375**	**90**	**3.0**	**1.0**	**1.0**	**4.0**	**5.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**
32854	Lung transplant with bypass	CY 2011	54.74	240	0	0	480	840	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	4.0	4.0
32854	Lung transplant with bypass	RUC Rec	95.00	80	20	30	400	90	3.0	1.0	1.0	6.0	6.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0
32854	**Lung transplant with bypass**	**CY 2012**	**90.00**	**80**	**20**	**30**	**400**	**90**	**3.0**	**1.0**	**1.0**	**6.0**	**6.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**
33030	Partial removal of heart sac	CY 2011	22.39	37	26	25	179	50	4.5	0.0	6.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.5	0.0
33030	Partial removal of heart sac	RUC Rec	39.50	40	3	20	180	45	2.0	0.0	1.0	2.0	2.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0	0.0
33030	**Partial removal of heart sac**	**CY 2012**	**36.00**	**40**	**3**	**20**	**180**	**45**	**2.0**	**0.0**	**1.0**	**2.0**	**2.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**1.0**	**0.0**
33120	Removal of heart lesion	CY 2011	27.45	42	17	25	191	56	2.5	0.0	8.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.5	0.0
33120	Removal of heart lesion	RUC Rec	42.88	40	3	20	205	60	1.0	0.0	1.0	2.0	2.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
33120	**Removal of heart lesion**	**CY 2012**	**38.45**	**40**	**3**	**20**	**205**	**60**	**1.0**	**0.0**	**1.0**	**2.0**	**2.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**
33412	Replacement of aortic valve	CY 2011	43.94	40	0	0	300	60	0.0	0.0	6.0	1.0	0.0	0.0	1.0	0.0	0.0	1.0	1.0	1.0	1.0	0.0
33412	Replacement of aortic valve	RUC Rec	60.00	40	3	20	300	60	2.0	0.0	1.0	1.0	3.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
33412	**Replacement of aortic valve**	**CY 2012**	**59.00**	**40**	**3**	**20**	**300**	**60**	**2.0**	**0.0**	**1.0**	**1.0**	**3.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**
33468	Revision of tricuspid valve	CY 2011	32.94	47	37	25	228	49	2.5	0.0	8.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	1.5	0.0
33468	Revision of tricuspid valve	RUC Rec	50.00	40	3	20	240	60	2.0	0.0	1.0	1.0	3.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
33468	**Revision of tricuspid valve**	**CY 2012**	**45.13**	**40**	**3**	**20**	**240**	**60**	**2.0**	**0.0**	**1.0**	**1.0**	**3.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**
33645	Revision of heart veins	CY 2011	28.10	41	30	25	185	58	3.5	0.0	7.5	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	1.5	0.0
33645	Revision of heart veins	RUC Rec	33.00	40	3	20	175	45	1.0	0.0	1.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
33645	**Revision of heart veins**	**CY 2012**	**31.30**	**40**	**3**	**20**	**175**	**45**	**1.0**	**0.0**	**1.0**	**1.0**	**1.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**
33647	Repair heart septum defects	CY 2011	29.53	120	0	0	240	300	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0
33647	Repair heart septum defects	RUC Rec	35.00	40	3	20	180	53	1.0	0.0	1.0	1.0	2.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
33647	**Repair heart septum defects**	**CY 2012**	**33.00**	**40**	**3**	**20**	**180**	**53**	**1.0**	**0.0**	**1.0**	**1.0**	**2.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**
33692	Repair of heart defects	CY 2011	31.54	120	0	0	390	300	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0
33692	Repair of heart defects	RUC Rec	38.75	40	3	20	218	60	1.0	0.0	3.0	2.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
33692	**Repair of heart defects**	**CY 2012**	**36.15**	**40**	**3**	**20**	**218**	**60**	**1.0**	**0.0**	**3.0**	**2.0**	**1.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**
33710	Repair of heart defects	CY 2011	30.41	120	0	0	240	270	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0
33710	Repair of heart defects	RUC Rec	43.00	40	3	20	200	60	2.0	0.0	1.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
33710	**Repair of heart defects**	**CY 2012**	**37.50**	**40**	**3**	**20**	**200**	**60**	**2.0**	**0.0**	**1.0**	**1.0**	**1.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**
33875	Thoracic aortic graft	CY 2011	35.78	60	0	0	300	60	0.0	0.0	4.0	5.0	0.0	1.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0

HCPCS Code	Short Descriptor	Year	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Critical Care, First Hour- 99291	Critical Care, Addl 30 Mins- 99292	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day-99238	Hospital Discharge Day-99239	Subsequent Observation Care- 99224	Subsequent Observation Care- 99225	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213	Office/Outpatient Visit, Est- 99214	Office/Outpatient Visit, Est- 99215
33875	Thoracic aortic graft	RUC Rec	56.83	50	30	20	240	60	3.0	0.0	1.0	2.0	3.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0
33875	**Thoracic aortic graft**	**CY 2012**	**50.72**	**50**	**30**	**20**	**240**	**60**	**3.0**	**0.0**	**1.0**	**2.0**	**3.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**
33910	Remove lung artery emboli	CY 2011	29.71	28	24	25	186	52	7.0	0.0	8.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	1.5	0.0
33910	Remove lung artery emboli	RUC Rec	52.33	40	3	20	190	60	3.0	0.0	1.0	2.0	3.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0	0.0
33910	**Remove lung artery emboli**	**CY 2012**	**48.21**	**40**	**3**	**20**	**190**	**60**	**3.0**	**0.0**	**1.0**	**2.0**	**3.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**
33935	Transplantation heart/lung	CY 2011	62.01	180	0	0	360	650	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0
33935	Transplantation heart/lung	RUC Rec	100.00	80	20	60	380	90	3.0	1.0	1.0	8.0	6.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0
33935	**Transplantation heart/lung**	**CY 2012**	**91.78**	**80**	**20**	**60**	**380**	**90**	**3.0**	**1.0**	**1.0**	**8.0**	**6.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**1.0**
33980	Remove intracorporeal device	CY 2011	65.20	178.0	0.0	0.0	360.0	80.0	4.0	3.0	2.0	9.0	2.0	0.0	1.0	0.0	0.0	0.0	0.0	2.0	3.0	0.0
33980	Remove intracorporeal device	RUC Rec	40.00	60.0	15.0	20.0	300.0	90.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
33980	**Remove intracorporeal device**	**CY 2012**	**33.50**	**60.0**	**15.0**	**20.0**	**300.0**	**90.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
35188	Repair blood vessel lesion	CY 2011	15.16	35	12	25	140	35	0.0	0.0	6.0	0.0	0.0	0.0	0.0	0.0	0.0	3.5	0.0	0.0	0.0	0.0
35188	Repair blood vessel lesion	RUC Rec	18.50	40	3	20	150	30	0.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0	0.0
35188	**Repair blood vessel lesion**	**CY 2012**	**18.00**	**40**	**3**	**20**	**150**	**30**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**	**0.0**
35612	Artery bypass graft	CY 2011	16.82	37	13	25	167	36	0.0	0.0	7.5	0.0	0.0	1.0	0.0	0.0	0.0	3.5	0.0	2.0	0.0	0.0
35612	Artery bypass graft	RUC Rec	22.00	40	5	20	180	40	0.0	0.0	1.0	2.0	0.0	1.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0	0.0
35612	**Artery bypass graft**	**CY 2012**	**20.35**	**40**	**5**	**20**	**180**	**40**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**0.0**	**0.0**
35800	Explore neck vessels	CY 2011	8.07	25	8	25	66	27	1.0	0.0	3.5	0.0	0.0	1.0	0.0	0.0	0.0	2.5	0.0	1.0	0.0	0.0
35800	Explore neck vessels	RUC Rec	13.89	30	3	5	60	30	0.0	0.0	1.0	1.0	1.0	1.0	0.0	0.0	0.0	2.0	1.0	0.0	0.0	0.0
35800	**Explore neck vessels**	**CY 2012**	**12.00**	**30**	**3**	**5**	**60**	**30**	**0.0**	**0.0**	**1.0**	**1.0**	**1.0**	**1.0**	**0.0**	**0.0**	**0.0**	**2.0**	**1.0**	**0.0**	**0.0**	**0.0**
35840	Explore abdominal vessels	CY 2011	10.96	31	10	25	103	32	1.0	0.0	4.5	0.0	0.0	1.0	0.0	0.0	0.0	3.0	0.0	0.0	0.0	0.0
35840	Explore abdominal vessels	RUC Rec	21.19	30	3	5	120	30	0.0	0.0	1.0	2.0	2.0	1.0	0.0	0.0	0.0	2.0	1.0	0.0	0.0	0.0
35840	**Explore abdominal vessels**	**CY 2012**	**20.75**	**30**	**3**	**5**	**120**	**30**	**0.0**	**0.0**	**1.0**	**2.0**	**2.0**	**1.0**	**0.0**	**0.0**	**0.0**	**2.0**	**1.0**	**0.0**	**0.0**	**0.0**
35860	Explore limb vessels	CY 2011	6.80	25	8	25	71	27	1.5	0.0	3.0	0.0	0.0	1.0	0.0	0.0	0.0	2.5	0.0	0.0	0.0	0.0
35860	Explore limb vessels	RUC Rec	16.89	30	3	5	90	30	0.0	0.0	1.0	2.0	1.0	1.0	0.0	0.0	0.0	2.0	1.0	0.0	0.0	0.0
35860	**Explore limb vessels**	**CY 2012**	**15.25**	**30**	**3**	**5**	**90**	**30**	**0.0**	**0.0**	**1.0**	**2.0**	**1.0**	**1.0**	**0.0**	**0.0**	**0.0**	**2.0**	**1.0**	**0.0**	**0.0**	**0.0**
36247	Place catheter in artery	CY 2011	6.29	0.0	0.0	0.0	86.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
36247	Place catheter in artery	RUC Rec	7.00	33.0	3.0	5.0	60.0	30.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
36247	**Place catheter in artery**	**CY 2012**	**6.29**	**33.0**	**3.0**	**5.0**	**60.0**	**30.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
36600	Withdrawal of arterial blood	CY 2011	0.32	0.0	0.0	0.0	8.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
36600	Withdrawal of arterial blood	RUC Rec	0.32	5.0	0.0	0.0	10.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
36600	**Withdrawal of arterial blood**	**CY 2012**	**0.32**	**3.0**	**0.0**	**0.0**	**10.0**	**3.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
36819	Av fuse uppr arm basilic	CY 2011	14.47	55.0	0.0	0.0	120.0	15.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	1.0	1.0	1.0	0.0	0.0
36819	Av fuse uppr arm basilic	RUC Rec	14.47	40.0	5.0	20.0	130.0	25.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	1.0	1.0	1.0	0.0	0.0
36819	**Av fuse uppr arm basilic**	**CY 2012**	**13.29**	**40.0**	**5.0**	**20.0**	**130.0**	**35.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**1.0**	**0.0**	**0.0**

HCPCS Code	Short Descriptor	Year	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Critical Care, First Hour- 99291	Critical Care, Addl 30 Mins- 99292	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day-99238	Hospital Discharge Day-99239	Subsequent Observation Care- 99224	Subsequent Observation Care- 99225	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213	Office/Outpatient Visit, Est- 99214	Office/Outpatient Visit, Est- 99215
36825	Artery-vein autograft	CY 2011	15.13	40.0	10.0	20.0	120.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0
36825	Artery-vein autograft	RUC Rec	15.13	40.0	10.0	20.0	120.0	30.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	1.0	2.0	0.0	0.0
36825	**Artery-vein autograft**	**CY 2012**	**14.17**	**40.0**	**10.0**	**20.0**	**120.0**	**40.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.5**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**0.0**
42415	Excise parotid gland/lesion	CY 2011	18.12	40.0	12.0	20.0	150.0	20.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0
42415	Excise parotid gland/lesion	RUC Rec	18.12	40.0	12.0	20.0	150.0	20.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	1.0	2.0	0.0	0.0
42415	**Excise parotid gland/lesion**	**CY 2012**	**17.16**	**40.0**	**12.0**	**20.0**	**150.0**	**30.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**0.0**
42420	Excise parotid gland/lesion	CY 2011	21.00	40.0	12.0	20.0	180.0	20.0	0.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0
42420	Excise parotid gland/lesion	RUC Rec	21.00	40.0	12.0	20.0	180.0	20.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	1.0	2.0	0.0	0.0
42420	**Excise parotid gland/lesion**	**CY 2012**	**19.53**	**40.0**	**12.0**	**20.0**	**180.0**	**50.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.5**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**0.0**
42440	Excise submaxillary gland	CY 2011	7.13	30	10	15	60	20	0	0	0	0	0	0.5	0	0	0	0	1	1	0	0
42440	Excise submaxillary gland	RUC Rec	7.13	30	10	15	60	20	0	0	0	0	0	0.5	0	0	0	0	1	1	0	0
42440	**Excise submaxillary gland**	**CY 2012**	**6.14**	**30**	**10**	**15**	**60**	**25**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**1**	**1**	**0**	**0**
43262	Endo cholangiopancreatograph	CY 2011	7.38	25.0	0.0	25.0	75.0	28.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
43262	Endo cholangiopancreatograph	RUC Rec	7.38	15.0	5.0	5.0	45.0	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
43262	**Endo cholangiopancreatograph**	**CY 2012**	**7.38**	**25.0**	**0.0**	**25.0**	**75.0**	**28.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
45331	Sigmoidoscopy and biopsy	CY 2011	1.15	7.0	0.0	0.0	18.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
45331	Sigmoidoscopy and biopsy	RUC Rec	1.15	13.0	1.0	1.0	15.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
45331	**Sigmoidoscopy and biopsy**	**CY 2012**	**1.15**	**5.0**	**5.0**	**5.0**	**10.0**	**10.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
47563	Laparo cholecystectomy/graph	CY 2011	12.11	32.0	0.0	25.0	143.0	29.0	0.0	0.5	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	2.5	0.0	0.0	0.0
47563	Laparo cholecystectomy/graph	RUC Rec	12.11	40.0	10.0	15.0	90.0	25.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
47563	**Laparo cholecystectomy/graph**	**CY 2012**	**11.47**	**40.0**	**10.0**	**15.0**	**90.0**	**25.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**
47564	Laparo cholecystectomy/explr	CY 2011	14.24	30	0	0	112	45	0.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
47564	Laparo cholecystectomy/explr	RUC Rec	20.00	40	10	15	120	30	0.0	0.0	1.0	2.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0
47564	**Laparo cholecystectomy/explr**	**CY 2012**	**18.00**	**40**	**10**	**15**	**120**	**30**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**0.0**
49507	Prp i/hern init block >5 yr	CY 2011	10.05	40.0	3.0	20.0	70.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
49507	Prp i/hern init block >5 yr	RUC Rec	10.05	40.0	3.0	20.0	70.0	30.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	1.0	1.0	0.0	0.0
49507	**Prp i/hern init block >5 yr**	**CY 2012**	**9.09**	**40.0**	**3.0**	**20.0**	**70.0**	**40.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**
49521	Rerepair ing hernia, blocked	CY 2011	12.44	40.0	3.0	20.0	90.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
49521	Rerepair ing hernia, blocked	RUC Rec	12.44	40.0	3.0	20.0	90.0	30.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	1.0	1.0	0.0	0.0
49521	**Rerepair ing hernia, blocked**	**CY 2012**	**11.48**	**40.0**	**3.0**	**20.0**	**90.0**	**40.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**
49587	Rpr umbil hern, block > 5 yr	CY 2011	8.04	40.0	3.0	20.0	60.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
49587	Rpr umbil hern, block > 5 yr	RUC Rec	8.04	40.0	3.0	20.0	60.0	30.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	1.0	1.0	0.0	0.0
49587	**Rpr umbil hern, block > 5 yr**	**CY 2012**	**7.08**	**40.0**	**3.0**	**20.0**	**60.0**	**40.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**

HCPCS Code	Short Descriptor	Year	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Critical Care, First Hour- 99291	Critical Care, Addl 30 Mins- 99292	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day-99238	Hospital Discharge Day-99239	Subsequent Observation Care- 99224	Subsequent Observation Care- 99225	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213	Office/Outpatient Visit, Est- 99214	Office/Outpatient Visit, Est- 99215
49652	Lap vent/abd hernia repair	CY 2011	12.88	45.0	15.0	15.0	90.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
49652	Lap vent/abd hernia repair	RUC Rec	12.88	40.0	15.0	15.0	90.0	30.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	1.0	1.0	0.0	0.0
49652	**Lap vent/abd hernia repair**	**CY 2012**	**11.92**	**40.0**	**15.0**	**15.0**	**90.0**	**40.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**
49653	Lap vent/abd hern proc comp	CY 2011	16.21	45.0	15.0	15.0	120.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	2.0	1.0	0.0	0.0
49653	Lap vent/abd hern proc comp	RUC Rec	16.21	40.0	15.0	15.0	120.0	30.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	2.0	0.0	0.0	2.0	1.0	0.0	0.0
49653	**Lap vent/abd hern proc comp**	**CY 2012**	**14.94**	**40.0**	**15.0**	**15.0**	**120.0**	**50.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**1.0**	**0.0**	**0.0**
49654	Lap inc hernia repair	CY 2011	15.03	45.0	15.0	15.0	120.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
49654	Lap inc hernia repair	RUC Rec	15.03	40.0	15.0	15.0	120.0	30.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	2.0	0.0	0.0	1.0	1.0	0.0	0.0
49654	**Lap inc hernia repair**	**CY 2012**	**13.76**	**40.0**	**15.0**	**15.0**	**120.0**	**50.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**0.0**	**0.0**
49655	Lap inc hern repair comp	CY 2011	18.11	50.0	15.0	15.0	150.0	30.0	0.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	2.0	1.0	0.0	0.0
49655	Lap inc hern repair comp	RUC Rec	18.11	40.0	15.0	15.0	150.0	30.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	2.0	0.0	0.0	2.0	1.0	0.0	0.0
49655	**Lap inc hern repair comp**	**CY 2012**	**16.84**	**40.0**	**15.0**	**15.0**	**150.0**	**50.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**1.0**	**0.0**	**0.0**
51710	Change of bladder tube	CY 2011	1.52	13.0	0.0	0.0	26.0	11.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0
51710	Change of bladder tube	RUC Rec	1.35	7.0	10.0	0.0	15.0	15.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
51710	**Change of bladder tube**	**CY 2012**	**1.35**	**7.0**	**5.0**	**0.0**	**15.0**	**15.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
52341	Cysto w/ureter stricture tx	CY 2011	5.35	45	10	15	45	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52341	Cysto w/ureter stricture tx	RUC Rec	5.35	45	10	15	45	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52341	**Cysto w/ureter stricture tx**	**CY 2012**	**5.35**	**45**	**10**	**15**	**45**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
52342	Cysto w/up stricture tx	CY 2011	5.85	40	10	10	60	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52342	Cysto w/up stricture tx	RUC Rec	5.85	40	10	10	60	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52342	**Cysto w/up stricture tx**	**CY 2012**	**5.85**	**40**	**10**	**10**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
52343	Cysto w/renal stricture tx	CY 2011	6.55	45	10	10	60	25	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52343	Cysto w/renal stricture tx	RUC Rec	6.55	45	10	10	60	25	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52343	**Cysto w/renal stricture tx**	**CY 2012**	**6.55**	**45**	**10**	**10**	**60**	**25**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
52344	Cysto/uretero, stricture tx	CY 2011	7.05	40	10	10	45	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52344	Cysto/uretero, stricture tx	RUC Rec	7.05	40	10	10	45	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52344	**Cysto/uretero, stricture tx**	**CY 2012**	**7.05**	**40**	**10**	**10**	**45**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
52345	Cysto/uretero w/up stricture	CY 2011	7.55	45	10	15	45	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52345	Cysto/uretero w/up stricture	RUC Rec	7.55	45	10	15	45	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52345	**Cysto/uretero w/up stricture**	**CY 2012**	**7.55**	**45**	**10**	**15**	**45**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
52346	Cystouretero w/renal strict	CY 2011	8.58	40	10	10	60	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52346	Cystouretero w/renal strict	RUC Rec	8.58	40	10	10	60	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52346	**Cystouretero w/renal strict**	**CY 2012**	**8.58**	**40**	**10**	**10**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
52400	Cystouretero w/congen repr	CY 2011	8.69	72.5	10	15	40	25	0	0	0	0	0	0.5	0	0	0	0	1	0	0	0
52400	Cystouretero w/congen repr	RUC Rec	8.69	72.5	10	15	40	25	0	0	0	0	0	0.5	0	0	0	0	1	0	0	0

HCPCS Code	Short Descriptor	Year	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Critical Care, First Hour- 99291	Critical Care, Addl 30 Mins- 99292	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day-99238	Hospital Discharge Day-99239	Subsequent Observation Care- 99224	Subsequent Observation Care- 99225	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213	Office/Outpatient Visit, Est- 99214	Office/Outpatient Visit, Est- 99215
52400	**Cystouretero w/congen repr**	**CY 2012**	**8.69**	**72.5**	**10**	**15**	**40**	**25**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**
52500	Revision of bladder neck	CY 2011	8.14	45	10	15	45	27.5	0	0	0	0	0	0.5	0	0	0	0	0	3	0	0
52500	Revision of bladder neck	RUC Rec	8.14	45	10	15	45	27.5	0	0	0	0	0	0.5	0	0	0	0	0	3	0	0
52500	**Revision of bladder neck**	**CY 2012**	**8.14**	**45**	**10**	**15**	**45**	**27.5**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**0**	**3**	**0**	**0**
52630	Remove prostate regrowth	CY 2011	7.73	23.0	0.0	25.0	49.0	20.0	0.0	0.0	1.5	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.5	0.0	0.0
52630	Remove prostate regrowth	RUC Rec	7.73	33.0	5.0	15.0	60.0	25.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	2.0	1.0	0.0	0.0
52630	**Remove prostate regrowth**	**CY 2012**	**6.55**	**33.0**	**5.0**	**15.0**	**60.0**	**35.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**1.0**	**0.0**	**0.0**
52649	Prostate laser enucleation	CY 2011	17.29	70.0	10.0	15.0	180.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0
52649	Prostate laser enucleation	RUC Rec	15.20	33.0	5.0	15.0	120.0	25.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0
52649	**Prostate laser enucleation**	**CY 2012**	**14.56**	**33.0**	**5.0**	**15.0**	**120.0**	**25.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**0.0**
53440	Male sling procedure	CY 2011	15.54	58.0	0.0	0.0	100.0	30.0	0.0	0.0	0.0	2.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0	0.0
53440	Male sling procedure	RUC Rec	14.00	33.0	7.0	15.0	90.0	22.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0
53440	**Male sling procedure**	**CY 2012**	**13.36**	**33.0**	**7.0**	**15.0**	**90.0**	**22.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**0.0**
53445	Insert uro/ves nck sphincter	CY 2011	15.39	50	15	20	90	25	0	0	1	1	0	1	0	0	0	0	1	3	0	0
53445	Insert uro/ves nck sphincter	RUC Rec	13.00	50	15	20	90	25	0	0	0	0	0	1	0	1	0	0	1	3	0	0
53445	**Insert uro/ves nck sphincter**	**CY 2012**	**13.00**	**50**	**15**	**20**	**90**	**25**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**0**	**1**	**3**	**0**	**0**
54410	Remove/replace penis prosth	CY 2011	15.18	40	10	15	120	30	0	0	0	0	0	1	0	0	0	0	1	3	0	0
54410	Remove/replace penis prosth	RUC Rec	15.18	40	10	15	120	30	0	0	0	0	0	1	0	1	0	0	1	3	0	0
54410	**Remove/replace penis prosth**	**CY 2012**	**15.18**	**40**	**10**	**15**	**120**	**30**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**1**	**3**	**0**	**0**
54530	Removal of testis	CY 2011	8.46	57.5	10	15	60	30	0	0	0	0	0	0.5	0	0	0	0	2	1	0	0
54530	Removal of testis	RUC Rec	8.46	57.5	10	15	60	30	0	0	0	0	0	0.5	0	0	0	0	2	1	0	0
54530	**Removal of testis**	**CY 2012**	**8.46**	**57.5**	**10**	**15**	**60**	**30**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**2**	**1**	**0**	**0**
60220	Partial removal of thyroid	CY 2011	12.37	62.5	0.0	0.0	90.0	25.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
60220	Partial removal of thyroid	RUC Rec	12.37	40.0	12.0	20.0	90.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0
60220	**Partial removal of thyroid**	**CY 2012**	**11.19**	**40.0**	**12.0**	**20.0**	**90.0**	**40.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**2.0**	**0.0**	**0.0**
60240	Removal of thyroid	CY 2011	16.22	34.0	0.0	25.0	159.0	27.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0	0.0
60240	Removal of thyroid	RUC Rec	16.22	40.0	12.0	20.0	150.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0
60240	**Removal of thyroid**	**CY 2012**	**15.04**	**40.0**	**12.0**	**20.0**	**150.0**	**40.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**2.0**	**0.0**	**0.0**
60500	Explore parathyroid glands	CY 2011	16.78	40.0	0.0	25.0	138.0	22.0	0.0	0.0	3.5	0.0	0.0	1.0	0.0	0.0	0.0	0.0	3.0	0.0	0.0	0.0
60500	Explore parathyroid glands	RUC Rec	16.78	40.0	12.0	20.0	120.0	30.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0
60500	**Explore parathyroid glands**	**CY 2012**	**15.60**	**40.0**	**12.0**	**20.0**	**120.0**	**40.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**0.0**
62263	Epidural lysis mult sessions	CY 2011	6.54	33	10	5	45	20	0	0	0	0	0	0.5	0	0	0	0	1	2	0	0
62263	Epidural lysis mult sessions	RUC Rec	6.54	33	10	5	45	20	0	0	0	0	0	0.5	0	0	0	0	1	2	0	0
62263	**Epidural lysis mult sessions**	**CY 2012**	**5.00**	**33**	**10**	**5**	**45**	**40**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**1**	**2**	**0**	**0**
62350	Implant spinal canal cath	CY 2011	6.05	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0

HCPCS Code	Short Descriptor	Year	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Critical Care, First Hour- 99291	Critical Care, Addl 30 Mins- 99292	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day-99238	Hospital Discharge Day-99239	Subsequent Observation Care- 99224	Subsequent Observation Care- 99225	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213	Office/Outpatient Visit, Est- 99214	Office/Outpatient Visit, Est- 99215
62350	Implant spinal canal cath	RUC Rec	6.05	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
62350	**Implant spinal canal cath**	**CY 2012**	**6.05**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
62355	Remove spinal canal catheter	CY 2011	4.35	33	10	5	30	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
62355	Remove spinal canal catheter	RUC Rec	4.35	33	10	5	30	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
62355	**Remove spinal canal catheter**	**CY 2012**	**3.55**	**33**	**10**	**5**	**30**	**20**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
62360	Insert spine infusion device	CY 2011	4.33	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
62360	Insert spine infusion device	RUC Rec	4.33	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
62360	**Insert spine infusion device**	**CY 2012**	**4.33**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
62361	Implant spine infusion pump	CY 2011	5.65	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
62361	Implant spine infusion pump	RUC Rec	5.65	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
62361	**Implant spine infusion pump**	**CY 2012**	**5.00**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
62362	Implant spine infusion pump	CY 2011	6.10	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
62362	Implant spine infusion pump	RUC Rec	6.10	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
62362	**Implant spine infusion pump**	**CY 2012**	**5.60**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
62365	Remove spine infusion device	CY 2011	4.65	33	10	5	45	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
62365	Remove spine infusion device	RUC Rec	4.65	33	10	5	45	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
62365	**Remove spine infusion device**	**CY 2012**	**3.93**	**33**	**10**	**5**	**45**	**20**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
63650	Implant neuroelectrodes	CY 2011	7.20	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
63650	Implant neuroelectrodes	RUC Rec	7.20	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
63650	**Implant neuroelectrodes**	**CY 2012**	**7.15**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
63655	Implant neuroelectrodes	CY 2011	11.56	33.0	15.0	15.0	90.0	20.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0
63655	Implant neuroelectrodes	RUC Rec	11.56	33.0	15.0	15.0	90.0	20.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0
63655	**Implant neuroelectrodes**	**CY 2012**	**10.92**	**33.0**	**15.0**	**15.0**	**90.0**	**20.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**2.0**	**0.0**	**0.0**
63685	Insrt/redo spine n generator	CY 2011	6.05	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
63685	Insrt/redo spine n generator	RUC Rec	6.05	33	10	5	60	20	0	0	0	0	0	0.5	0	0	0	0	0	1	0	0
63685	**Insrt/redo spine n generator**	**CY 2012**	**5.19**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
64405	N block inj occipital	CY 2011	1.32	11	0	0	12	11	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
64405	N block inj occipital	RUC Rec	1.00	7	0	0	5	10	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
64405	**N block inj occipital**	**CY 2012**	**0.94**	**7**	**0**	**0**	**5**	**10**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
64708	Revise arm/leg nerve	CY 2011	6.36	35	10	10	60	15	0	0	0	0	0	0.5	0	0	0	0	3	1	0	0
64708	Revise arm/leg nerve	RUC Rec	6.36	35	10	10	60	15	0	0	0	0	0	0.5	0	0	0	0	3	1	0	0
64708	**Revise arm/leg nerve**	**CY 2012**	**6.36**	**35**	**10**	**10**	**60**	**15**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**3**	**1**	**0**	**0**
64831	Repair of digit nerve	CY 2011	9.16	40	10	15	60	15	0	0	0	0	0	0.5	0	0	0	0	2	2	0	0
64831	Repair of digit nerve	RUC Rec	9.16	40	10	15	60	15	0	0	0	0	0	0.5	0	0	0	0	2	2	0	0
64831	**Repair of digit nerve**	**CY 2012**	**9.16**	**40**	**10**	**15**	**60**	**15**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**2**	**2**	**0**	**0**

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65285	Repair of eye wound	CY 2011	14.71	37	0	15	79	32	0	0	0.5	0	0	1	0	0	0	0	0	5.5	0	0
65285	Repair of eye wound	RUC Rec	16.00	30	10	20	90	30	0	0	0	0	0	1	0	0	0	0	1	6	0	0
65285	**Repair of eye wound**	**CY 2012**	**15.36**	**30**	**10**	**20**	**90**	**30**	**0**	**0**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**0**	**1**	**6**	**0**	**0**
78264	Gastric emptying study	CY 2011	0.78	0.0	0.0	0.0	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
78264	Gastric emptying study	RUC Rec	0.95	5.0	0.0	0.0	12.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
78264	**Gastric emptying study**	**CY 2012**	**0.80**	**5.0**	**0.0**	**0.0**	**12.0**	**10.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
92511	Nasopharyngoscopy	CY 2011	0.84	0.0	0.0	0.0	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
92511	Nasopharyngoscopy	RUC Rec	0.61	6.0	0.0	5.0	5.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
92511	**Nasopharyngoscopy**	**CY 2012**	**0.61**	**4.0**	**0.0**	**5.0**	**5.0**	**3.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
92950	Heart/lung resuscitation cpr	CY 2011	3.79	1.0	0.0	0.0	51.0	51.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
92950	Heart/lung resuscitation cpr	RUC Rec	4.50	2.0	1.0	0.0	45.0	30.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
92950	**Heart/lung resuscitation cpr**	**CY 2012**	**4.00**	**1.0**	**1.0**	**0.0**	**45.0**	**20.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
98925	Osteopathic manipulation	CY 2011	0.45	0.0	0.0	0.0	13.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
98925	Osteopathic manipulation	RUC Rec	0.50	2.0	1.0	0.0	10.0	3.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
98925	**Osteopathic manipulation**	**CY 2012**	**0.46**	**1.0**	**1.0**	**0.0**	**10.0**	**2.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
98926	Osteopathic manipulation	CY 2011	0.65	0.0	0.0	0.0	18.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
98926	Osteopathic manipulation	RUC Rec	0.75	2.0	1.0	0.0	15.0	3.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
98926	**Osteopathic manipulation**	**CY 2012**	**0.71**	**1.0**	**1.0**	**0.0**	**15.0**	**2.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
98927	Osteopathic manipulation	CY 2011	0.87	0.0	0.0	0.0	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
98927	Osteopathic manipulation	RUC Rec	1.00	2.0	1.0	0.0	20.0	3.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
98927	**Osteopathic manipulation**	**CY 2012**	**0.96**	**1.0**	**1.0**	**0.0**	**20.0**	**2.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
98928	Osteopathic manipulation	CY 2011	1.03	0.0	0.0	0.0	29.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
98928	Osteopathic manipulation	RUC Rec	1.25	2.0	1.0	0.0	25.0	3.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
98928	**Osteopathic manipulation**	**CY 2012**	**1.21**	**1.0**	**1.0**	**0.0**	**25.0**	**2.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
98929	Osteopathic manipulation	CY 2011	1.19	0.0	0.0	0.0	33.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
98929	Osteopathic manipulation	RUC Rec	1.50	2.0	1.0	0.0	30.0	3.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
98929	**Osteopathic manipulation**	**CY 2012**	**1.46**	**1.0**	**1.0**	**0.0**	**30.0**	**2.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
99218	Initial observation care	CY 2011	1.28	0.0	0.0	0.0	40.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99218	Initial observation care	RUC Rec	1.92	10.0	0.0	0.0	30.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99218	**Initial observation care**	**CY 2012**	**1.92**	**10.0**	**0.0**	**0.0**	**30.0**	**10.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
99219	Initial observation care	CY 2011	2.14	0.0	0.0	0.0	67.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99219	Initial observation care	RUC Rec	2.60	10.0	0.0	0.0	40.0	14.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99219	**Initial observation care**	**CY 2012**	**2.60**	**10.0**	**0.0**	**0.0**	**40.0**	**14.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
99220	Initial observation care	CY 2011	2.99	0.0	0.0	0.0	90.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99220	Initial observation care	RUC Rec	3.56	15.0	0.0	0.0	45.0	15.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

HCPCS Code	Short Descriptor	Year	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Critical Care, First Hour- 99291	Critical Care, Addl 30 Mins- 99292	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day-99238	Hospital Discharge Day-99239	Subsequent Observation Care- 99224	Subsequent Observation Care- 99225	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213	Office/Outpatient Visit, Est- 99214	Office/Outpatient Visit, Est- 99215
99220	**Initial observation care**	**CY 2012**	**3.56**	**15.0**	**0.0**	**0.0**	**45.0**	**15.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
99224	Subsequent observation care	CY2011	0.54	0.0	0.0	0.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99224	Subsequent observation care	RUC Rec	0.76	5.0	0.0	0.0	10.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99224	**Subsequent observation care**	**CY 2012**	**0.76**	**5.0**	**0.0**	**0.0**	**10.0**	**5.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
99225	Subsequent observation care	CY2011	0.96	0.0	0.0	0.0	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99225	Subsequent observation care	RUC Rec	1.39	10.0	0.0	0.0	20.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99225	**Subsequent observation care**	**CY 2012**	**1.39**	**10.0**	**0.0**	**0.0**	**20.0**	**10.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
99226	Subsequent observation care	CY2011	1.44	0.0	0.0	0.0	30.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99226	Subsequent observation care	RUC Rec	2.00	10.0	0.0	0.0	30.0	15.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99226	**Subsequent observation care**	**CY 2012**	**2.00**	**10.0**	**0.0**	**0.0**	**30.0**	**15.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
99234	Observ/hosp same date	CY 2011	2.56	10.0	0.0	0.0	60.0	15.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99234	Observ/hosp same date	RUC Rec	2.56	14.0	0.0	0.0	40.0	15.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99234	**Observ/hosp same date**	**CY 2012**	**1.92**	**14.0**	**0.0**	**0.0**	**35.0**	**15.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
99235	Observ/hosp same date	CY 2011	3.41	10.0	0.0	0.0	75.0	15.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99235	Observ/hosp same date	RUC Rec	3.24	14.0	0.0	0.0	50.0	19.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99235	**Observ/hosp same date**	**CY 2012**	**2.78**	**14.0**	**0.0**	**0.0**	**40.0**	**19.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
99236	Observ/hosp same date	CY 2011	4.26	0.0	0.0	0.0	110.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99236	Observ/hosp same date	RUC Rec	4.20	19.0	0.0	0.0	55.0	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
99236	**Observ/hosp same date**	**CY 2012**	**3.63**	**19.0**	**0.0**	**0.0**	**50.0**	**20.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

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2. Finalizing CY 2011 Interim Direct PE RVUs for CY 2012

a. Background and Methodology

In this section, we address interim final direct PE inputs as presented in the CY 2011 PFS final rule with comment period and displayed in the final CY 2011 direct PE database (as subsequently corrected on December 30, 2010) available on the CMS Web site under the downloads for the ''Payment Policies under Physician Fee Schedule and other Revisions to Part B for CY 2011; Corrections'' at: *http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp*.

On an annual basis, the AMA RUC provides CMS with recommendations regarding direct PE inputs, including clinical labor, supplies, and equipment, for new, revised, and potentially misvalued codes. We review the AMA RUC-recommended direct PE inputs on a code-by-code basis, including the recommended facility PE inputs and/or nonfacility PE inputs, as clinically appropriate for the code. We determine whether we agree with the AMA RUC's recommended direct PE inputs for a service or, if we disagree, we refine the PE inputs to represent inputs that better reflect our estimate of the PE resources required for the service in the facility and/or nonfacility settings. We also confirm that CPT codes should have facility and/or nonfacility direct PE inputs and make changes based on our clinical judgment and any PFS payment policies that would apply to the code.

In the CY 2011 PFS final rule with comment period (75 FR 73350), we addressed the general nature of some common refinements to the AMA RUC-recommended direct PE inputs as well as the reasons for refinements to particular inputs. In the following subsections, we respond to comments we received regarding common refinements and the direct PE inputs specific to particular codes.

b. Common Refinements

(1) General Equipment Time

As we stated in the CY 2011 PFS final rule with comment period (75 FR 73350), many of the refinements to the AMA RUC direct PE recommendations were made in the interest of promoting a transparent and consistent approach to equipment time inputs. In the past, the AMA RUC had not always provided us with recommendations regarding equipment time inputs. In CY 2010, we requested that the AMA RUC provide equipment times along with the other direct PE recommendations, and we provided the AMA RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the AMA RUC's willingness to provide us with these additional inputs as part of their direct PE recommendations.

In general, the equipment time inputs correspond to the intra-service portion of the clinical labor times. We have clarified that assumption to consider equipment time as the sum of the times within the intra-service period when a clinician is using the piece of equipment, plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. In addition, when a piece of equipment is typically used during additional visits included in a service's global period, the equipment time should also reflect that use.

Certain highly technical pieces of equipment and equipment rooms are less likely to be used by a clinician over the full course of a procedure and are typically available for other patients during time that may still be in the intra-service portion of the service. We adjust those equipment times accordingly. For example, CPT code 74178 (Computed tomography, abdomen and pelvis; without contrast material in more than one body region) includes 3 minutes of intra-service clinical labor time associated with obtaining the patient's consent for the procedure. Since it would be atypical for this activity to occur within the CT room, we believe these 3 minutes should not be attributed to the CT room as equipment time. We refined the CY 2011 AMA RUC direct PE recommendations to conform to these equipment time policies.

Comment: One commenter expressed concerns with CMS' overall methodology for computing equipment times. The commenter specifically addressed CMS' refinement of minutes allocated to an angiography room for a series of endovascular revascularization procedures. The commenter claimed that in the case of interventional radiology procedures, a nurse typically greets and gowns the patient, provides pre-service education, and obtains consent and vital signs in an angiography room or other procedure room. Additionally, the commenter asserted that since CMS provided general guidelines to the RUC regarding appropriate equipment time inputs, CMS should defer to the expertise of the AMA RUC and accept the recommendations for equipment times. Further, the commenter argued that by not allocating minutes for certain highly technical pieces of equipment and equipment rooms for greeting/gowning, obtaining vital signs or providing pre-service education, CMS is instituting a change in practice expense methodology without discussing it with stakeholders prior to implementation.

Another commenter expressed similar concerns regarding CMS' refinements of equipment minutes allocated to a CT room for a series of new codes that describe combined CTs of the abdomen and pelvis. This commenter argued that equipment minutes should be allocated based on the full number of minutes in the clinical labor intraservice time since, for example, even when a CT technologist greets a patient in a different room, the CT room cannot be used for another patient. This commenter argued that current CMS allocation of room minutes is inconsistent with the historically accepted premise that if the technologists are involved with a patient, the room cannot be used for a different patient until after it has been cleaned and therefore 100 percent of the clinical labor time should be attributed to ''Room Time.'' Both commenters argued that CMS should accept the direct PE input recommendations of the AMA RUC, without refining the equipment room minutes that were allocated for greeting/gowning, obtaining vital signs or providing pre-service education or obtaining consent.

Response: We continue to believe that equipment minutes should be allocated as the sum of the intra-service minutes that a clinician typically uses a piece of equipment and the equipment is typically unavailable to other patients due to its use during the designated procedure. For many services, this means that the equipment is allocated the full number of minutes during the intra-service period. For example, for many services, the three clinical labor minutes attributed to a nurse for greeting and gowning the patient prior to the procedure are then also logically allocated to the exam table (EF023). We believe that this allocation reflects typical use of the equipment since it is logical to assume that the patient is usually greeted and gowned in the room that contains the exam table.

In the case of services that require the use of certain highly technical pieces of equipment and equipment rooms, however, we believe it is inappropriate to assume that all of the same intra-service clinical labor activities typically make these equipment items unavailable for use in furnishing services to other patients. For example, we do not believe it is typical to occupy a CT room while gowning a patient, providing pre-service education, or

obtaining consent of a patient prior to performing a procedure since those activities are not dependent on access to the equipment. Therefore, we do not agree with the commenter's assertion that these highly technical pieces of equipment and equipment rooms are typically unavailable to other patients whenever any patient is greeted, gowned, provided pre-service education, or has vital signs taken. That is why we do not allocate equipment minutes in those cases. We reiterate that equipment minutes are allocated based on the time a clinician typically uses a piece of equipment and the equipment is typically unavailable to other patients due to its use during the designated procedure.

While recent RUC recommendations have often reflected an agreement with that principle, some of the recommendations have required CMS refinements to make sure the equipment time minutes adhere to these principles. We note that we have only recently asked the RUC to provide CMS with recommendations regarding equipment time, and both CMS and the RUC considered the CY 2011 refinements to be technical modifications to the direct PE input recommendations instead of disagreements. Therefore, we do not agree with the commenters' premise that these refinements to equipment time are necessarily in conflict with the clinical judgment of the RUC.

We understand commenters' concerns regarding the importance of accurate and consistent allocation of equipment minutes as direct PE inputs. We agree that equipment minutes have not always been allocated with optimal precision, and we believe that imprecise allocation of equipment minutes may be a factor in certain potentially misvalued codes. We point the reader to section II.B.5.b.1. of this final rule with comment period for an example of this issue.

We believe that our CY 2011 refinements of equipment minutes for new and revised, and potentially misvalued codes most accurately reflect typical use of resources required to furnish PFS services to Medicare beneficiaries. We will continue to work to improve the accuracy of the equipment minutes and will address any further improvements in future rulemaking.

(2) Supply and Equipment Items Missing Invoices

When clinically appropriate, the AMA RUC generally recommends the use of supply and equipment items that already exist in the direct PE database as inputs for new, revised, and potentially misvalued codes. Some recommendations include supply or equipment items that are not currently in the direct PE database. In these cases, the AMA RUC has historically recommended a new item be created and has facilitated CMS' pricing of that item by working with the specialty societies to provide sales invoices to us. We appreciate the contributions of the AMA RUC in that process.

Despite the assistance of the AMA RUC for CY 2011, we did not receive adequate information for pricing the following new supply items included in the AMA RUC's CY 2011 direct PE recommendations: SC098 (Catheter, angiographic, Berman); SD251 (Sheath Shuttle (Cook); SD255 (Reentry Device (Frontier, Outback, Pioneer); SD257 (Tunneler); and SD258 (Vacuum Bottle). Therefore, for CY 2011, these supply items had no price inputs associated with them in the direct PE database. In the CY 2011 PFS final rule (75 FR 73351), we noted that we would consider any newly submitted information for these items as part of our annual supply and equipment price update process.

Comment: One commenter pointed out that the ''vacuum bottle'' already has an established supply code, SD 144, and is referred to as ''canister, vacuum, pleural (w-drainage line).'' The commenter also claimed that invoice pricing for the Sheath Shuttle (Cook) had already been submitted to CMS.

Response: We agree with the commenter's assessment regarding the vacuum bottle being captured by the existing supply code SD144, and we have subsequently removed SD258 from the direct PE database. The only information we have received regarding the Sheath Shuttle was a page from the vendor's catalog that described the item. However, that information did not include a price, so we were unable to use that information in pricing the supply input.

We remind stakeholders that we established a process that allows the public to submit requests for updates to supply price inputs or equipment price or useful life inputs in the CY 2011 PFS final rule with comment period (75 FR 73205 through 73207). As part of this established process, we ask that requests be submitted as comments to the PFS final rule with comment period each year, subject to the deadline for public comments applicable to that rule. Alternatively, stakeholders may submit requests to CMS on an ongoing basis throughout a given calendar year to *PE_Price_Input_Update@cms.hhs.gov*. Requests received by the end of a calendar year will be considered in rulemaking during the following year. We refer readers to the description available in the CY 2011 PFS final rule (75 FR 73206) that details the minimum information we request that stakeholders provide in order to facilitate our review and preparation of issues for the proposed rule.

c. Code-Specific Direct PE Inputs

(1) CT Abdomen and Pelvis

For CY 2011, AMA CPT created a series of new codes that describe combined CTs of the abdomen and pelvis. Prior to 2011, these services would have been billed using multiple stand-alone codes for each body region. The new codes are: 74176 (Computed tomography, abdomen and pelvis; without contrast material); 74177 (Computed tomography, abdomen and pelvis; with contrast material); and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by with contrast material(s) and further sections in one or both body regions.)

Comment: One commenter stated that there were discrepancies between the inputs for these codes and the AMA RUC recommendations that were not addressed as refinements in the CY 2011 PFS final rule with comment period. Specifically, the commenter suggested that CMS did not include a power injector recommended by the RUC. Another commenter stated that the clinical labor type in the codes should be a ''CT technologist'' (L046A) instead of a ''Radiologic Technologist'' (L041B).

Response: We have reexamined the CY 2011 AMA RUC direct PE recommendations for these codes and confirmed that the RUC recommendation we received does not include power injector as an input for these codes. We also confirmed that the RUC recommendation included labor code ''Radiologic Technologist'' (L041B) for these codes. We also confirmed that the information the specialty society presented to the RUC also included the ''Radiologic Technologist'' as the clinical labor time for the service. However, we note that both the RUC and other commenters now believe the labor type was included in error, and all similar codes include the ''CT technologist'' (L046A) as the appropriate labor type, including the codes that describe a CT of the abdomen and a CT of the pelvis independently. Therefore, we consider the labor code included with the recommendation to be a technical oversight, and we have amended the labor category in each of the three codes to include a ''CT technologist'' (L046A).

Comment: One commenter stated that each of these codes is missing the film jacket and CD supply inputs which are proxies for digital storage of images.

Response: We did not accept the film jacket as a disposable supply item because film jackets are not disposable/consumable supplies. We did not incorporate the CD as a supply item since the codes also included x-ray film, which can also be a proxy for digital image storage. We mistakenly omitted these refinements from the list of refinements in the CY 2011 PFS final rule with comment period.

After consideration of these comments, for CY 2012, we are finalizing the direct PE inputs, with the labor category refinement, for CPT codes 74176, 74177, and 74178.

(2) Endovascular Revascularization

In the CY 2011 PFS final rule with comment period (75 FR 73351), we explained our refinements of the supply input recommendations from the AMA RUC for CPT codes describing certain endovascular revascularization services. The recommendations included two or three high-cost stents for each of the following six CPT codes: 37226 (Revascularization, femoral/popliteal artery(s), unilateral; with transluminal stent placement(s); 37227 (Revascularization, femoral/popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy); 37230 (Revascularization, tibial/peroneal artery, unilateral, initial vessel; with transluminal stent placement(s)); 37231 (Revascularization, tibial/peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy); 37234 (Revascularization, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) (List separately in addition to code for primary procedure)); and 37235 (Revascularization, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy (List separately in addition to code for primary procedure)).

Given the complex clinical nature of these services, their new pricing in the nonfacility setting under the PFS, and the high cost of each stent, we were concerned that inclusion of two or three stents could overestimate the number of stents used in the typical office procedure that would be reported under one of the CPT codes. Therefore, we examined CY 2009 hospital OPPS claims data for the combinations of predecessor codes that would have historically been reported for each case reported in under CY 2011 under a single comprehensive code. Because of the OPPS device-to-procedure claims processing edits, all prior cases would have included a HCPCS C-code for at least one stent on the claim for the case. Based on our analysis of these data, we determined that for each new CY 2011 comprehensive code, the predecessor code combinations would have used only one stent in 65 percent or more of the cases. We had no reason to believe that when these new CPT codes were reported for procedures performed in the nonfacility setting, the typical patient would receive more than the one stent typically used in the hospital outpatient setting. Therefore, we refined the CY 2011 AMA RUC recommendations to include one stent in the direct PE inputs for each of the six endovascular revascularization stent insertion codes, including the add-on codes. These refinements were reflected in the final CY 2011 PFS direct PE database.

Comment: One commenter asserted that the CMS analysis of the OPPS data was flawed because the predecessor codes included treatments of all vascular territories instead of only the lower extremities described by the new codes. Additionally, the commenter argued that hospital payment does not depend on correctly coding the number of stents, so the claims data are probably inaccurate. In order to account for the latter possibility, the commenter reported conducting a review of similar claims data that excluded all hospitals that reported only one unit for stents for all of their claims. After examining that data, the commenter reported that the percentage of one stent dropped ''closer to 50 percent.'' The commenter argued that this analysis, combined with the former assertion regarding the limitations of anatomic non-specificity, invalidates the CMS' analysis that supported the refinement of the RUC-recommended direct PE inputs. Therefore, the commenter argued that CMS should accept the RUC recommendation without refinement and use the quantity of stents originally recommended in the direct PE database.

Response: As we stated in the CY 2011 PFS final rule (75 FR 73351), we have no reason to believe that more than one stent is typically used in furnishing the services reported under one of the CPT code in the nonfacility setting. While the commenter did not submit detailed results from the data used in reaching conclusions, we believe it important to note that even after reviewing preferred data, the commenter reported results that continued to indicate that one stent was used in at least half of the cases. While we appreciate the commenter's arguments regarding the potential differences between the stents required in the lower extremities and the pooled data reported by hospitals in the predecessor codes, we believe the possibility of such disparity is likely more than offset by the difference in typical patient acuity in the hospital outpatient and nonfacility settings. Finally, we note that neither the AMA RUC nor the medical specialty society that reports the highest utilization of these codes submitted comments in opposition to refinement of these direct PE inputs.

Comment: One commenter stated that there were discrepancies between the clinical labor inputs for these codes and the AMA RUC recommendations that were not addressed as refinements in the CY 2011 PFS final rule with comment period.

Response: We have reexamined the CY 2011 AMA RUC direct PE recommendations for these codes and confirmed that the labor minutes associated with the codes in the direct PE database match the AMA RUC recommendations regarding clinical labor inputs, which we accepted without refinement.

Comment: One commenter alerted CMS that the minutes allocated for two particular equipment items (a printer and a stretcher) had been inverted in three of these codes.

Response: We appreciate the commenter's informing us of the inverted minutes. We made a proposal to correct these inputs in the CY 2012 PFS proposed rule, and we are finalizing that correction in section II.A.3.a. of this final rule with comment period.

After consideration of all comments received, we are finalizing the direct PE inputs, as amended in section II.A.3.a. of this final rule with comment period, for these codes for CY 2012.

(3) Nasal/Sinus Endoscopy

The CY 2011 AMA RUC recommendation for direct PE inputs for CPT code 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (*e.g.,* balloon dilation), transnasal or via canine fossa), included irregular supply and equipment inputs. The AMA RUC recommended two similar, new supply items, specifically ''kit, sinus surgery, balloon (maxillary, frontal, or sphenoid)'' and ''kit, sinus surgery, balloon (maxillary)'' as supply inputs with a quantity of one-half for each item. In the CY 2011 PFS final rule with comment period (75 FR 73351), we explained that we believed that this

recommendation was intended to reflect an assumption that each of these distinct supplies is used in approximately half of the cases when the service is furnished. We noted that, in general, the direct PE inputs should reflect the items used when the service is furnished in the typical case. Therefore, the quantity of supply items associated with a code should reflect the actual units of the item used in the typical case, and not be reflective of any estimate of the proportion of cases in which any supply item is used. We also noted, however, that fractional inputs are appropriate when fractional quantities of a supply item are typically used, as is commonly the case when the unit of a particular supply reflects the volume of a liquid supply item instead of quantity.

Upon receipt of these recommendations, we requested that the AMA RUC clarify the initial recommendation by determining which of these supply items would be used in the typical case. The AMA RUC recommended that the supply item ''kit, sinus surgery, balloon (maxillary, frontal, or sphenoid)'' be included in the inputs for the code. We considered that recommendation, but we believed the item ''kit, sinus surgery, balloon (maxillary)'' to be more clinically appropriate based on the description of CPT code 32195.

The AMA RUC recommendation for equipment inputs for the same code (CPT code 31295) included a parallel irregularity by distributing half of the equipment minutes to each of two similar pieces of equipment, one existing and one new: ''endoscope, rigid, sinoscopy'' (ES013) and ''fiberscope, flexible, sinoscopy'' (ES035 and new for CY 2011). We believed that this recommendation was intended to reflect an assumption that each of these distinct pieces of equipment is used in approximately half of the cases in which the service is furnished. Again, we noted that, in general, the direct PE inputs should reflect the items used when the service is furnished in the typical case. Therefore, the equipment time inputs associated with a code should reflect the number of minutes an equipment item is used in the typical case, and not be distributed among a set of equipment items to reflect an estimate of the proportion of cases in which a particular equipment item might be used. Upon review of these items, we believed the new piece of equipment, ''fiberscope, flexible, sinoscopy'' to be more clinically appropriate based on the description of CPT code 32195. We refined the CY 2011 AMA RUC direct PE recommendations to conform to these determinations.

Comment: Two commenters claimed that CMS had misunderstood the recommendation of the AMA RUC, that two kits are typically used each time that the maxillary sinus surgery is furnished, and that both the rigid and the flexible scope are used in furnishing the service. One of commenters also suggested that the service requires the use of a light pipe so the direct PE database should include a light pipe for the codes. Both commenters also suggested that CMS institute PE RVUs that directly reimburse the costs of furnishing the service as calculated by the commenters.

As part of their CY 2012 recommendations, the AMA RUC provided a new recommendation regarding the disposable sinus surgery kits included as direct PE supply inputs for each of these three codes. When developing direct PE input recommendations for these new codes, the AMA RUC believed that the codes would be typically billed in one unit per patient encounter. Following implementation of these codes for Medicare purposes at the start of CY 2011, the RUC received reports that multiple units of services were being reported in the same patient encounter and that corresponding number of kits was not utilized. The RUC reported this information to CMS in conjunction with a request for preliminary claims data. The RUC then examined partial year sample claims data that overwhelmingly demonstrated each of the codes was typically billed with another code in the family and more often billed in multiples of three than singularly. Using this information to corroborate the reports the RUC had previously received, the RUC submitted a refined recommendation for CMS to consider for CY 2012. The new recommendation requests that CMS remove the disposable sinus surgery kits from each of the codes for CY 2012 and implement separately billable alpha-numeric HCPCS codes when possible to allow practitioners to be paid the cost of the disposable kits per patient encounter instead of per CPT code.

Response: We agree with the RUC that only one kit is used when typically furnishing the maxillary sinus procedure. We also continue to believe that in the typical case only one of the scopes is used. Neither commenter submitted evidence to support their claims that more than one kit or scope is required to furnish these services. In response to the commenter's statement regarding the missing input for a light pipe, we confirmed that the RUC recommendations and the CY 2011 direct PE database include minutes allocated to ''light, fiberoptic headlight w-source'' equipment (EQ170). We do not understand why the commenter requests that minutes should be allocated for an additional light source.

We appreciate and agree with the RUC's concern that the CY 2011 recommendations reflect an incorrect assumption about the number of services furnished per disposable sinus surgery kit used. We have considered the RUC's recommendation to remove the sinus surgery kits from the codes immediately and establish separately payable alpha-numeric HCPCS codes to use to report using the kits in furnishing the services described by these codes, and we agree that it provides one potential long-term solution to the problem with the high-cost disposable supply inputs for these particular codes. However, the RUC's solution presents a series of potential problems that we have addressed previously in the context of the broader challenges regarding our ability to price high cost disposable supply items. For the most recent discussion of this issue, we direct the reader to our discussion in the CY 2011 PFS final rule with comment period (75 FR 73251). However, we will consider the recommendation of the RUC regarding these and similar supply items during preparation for future rulemaking.

For CY 2012, we do not believe it would be appropriate to remove these items as supply inputs for these codes without providing an alternative means for paying practitioners for the resources associated with furnishing the related services. At the same time, however, we do not believe that it would be appropriate to maintain supply inputs that are based on an incorrect assumption about the relationship between how a service is furnished and how it is reported. Given the recent recommendation from the RUC, as well as our concurring interpretation of preliminary claims data for these codes, we believe that modifying the supply inputs for these codes is the most appropriate means for achieving accurate payment for CY 2012. Recognizing that these codes are typically billed in units of two, we believe that reducing the sinus surgery kit supply quantity to one-half for each of the codes will best reflect the number of kits used when the services are typically furnished. As part of our initial refinements, we only included the sinus surgery kit specific to the maxillary sinus in CPT code 32195. Since we now understand that the non-specific kits can be used when

furnishing more than one service to the same beneficiary on the same day, we believe that it would be appropriate to include one-half non-specific sinus-surgery kit for each code, including CPT code 32195.

After consideration of both the public comments and the recommendations of the AMA RUC, we are altering the direct PE inputs for these codes as follows. The ''kit, sinus surgery, balloon (maxillary, frontal, or sphenoid)'' (SA106) will be included in the direct PE database at the quantity of one-half for each of the three CPT codes: 31295, 31296, and 31297. The ''kit, sinus surgery, balloon (maxillary)'' (SA107) will be removed as an input for 31295 in the direct PE database. We are not allocating equipment for an additional scope or an additional light source for any of the codes. However, we are not finalizing the direct PE inputs for 31295, 31296, or 31297 for CY 2012. Instead, we will keep these direct PE inputs as interim final for CY 2012. We seek additional public comments regarding the appropriate direct PE inputs for these codes and we will continue to consider the AMA RUC's solution for future rulemaking.

(4) Insertion of Intraperitoneal Catheter

For CY 2011, CPT created a new code to describe percutaneous procedures: 49418 (Insertion of tunneled intraperitoneal catheter (*e.g.,* dialysis, intraperitoneal chemotherapy instillation, management of ascites), complete procedure, including imaging guidance, catheter placement, contrast injection when performed, and radiological supervision and interpretation; percutaneous).

Comment: Two commenters stated that CMS had not addressed some of the direct PE input recommendations for CPT Code 49418 (Insertion of tunneled intraperitoneal catheter, complete procedure). In particular, the commenters suggested that a film jacket and a CD approved by the RUC as disposable supply inputs for the codes were not included in the direct PE database but were not were not addressed as refinements in the CY 2011 PFS final rule with comment period. Another commenter suggested that there were discrepancies between the clinical labor inputs for these codes and the AMA RUC recommendations that were not addressed as refinements in the CY 2011 PFS final rule with comment period.

Response: We did not accept the film jacket as a disposable supply item because film jackets are not disposable/consumable supplies. This refinement was included in the CY 2011 PFS final rule (75 FR 73362). We did not incorporate the CD as a supply item for 49418 since the code also included x-ray film, which can also be a proxy for digital image storage. We mistakenly omitted this refinement from the list of refinement in the CY 2011 PFS final rule. We have reexamined the CY 2011 AMA RUC direct PE recommendations for these codes and confirmed that the labor minutes associated with the codes in the direct PE database match the AMA RUC recommendations regarding clinical labor inputs, which we accepted without refinement.

In addition to the public comments, we have reviewed the inputs for this code and are concerned with one of the disposable supplies included in the recommendation. We accepted an item called ''Y-set connection tubing'' (SD260). The invoice submitted with the recommendation describes an item that is used to replace a plastic catheter connecter included with a disposable flex-neck catheter. We are asking for public comment regarding the accuracy of this item.

We are maintaining the direct PE inputs for CPT code 49418 for CY 2012, but since we are seeking public comment regarding a particular supply item, we are keeping the direct PE inputs as interim for CY 2012.

(5) In Situ Hybridization Testing

We note that we also received comments on the interim final direct PE inputs for CPT codes 88120 (Cytopathology, in situ hybridization (*e.g.,* FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; manual) and 88121 (Cytopathology, in situ hybridization (*e.g.,* FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; using computer-assisted technology). We addressed those comments in CY 2012 PFS proposed rule and again in section II.B.5.b. of this final rule. We refer readers there for additional discussion of these codes. As we note in that section, for CY 2012 we are maintaining the current direct PE inputs for CPT codes 88120 and 88121, but they will remain interim and open for public comment.

(6) External Mobile Cardivascular Telemetry

In the CY 2011 PFS final rule with comment period, after consideration of the public comments we received, we established a national price for CPT code 93229 (Wearable mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG-triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and physician prescribed transmission of daily and emergent data reports) instead of maintaining the code as contractor-priced as we had proposed for CY 2011. We adopted the AMA RUC's recommendations for the clinical labor and supply inputs, and utilized price, utilization, and useful life information provided by commenters as equipment inputs for the cardiac telemetry monitoring device worn by the patient. In developing PE RVUS for this service, we classified the costs associated with the centralized monitoring equipment, including the hardware and software, workstation, webserver, and call recording system, as indirect costs.

Comment: We received comments objecting to the manner in which CPT 93229 was nationally priced. These objections included reiterations of earlier comments received on the CY 2011 PFS proposed rule that we should treat the centralized hardware and software as a direct cost similar to the treatment of the cardiac telemetry monitoring device worn by the patient and we should incorporate a new PE/HR value into the methodology for services such as remote cardiac monitoring.

Response: As we noted in the CY 2011 PFS final rule, we believe it is more appropriate to classify the costs associated with the centralized monitoring equipment, including the hardware and software, workstation, webserver, and call recording system, as indirect costs since it is difficult to allocate those costs to services furnished to individual patients in a manner that adequately reflects the number of patients being tested. As we also indicated in the CY 2011 PFS final rule, it would be inappropriate to deviate from our standard PFS PE methodology to adopt a PE/HR that is specific to CPT code 93229 or any other set of cardiac monitoring codes based on data from two telemetry providers, from a subset of services provided by certain specialty cardiac monitoring providers, or from a certain group of specialty providers that overall furnish only a portion of cardiac monitoring services, nor to change our established indirect PE allocation methodology. We believe the current PE methodology appropriately captures the relative costs of these services in setting their PE RVUs, based on the conclusion we have drawn following our assessment of the centralized

monitoring system that is especially characteristic of services such as CPT code 93229. For these reasons, after careful consideration of the comments received on this issue, we continue to disagree with commenters who believe we should treat the centralized hardware and software as a direct cost and that we should incorporate a new PE/HR value into the methodology for services such as remote cardiac monitoring. We are finalizing, without modification, the development of PE RVUs for CPT 93229.

3. Finalizing CY 2011 Interim Final and CY 2012 Proposed Malpractice RVUs

a. Finalizing CY 2011 Interim Final Malpractice RVUs

Consistent with our malpractice methodology described in section II.C.1. of this final rule with comment period, for the CY 2011 PFS final rule, we developed malpractice RVUs for new codes and adjusted malpractice RVUs for revised codes by scaling the malpractice RVUs of the CY 2011 new/revised codes for differences in work RVUs between a source code and the new/revised codes. For CY 2011 we adopted the AMA RUC-recommended source code crosswalks for all new and revised codes on an interim final basis.

Comment: Commenters supported the adoption of the AMA RUC-recommended malpractice crosswalks for the CY 2011 new and revised codes and encouraged CMS to continue to adopt the AMA RUC recommendations in future rulemaking.

Response: We thank commenters for their support of the CY 2011 interim final malpractice crosswalks. We will continue to consider the AMA RUC–recommended malpractice crosswalks and public comments when determining the appropriate risk-of-service for new/revised codes. For CY 2012 we are finalizing, without modification, the CY 2011 interim final malpractice source code crosswalks. The CY 2011 interim final malpractice crosswalk, finalized for CY 2012, is available at the CMS Web site at: *http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp*.

We did not receive any comments to the CY 2011 PFS final rule with comment period disagreeing with the malpractice crosswalk for any of the CY 2011 new and revised codes. However, we note that we did receive a comment to the CY 2012 PFS proposed rule for CPT codes 88120 (Cytopathology, in situ hybridization (*e.g.,* FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; manual) and 88121 (Cytopathology, in situ hybridization (*e.g.,* FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; using computer-assisted technology); both CPT codes had CY 2011 interim final PE, work, and malpractice RVUs. The commenter requested that we increase the physician work and malpractice RVUs assigned to CPT code 88121 to match the physician work and malpractice RVUs assigned to CPT code 88120. As discussed in detail in section II.B.5. of this final rule with comment period, we are holding the PE, work, and malpractice RVUs for CPT code 88120 and 88121 as interim for CY 2012, pending re-review by the AMA RUC.

Additionally, we received a comment to the CY 2011 PFS final rule requesting that we reevaluate the malpractice risk factor for a number of largely pediatric cardiothoracic surgery CPT codes. These CPT codes were not open for comment for CY 2011, however we addressed this malpractice comment in the CY 2012 PFS proposed rule (76 FR 42814), and it is discussed in greater detail in section II.A.3.d. of this final rule with comment period.

b. Finalizing CY 2012 Proposed Malpractice RVUs, Including Malpractice RVUs for Certain Cardiothoracic Surgery Services

As described in the Five Year Review (76 FR 32469) for CPT codes with work RVU changes included in the Fourth Five-Year Review, the malpractice source code for nearly all reviewed codes was the code itself (a 1 to 1 crosswalk). For these CPT codes, we calculated the revised malpractice RVUs by scaling the current (CY 2011) malpractice RVU by the percent difference in work RVU between the current (CY 2011) work RVU and the proposed work RVU. However, there were three CPT codes included in the Five Year Review that were previously contractor priced and did not have current (CY 2011) work RVUs—CPT codes 33981 (Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump), 33982 (Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass), and 33983 (Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass). For all three CPT codes, we applied the AMA RUC-recommended malpractice crosswalks to obtain the appropriate malpractice RVUs. The crosswalk source code for CPT code 33981 was CPT code 33976 (Insertion of ventricular assist device; extracorporeal, biventricular), and the crosswalk source for CPT codes 33982 and 33983 was CPT code 33979 (Insertion of ventricular assist device, implantable intracorporeal, single ventricle). Consistent with the malpractice methodology, the malpractice RVUs for these three newly-valued CPT codes were developed by adjusting the malpractice RVU of the source codes for the difference in work RVU between the source code and the newly-valued codes.

We received no comments on the malpractice crosswalks included in the Five-Year Review. We are finalizing the Five-Year Review malpractice crosswalks without modification for CY 2012.

In the CY 2012 PFS proposed rule there were a number of codes for which we reviewed the physician work and practice expense. Like the Five-Year Review, for these CPT codes the source code for each code was the code itself (a 1-to-1 crosswalk). Therefore, we calculated the revised malpractice RVUs for these codes by scaling the current (CY 2011) malpractice RVU by the percent difference in work RVU between the current (CY 2011) work RVU and the proposed work RVU (76 FR 42813).

In addition to the scaling of malpractice RVUs to account for the proportionate difference between current and proposed work RVUs, there were 19 cardiothoracic surgery codes for which we proposed to scale the malpractice RVUs to account for the proportionate difference between the current and proposed revised specialty risk factor (76 FR 42813). These codes and their short descriptors are listed in Table 17. We assign malpractice RVUs to each service based upon a weighted average of the malpractice risk factors of all specialties that furnish the service. For the CY 2010 review of malpractice RVUs, we used CY 2008 Medicare claims data on allowed services to establish the frequency of a service by specialty. For a number of cardiothoracic surgery CPT codes representing major open heart procedures performed primarily on neonates and infants, CY 2008 Medicare claims data showed zero allowed services. Therefore, our contractor set the number of services to 1, and assigned a risk factor according to the average risk factor for all services that do not explicitly have a separate technical or professional component (average risk factor = 1.95). In the CY 2010 PFS final rule with comment period, we published interim final malpractice RVUs for these codes calculated using the average physician risk factor, and finalized them in the CY

2011 PFS final rule with comment period. However, since publication of the CY 2010 PFS final rule with comment period, stakeholders expressed concern that the average risk factor was not appropriate for these services, and that a cardiac surgery risk factor would be more appropriate (cardiac surgery risk factor = 6.93). While these CPT codes continued to have little to no Medicare claims data, upon clinical review we agreed that these CPT codes represent cardiac surgery services and that the malpractice RVUs should be calculated using the cardiac surgery risk factor. Accordingly, we proposed to scale the malpractice RVUs for these CPT codes to reflect the proportionate difference between the average risk factor and the cardiac surgery risk factor.

We also proposed to scale the malpractice RVUs to reflect a change in risk factor for CPT code 32442 (Removal of lung, total pneumonectomy; with resection of segment of trachea followed by broncho-tracheal anastomosis (sleeve pneumonectomy)). In the CY 2010 review of malpractice RVUs we assigned CPT code 32442 the pulmonary disease risk factor (2.09) and published the interim final malpractice RVU calculated from this risk factor in the CY 2010 PFS final rule with comment period. This value was finalized in the CY 2011 PFS final rule with comment period. Since finalizing this value, stakeholders have suggested that a blended risk factor of thoracic surgery (6.49) and general surgery (5.91) would be more appropriate for this service. As described in the CY 2010 PFS final rule with comment period (74 FR 61760), we do not use a blended risk factor for services with Medicare utilization under 100; instead, we use the malpractice risk factor of the specialty that performs the given service the most (the dominant specialty). As CPT code 32442 has Medicare utilization well below the 100 occurrences threshold, and current Medicare claims data show that the dominant specialty for CPT code 32442 is thoracic surgery, we believed that the thoracic surgery risk factor is the appropriate risk factor for this service. Adjusting the malpractice RVU to reflect the thoracic surgery risk factor rather than the pulmonary disease risk factor resulted in a malpractice RVU of 13.21 for CPT code 32442. Therefore, we proposed a malpractice RVU of 13.21 for CPT code 32442 for CY 2012.

TABLE 17: CY 2012 PROPOSED MP RVUS FOR CERTAIN CARDIOTHORACIC SURGERY SERVICES

CPT Code	Short Descriptor	CY 2011 MP RVU	Proposed CY 2012 MP RVU
33471	Valvotomy pulmonary valve	1.62	5.76
33472	Revision of pulmonary valve	1.63	5.80
33676	Close mult vsd w/resection	2.63	9.36
33677	Cl mult vsd w/rem pul band	2.74	9.75
33692	Repair of heart defects	*2.56	9.11
33762	Major vessel shunt	1.61	5.73
33768	Cavopulmonary shunting	0.56	1.99
33771	Repair great vessels defect	2.90	10.32
33775	Repair great vessels defect	2.33	8.29
33776	Repair great vessels defect	2.45	8.72
33777	Repair great vessels defect	2.42	8.61
33778	Repair great vessels defect	3.05	10.85
33779	Repair great vessels defect	3.09	10.99
33780	Repair great vessels defect	3.13	11.14
33781	Repair great vessels defect	3.09	10.99
33786	Repair arterial trunk	2.98	10.60
33788	Revision of pulmonary artery	1.93	6.87
33822	Revise major vessel	1.25	4.45
32442	Sleeve pneumonectomy	4.25	13.21

*The MP RVU listed for CPT code 33692 is the Five-Year Review-adjusted MP RVU, not the CY 2011 MP

Comment: Commenters noted their appreciation of our review and revisions to these 19 cardiothoracic surgery services. Commenters stated that setting the risk factor to the all physician average penalized the providers of these procedures, and expressed concern that this will occur again unless CMS considers using an assigned specialty for CPT codes with fewer than 100 claims per year. Commenters believe that it would be prudent to re-examine the use of claims data to identify the appropriate specialty for services with less than 100 claims.

Response: We appreciate commenters support for our proposal to revise the malpractice RVUs for certain cardiothoracic surgery services. We note commenters' concern with the malpractice methodology as it relates to services with less than 100 claims and will consider this recommendation for future rulemaking. We received no comments on the 1-to-1 crosswalks described previously for CPT codes with work and practice expense revisions in the CY 2012 PFS proposed rule. For CY 2012, we are finalizing without modification, the proposed crosswalks,

as well as the proposed revisions to the malpractice risk factors for the cardiothoracic surgery services described previously.

4. Payment for Bone Density Tests

Section 1848(b)(6) of the Act (as amended by section 3111(a) of the Affordable Care Act) changed the payment calculation for dual-energy x-ray absorptiometry (DXA) services described by two specified DXA CPT codes for CY s 2010 and 2011. This provision required payment for these services at 70 percent of the product of the CY 2006 RVUs for these DXA codes, the CY 2006 CF, and the geographic adjustment for the relevant payment year.

Effective January 1, 2007, the CPT codes for DXA services were revised. The former DXA CPT codes 76075 (Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites; axial skeleton (*e.g.,* hips, pelvis, spine)); 76076 (Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites; appendicular skeleton (peripheral) (for example, radius, wrist, heel)); and 76077 (Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites; vertebral fracture assessment) were deleted and replaced with new CPT codes 77080, 77081, and 77082 that have the same respective code descriptors as the predecessor codes. Section 1848(b) of the Act, as amended, specifies that the revised payment applies to two of the predecessor codes (CPT codes 76075 and 76077) and ''any succeeding codes,'' which are, in this case, CPT codes 77080 and 77082.

As mentioned previously, section 1848(b) of the Act revised the payment for CPT codes 77080 and 77082 during CY 2010 and CY 2011. We provided for payment in CY s 2010 and 2011 under the PFS for CPT codes 77080 and 77082 at the specified rates (70 percent of the product of the CY 2006 RVUs for these DXA codes, the CY 2006 CF, and the geographic adjustment for the relevant payment year). Because the statute specifies a payment calculation for these services for CY s 2010 and 2011 as described previously, for those years we implemented the payment provision by imputing RVUs for these services that would provide the specified payment amount for these services when multiplied by the current year's conversion factor.

As discussed in the CY 2012 PFS proposed rule (76 FR 42809 and 42810), for CY 2012, the payment rate for CPT codes 77080 and 77082 will be based upon resource-based, rather than imputed, RVUs, and the current year's conversion factor. The CY 2012 work, PE, and malpractice RVUs for these codes are shown in Table 18, CY 2012 RVUs for DXA CPT Codes 77080 and 77082, as well as in Addendum B of this final rule with comment period.

TABLE 18: CY 2012 RVUS FOR DXA CPT CODES 77080 AND 77082

CPT Code	Modifier	Work RVU	Fully Implemented Non-Facility PE RVU	Transitional Non-facility PE RVU	Fully Implemented Facility PE RVU	Transitional Facility PE RVU	Malpractice RVU
77080		0.20	1.28	1.45	N/A	N/A	0.02
77080	TC	0.00	1.20	1.37	N/A	N/A	0.01
77080	26	0.20	0.08	0.08	0.08	0.08	0.01
77082		0.17	0.64	0.66	N/A	N/A	0.02
77082	TC	0.00	0.57	0.59	N/A	N/A	0.01
77082	26	0.17	0.07	0.07	0.07	0.07	0.01

In addition to temporarily changing the payment rate for the two DXA CPT codes, section 3111(b) of the Affordable Care Act also authorizes the Secretary to enter into agreement with the Institute of Medicine of the National Academies to conduct a study on the ramifications of Medicare payment reductions for dual-energy x-ray absorptiometry (as described in section 1848(b)(6) of the Act) during years 2007, 2008, and 2009 on beneficiary access to bone mass density tests. This study has not yet been conducted. In the absence of this study, we have requested that the AMA RUC review CPT codes 77080 and 77082 during CY 2012.

5. Other New, Revised, or Potentially Misvalued Codes With CY 2011 Interim Final RVUs or CY 2012 Proposed RVUs Not Specifically Discussed in the CY 2012 Final Rule With Comment Period

For all other new, revised, or potentially misvalued codes with CY 2011 interim final RVUs or CY 2012 proposed RVUs that are not specifically discussed in this final rule with comment period, we are finalizing for CY 2012, without modification, the interim final or proposed work and malpractice RVUs and direct PE inputs. Unless otherwise indicated, we agreed with the time values recommended by the AMA RUC or HCPAC for all codes addressed in this section. The time values for all codes appear on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

C. Establishing Interim Final RVUs for CY 2012

1. Establishing Interim Final Work RVUs for CY 2012

a. Code-Specific Issues

As previously discussed in section III.A of this final rule with comment period, on an annual basis, the AMA RUC and HCPAC provide CMS with recommendations regarding physician work values for new and revised CPT codes. This section discusses the families of clinically related CPT codes where CMS disagreed with the AMA RUC or HCPAC recommended physician work RVU or time values for a service for a CY 2012 new or revised CPT code. The interim or interim final physician work RVUs for all new and revised codes, including those where CMS agreed with the recommended work RVU appear in Table 19 at the end of this section. Unless otherwise indicated, we agreed with the time values recommended by the AMA RUC or HCPAC for all codes addressed in this section. The time values for all codes appear on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.* We reviewed the AMA RUC's recommendations on physician work and time for 156 CY 2012 new and revised CPT codes. Upon clinical review, we agreed with the

AMA RUC's work RVU recommendation for 106 CPT codes, or 68 percent. We reviewed the HCPAC's recommendations on physician work and time for 8 CPT codes. Upon clinical review, we agreed with the HCPAC's work RVU recommendation for 6 CPT codes, or 75 percent.

We note that the AMA RUC also reviewed over 100 CPT codes describing molecular pathology services. These CPT codes are new for CY 2012, however they will not be valid for Medicare purposes for CY 2012—For CY 2012 Medicare will continue to use the current ''stacking'' codes for the reporting and payment for these services. These molecular pathology codes appear in Addendum B to this final rule with the procedure status indicator of I (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment for these services).

(1) Integumentary System: Skin, Subcutaneous, and Accessory Structures (CPT Codes 10060–10061, and 11056)

CPT/HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
10060	Drainage of skin abscess	1.22	1.50	1.22	Disagree	No
10061	Drainage of skin abscess	2.45	2.45	2.45	Agree	No
11056	Trim skin lesions 2 to 4	0.61	0.50	0.50	Agree	No

CPT code 10061 was identified by the AMA RUC Relativity Assessment Workgroup through the Harvard-Valued—Utilization > 100,000 screen. CPT code 10060 was identified as part of this family to be reviewed. We identified CPT code 11056 as part of the MPC List screen.

After clinical review of CPT codes 10060 (Incision and drainage of abscess (*e.g.,* carbuncle, suppurative hidradenitis, cutaneous or subcutaneous abscess, cyst, furuncle, or paronychia); simple or single) and 10061 (Incision and drainage of abscess (*e.g.,* carbuncle, suppurative hidradenitis, cutaneous or subcutaneous abscess, cyst, furuncle, or paronychia); complicated or multiple) we believe that the current work RVUs of 1.22 and 2.45 respectively, accurately reflect the work associated with these services. Upon review, we found no evidence that the work for these services has changed.

For the Third Five-Year Review for CY 2007, the HCPAC recommended increasing the work RVU for CPT code 10060 from 1.17 to 1.50 because the HCPAC believed the survey methodology used for this code in the original Harvard valuation was flawed. In reviewing this code for the Third Five-Year Review we compared the specialty society survey times with the Harvard-based times and found them comparable (71 FR 37236). As such, we found no grounds for increase, and ultimately maintained the work RVU of 1.17 for this service (71 FR 69733). For the CY 2010 PFS, the work RVU for CPT code 10060 was increased to 1.22 based on the redistribution of RVUs resulting from the CMS policy to no longer recognize the CPT consultation codes.

For CY 2012, the AMA RUC reviewed the survey results from physicians who perform this service. Citing the HCPAC rationale and recommendation in the Third Five-Year Review, the AMA RUC recommended the survey median work RVU of 1.50 for CPT code 10060 for CY 2012. We continue to believe that the original valuation of the service was appropriate, and since the work associated with the procedure has not changed, we believe that the current work RVU of 1.22 should be maintained. Therefore, we are assigning a work RVU of 1.22 to CPT code 10060 on an interim final basis for CY 2012.

We reviewed CPT code 11056 (Paring or cutting of benign hyperkeratotic lesion (*e.g.,* corn or callus); 2 to 4 lesions), and are accepting the HCPAC-recommended work RVU of 0.50, the survey 25th percentile value, on an interim basis for CY 2012. We request that the specialty society re-review CPT code 11056 along with CPT codes 11055 (Paring or cutting of benign hyperkeratotic lesion (*e.g.,* corn or callus); single lesion) and 11057 (Paring or cutting of benign hyperkeratotic lesion (*e.g.,* corn or callus); more than 4 lesions) as part of the family. Therefore, we are assigning a work RVU of 0.50 to CPT code 11056 on an interim basis for CY 2012, pending re-review of the family of services.

For the CY 2012 new, revised, and potentially misvalued CPT codes reviewed in this family of services and not specifically discussed here, we agree with the AMA RUC/HCPAC-recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

(2) Integumentary System: Nails (CPT codes 11719–11721)

CPT/HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
11719	Trim nail(s)	0.17	0.17	0.17	N/A	N/A
11720	Debride nail 1-5	0.32	0.32	0.32	Agree	No
11721	Debride nail 6 or more	0.54	0.54	0.54	Agree	No

We identified CPT code 11721 as part of the MPC List screen. The AMA RUC recommended that CPT codes 11721, along with CPT code 11719 and 11720 be surveyed for CY 2012.

After reviewing the survey data, the specialty society concluded that the survey data for CPT code 11719 (Trimming of nondystrophic nails, any number) was not reflective of the service, and is resurveying CPT code 11719 for CY 2013. We will review CPT code 11719 at that time, along with G0127 (Trimming of dystrophic nails, any number) which is crosswalked to CPT code 11719.

After clinical review of CPT code 11720 (Debridement of nail(s) by any method(s); 1 to 5.), and 11721 (Debridement of nail(s) by any method(s); 6 or more.), we believe that the current (CY 2011) work RVUs of 0.32 and 0.54 (respectively) continue to accurately account for the work of these services. The HCPAC also recommended maintaining the current (CY 2011) work RVUs for these services. Therefore, we are assigning a work RVU of 0.32 for CPT code 11720 and a work RVU of 0.54 for CPT code 11721 on an interim final basis for CY 2012.

(3) Integumentary System: Repair (Closure) (CPT Codes 15271–15278, 15777, 16020, 16025)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
15271	Skin sub graft trnk/arm/leg	New	1.50	1.50	Agree	No
15272	Skin sub graft t/a/l add-on	New	0.59	0.33	Disagree	No
15273	Skin sub grft t/arm/lg child	New	3.50	3.50	Agree	No
15274	Skn sub grft t/a/l child add	New	0.80	0.80	Agree	No
15275	Skin sub graft face/nk/hf/g	New	1.83	1.83	Agree	No
15276	Skin sub graft f/n/hf/g addl	New	0.59	0.50	Disagree	No
15277	Skn sub grft f/n/hf/g child	New	4.00	4.00	Agree	No
15278	Skn sub grft f/n/hf/g ch add	New	1.00	1.00	Agree	No
15777	Acellular derm matrix implt	New	3.65	3.65	Agree	No
16020	Dress/debrid p-thick burn s	0.80	0.80	0.71	Disagree	Yes
16025	Dress/debrid p-thick burn m	1.85	1.85	1.74	Disagree	Yes

For CY 2012, the CPT Editorial Panel deleted 24 skin substitute codes and established a 2-tier structure with 8 new codes (CPT codes 15271 through 15278) to report the application of skin substitute grafts, which are distinguished according to the anatomic location and surface area rather than by product description. Additionally, the CPT Editorial Panel created a new add-on code (CPT code 15777) to report implantation of a biological implant for soft ties reinforcement. For CY 2012, the AMA RUC Relativity Assessment Workgroup identified CPT codes 16020 and 16025 through its Different Performing Specialty from Survey screen.

For CY 2011, we created 2 HCPCS codes, G0440 (Application of tissue cultured allogeneic skin substitute or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; first 25 sq cm or less) and G0441 (Application of tissue cultured allogeneic skin substitute or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; each additional 25 sq cm), that are recognized for payment under the PFS for the application of products described by the codes to the lower limb. These codes will be deleted for CY 2012. Providers reporting the application of tissue cultured allogeneic skin substitute or dermal substitutes to the lower limb for payment under the PFS in CY 2012 should report under the appropriate new CPT code(s).

After clinical review of CPT code 15272 (Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)), we believe that a work RVU of 0.33 accurately reflects the work for associated with this service. The AMA RUC reviewed the survey results for CPT code 15272 and recommended the survey 25th percentile work RVU of 0.59 for this service.

However, we believe this value overstates the work of this procedure when compared to the base CPT code 15271 (Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area). We believe that CPT code 15272 is similar in intensity to CPT code 15341 (Tissue cultured allogeneic skin substitute; each additional 25 sq cm, or part thereof (List separately in addition to code for primary procedure)), and that the primary factor distinguishing the work of the two services is the intra-service physician time. CPT code 15341 has a work RVU of 0.50, 15 minutes of intra-service time, and an IWPUT of 0.0333. CPT code 15272 has 10 minutes of intra-service time. Ten minutes of intra-service work at the same intensity as CPT code 15341 is equal to a work RVU of 0.33 (10 minutes × 0.0333 IWPUT = 0.33 WRVU). Therefore, we are assigning a work RVU of 0.33 to CPT code 15272 on an interim final basis for CY 2012.

After clinical review of CPT code 15276 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)), we believe that a work RVU of 0.50 accurately reflects the work associated with this service. The AMA RUC reviewed the survey results for CPT code 15276 and recommended a work RVU of 0.59 which corresponds to the the AMA RUC's recommended work RVU for CPT code 15272. As discussed previously, we are assigning an interim final work RVU of 0.33 to CPT code 15272. We believe that the work associated with CPT code 15276, which describes work on the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple

digits, is more intense than the work associated with CPT code 15272, which describes work on the trunk, arms, legs. We believe that a work RVU of 0.50 for CPT code 15276 accurately captures the work associated with this service, and establishes the appropriate relativity between the services. Therefore, we are assigning a work RVU of 0.50 to CPT code 15276 on an interim final basis for CY 2012.

CPT codes 16020 (Dressings and/or debridement of partial-thickness burns, initial or subsequent; small (less than 5 percent total body surface area)) and 16025 (Dressings and/or debridement of partial-thickness burns, initial or subsequent; medium (*e.g.,* whole face or whole extremity, or 5 percent to 10 percent total body surface area)) are typically billed on the same day as an E/M service. We believe some of the activities conducted during the pre- and post-service times of the procedure code and the E/M visit overlap and, therefore, should not be counted twice in developing the procedure's work value. As described earlier in section III.A. of this final rule with comment period, to account for this overlap, we reduced the pre-service evaluation and post-service time by one-third. For CPT code 16020 we reduced the pre-service evaluation time from 7 minutes to 5 minutes and the post service time from 5 minutes to 3 minutes. For CPT code 16025 we reduced the pre-service evaluation time from 10 minutes to 7 minutes, and the post-service time from 5 minutes to 3 minutes. A complete listing of the times assigned to these CPT codes is available on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

In order to determine the appropriate work RVUs for these services given the time changes, we calculated the value of the extracted time and subtracted it from the AMA RUC-recommended work RVUs. For CPT code 16020, we removed a total of 4 minutes at an intensity of 0.0224 per minute, which amounts to the removal of 0.09 of a work RVU. The AMA RUC recommended a work RVU of 0.80, the current (CY 2011) work RVU. We are assigning an interim final work RVU of 0.71, with refinement to time, to CPT code 16020 for CY 2012. For CPT code 16025, we removed a total of 5 minutes at an intensity of 0.0224 per minute, which amounts to the removal of 0.11 of a work RVU. The AMA RUC recommended a work RVU of 1.85, the current (CY 2011) work RVU. We are assigning an interim final work RVU of 1.74, with refinement to time, to CPT code 16025 for CY 2012.

For the CY 2012 new, revised, and potentially misvalued CPT codes reviewed in this family of services and not specifically discussed here, we agree with the AMA RUC/HCPAC-recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

(4) Musculoskeletal: Hand and Fingers (CPT Code 26341)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
26341	Manipulat palm cord post inj	New	1.66	0.91	Disagree	No

For CY 2012, the CPT Editorial Panel created CPT codes 26341 and 20517 to describe a new technique for treating Dupuytren's contracture by injecting an enzyme into the Dupuytren's cord for full finger extension and manipulation.

After clinical review of CPT code 26341 (Manipulation, palmar fascial cord (ie, Dupuytren's cord), post enzyme injection (*e.g.,* collagenase), single cord), we believe that a work RVU of 0.91 accurately reflects the work associated with this service. The AMA RUC reviewed the survey results for CPT code 26341 and recommended a work RVU of 1.66, which corresponds to the survey 25th percentile value. We believe the service described by CPT code 26341 is analogous to CPT code 97140 (Manual therapy techniques (*e.g.,* mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes) which has a work RVU of 0.43. However, CPT code 97140 has no post-service visits (global period = XXX), while CPT code 26341 includes 1 CPT code 99212 level 2 office or outpatient visit (global period = 010). To account for this difference, we added the work RVU of 0.48 for CPT code 99212, to the work RVU of 0.43 for CPT code 97140, for a total work RVU of 0.91. Therefore, we are assigning an interim final work RVU of 0.91 to CPT code 26341 for CY 2012.

(5) Musculoskeletal: Application of Casts and Strapping (CPT Codes 29581–29584)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
29581	Apply multlay comprs lwr leg	0.60	0.60	0.25	Disagree	No
29582	Apply multlay comprs upr leg	New	0.35	0.35	Agree	No
29583	Apply multlay comprs upr arm	New	0.25	0.25	Agree	No
29584	Appl multlay comprs arm/hand	New	0.35	0.35	Agree	No

For CY 2012 the CPT Editorial Panel revised the descriptor for CPT code 29581, and also created CPT codes 29582, 29583, and 29584 to describe the application of multi-layer compression to the upper and lower extremities. The CPT Editorial Panel and AMA RUC concluded that the revisions to the descriptor for CPT code 29581 were

editorial only, and the AMA RUC related specialty society (Society for Vascular Surgery) believed that resurveying CPT code 29581 was not necessary. As such, the AMA RUC recommended ''No Change'' for CPT code 29581. The new CPT codes 29582, 29583, and 29584 were surveyed through the American Physical Therapy Association (the expected dominant providers of the services), and the HCPAC reviewed the results and issued recommendations to CMS for these 3 new CPT codes.

After clinical review, we believe that CPT codes 29581 (Application of multi-layer compression system; leg (below knee), including ankle and foot), 29582 (Application of multi-layer compression system; thigh and leg, including ankle and foot, when performed), 29583 (Application of multi-layer compression system; upper arm and forearm) and 29584 (Application of multi-layer compression system; upper arm, forearm, hand, and fingers) all describe similar services from a resource perspective and should be valued similarly. We believe CPT code 29581 (work RVU = 0.60) is valued inappropriately high in relation to newly created, surveyed, and HCPAC-reviewed CPT codes 29582, 29583, and 29584. We believe that the HCPAC recommended work RVUs of 0.35 for CPT code 29682, 0.25 for CPT code 29583, and 0.35 for CPT code 29584 accurately reflect the work associated with these services. Additionally, we believe that the clinical conditions treated by CPT codes 29581 and 29583 are essentially the same, namely the treatment of venus ulcers and lymphedema. We recognize that there will be mild differences and variation in the application of a multi-layer compression system to the upper extremity versus the lower extremity, which is accounted for in the intra-service times of the codes. As such, we believe a work RVU of 0.25 appropriately accounts for the work associated with CPT code 29581. We believe that a survey that addresses all 4 CPT codes together as a family and gathers responses from all clinicians who furnish the services described by CPT codes 29581 through 29584 would help assure the appropriate gradation in valuation of these 4 services. In sum, on an interim basis for CY 2012 we are assigning a work RVU of 0.25 to CPT code 29581, a work RVU of 0.35 to CPT code 29582, a work RVU of 0.25 to 29593, and a work RVU of 0.35 to CPT code 29584.

(6) Musculoskeletal: Endoscopy/ Arthroscopy (CPT Codes 29826, 29880, 29881)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
29826	Shoulder arthroscopy/surgery	9.16	3.00	3.00	Agree	No
29880	Knee arthroscopy/surgery	9.45	7.39	7.39	Agree	No
29881	Knee arthroscopy/surgery	8.71	7.03	7.03	Agree	No

CPT code 29826 was identified by the AMA RUC Relativity Assessment Workgroup through the Codes Reported Together 75 percent or More screen. This service is commonly performed with CPT codes 29824, 29827 and 29828. In addition, as part of the Fourth Five-Year Review, CMS identified 29826 through the Harvard-Valued—Utilization > 30,000 screen.

Given that CPT code 29826 (Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coraco-acromial ligament (ie, arch) release, when performed) is rarely performed as a stand-alone procedure (less than 1 percent of the time), the American Academy of Orthopaedic Surgeons (AAOS) sent us a request to change the global period from 090 to ZZZ. A global surgical period of 090 is reflects a major surgery with a 1-day preoperative period and a 90-day postoperative period included in the fee schedule payment amount. A global surgical period of ZZZ reflects a service that is related to another service and is always included in the global period of the other service. These are often referred to as ''add-on'' codes or services. We agreed to change the global surgical period for CPT code 29826, and CPT code 29826 was surveyed and presented as an add-on service with a ZZZ global period.

After clinical review of CPT code 29826, we believe that the AMA RUC-recommended work RVU of 3.00, the survey 25th percentile value, accurately values the work associated with this service. We are assigning a work RVU of 3.00 to CPT code 29826 on an interim final basis for CY 2012.

For the CY 2012 new, revised, and potentially misvalued CPT codes reviewed in this family of services and not specifically discussed here, we agree with the AMA RUC/HCPAC-recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

(7) Respiratory: Lungs and Pleura (CPT Codes 32096–32854)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
32096	Open wedge/bx lung infiltr	New	17.00	13.75	Disagree	No
32097	Open wedge/bx lung nodule	New	17.00	13.75	Disagree	No
32098	Open biopsy of lung pleura	New	14.99	12.91	Disagree	No
32100	Exploration of chest	16.16	17.00	13.75	Disagree	No
32505	Wedge resect of lung initial	New	18.79	15.75	Disagree	No
32506	Wedge resect of lung add-on	New	3.00	3.00	Agree	No
32507	Wedge resect of lung diag	New	3.78	3.00	Disagree	No
32601	Thoracoscopy diagnostic	5.45	5.50	5.50	Agree	No
32607	Thoracoscopy w/bx infiltrate	New	5.50	5.50	Agree	No
32608	Thoracoscopy w/bx nodule	New	6.84	6.84	Agree	No
32609	Thoracoscopy w/bx pleura	New	4.58	4.58	Agree	No
32663	Thoracoscopy w/lobectomy	24.64	24.64	24.64	Agree	No
32666	Thoracoscopy w/wedge resect	New	14.50	14.50	Agree	No
32667	Thoracoscopy w/w resect addl	New	3.00	3.00	Agree	No
32668	Thoracoscopy w/w resect diag	New	4.00	3.00	Disagree	No
32669	Thoracoscopy remove segment	New	23.53	23.53	Agree	No
32670	Thoracoscopy bilobectomy	New	28.52	28.52	Agree	No
32671	Thoracoscopy pneumonectomy	New	31.92	31.92	Agree	No
32672	Thoracoscopy for lvrs	New	27.00	27.00	Agree	No
32673	Thoracoscopy w/thymus resect	New	21.13	21.13	Agree	No
32674	Thoracoscopy lymph node exc	New	4.12	4.12	Agree	No

The CPT Editorial Panel reviewed the lung resection family of codes for CY 2012 and deleted 8 codes, revised 5 codes and created 18 new codes to describe new thoracoscopic procedures and to clarify coding confusion between lung biopsy and lung resection procedures. For the wedge resection procedures, the revisions were based on three tiers; first, the approach, thoracotomy or thoracoscopy; second, the target to remove nodules or infiltrates; and lastly the intent, diagnostic or therapeutic (for nodules only, all infiltrates will be removed for diagnostic purposes).

After clinical review of CPT code 32096 (Thoracotomy, with diagnostic biopsy(ies) of lung infiltrate(s) (*e.g.,* wedge, incisional), unilateral), we believe a work RVU of 13.75 accurately reflects the work associated with this service compared to other related services. The AMA RUC reviewed the survey results, compared the code to other services, and concluded that the survey 25th percentile work RVU of 17.00 appropriately accounts for the work and physician time required to perform this procedure. We determined that the work associated with CPT code 32096 was similar in terms of physician time and intensity to CPT code 44300 (Placement, enterostomy or cecostomy, tube open (*e.g.,* for feeding or decompression) (separate procedure)). We believe crosswalking to the work RVU of CPT code 44300 appropriately accounts for the work associated with CPT code 32096. Therefore, we are assigning a work RVU of 13.75 for CPT code 32096 on an interim final basis for CY 2012.

After clinical review of CPT code 32097 (Thoracotomy, with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (*e.g.,* wedge, incisional), unilateral), we believe a work RVU of 13.75 accurately reflects the work associated with this service compared to other related services. The AMA RUC reviewed the survey results, compared the code to other services, and recommended the survey 25th percentile work RVU of 17.00. We determined that the work associated with CPT code 32096 was similar to CPT code 32096, to which we have assigned a work RVU of 13.75. Therefore, we are assigning a work RVU of 13.75 for CPT code 32097 on an interim final basis for CY 2012.

After clinical review of CPT code 32098 (Thoracotomy, with biopsy(ies) of pleura), we believe a work RVU of 12.91 accurately reflects the work associated with this service compared to other related services. The AMA RUC reviewed the survey results, compared the code to other services, and recommended the survey 25th percentile work RVU of 14.99. We determined that the work associated with CPT code 32098 was similar in terms of physician time and intensity to CPT code 47100 (Biopsy of liver, wedge). We believe crosswalking to the work RVU of CPT code 47100 appropriately accounts for the work associated with CPT code 32098. Therefore, we are assigning a work RVU of 12.91 to CPT code 32098 on an interim final basis for CY 2012.

After clinical review of CPT code 32100 (Thoracotomy; with exploration), we believe a work RVU of 13.75 accurately reflects the work associated with this service compared to other related services. The AMA RUC reviewed the survey results, compared the code to other services, and recommended a work RVU of 17.00. The AMA RUC concluded that CPT code 32100 is similar to new CPT code 32096, for which the AMA RUC recommended a work RVU of 17.00. We recognize the specialty society and AMA RUC assertion that CPT code 32100 should be valued the same as CPT codes 32096 and 32097 based on the assessment that the work is similar between these three services. We note that we assigned a work RVU of 13.75 to CPT codes 32096 and 32097. Accordingly, we are assigning a work RVU of 13.75 for CPT code 32100 on an interim final basis for CY 2012.

After clinical review of CPT code 32505 (Thoracotomy; with therapeutic wedge resection (*e.g.,* mass, nodule), initial), we believe a work RVU of 15.75 accurately reflects the work associated

with this service compared to other related services. The AMA RUC reviewed the survey results, compared the code to other services, and recommended the survey 25th percentile work RVU of 18.79. We recognize that CPT code 32505 has greater physician work and intensity compared to CPT code 32096, and we believe the additional 30 minutes of intra-service work associated with CPT code 32505 accounts for the additional work RVUs assigned to this service as compared to CPT code 32096, and that this incremental difference is equivalent to 2.00 work RVUs. Accordingly, we are assigning a work RVU of 15.75 for CPT code 32505 on an interim final basis for CY 2012.

After clinical review of CPT code 32507 (Thoracotomy; with diagnostic wedge resection followed by anatomic lung resection (List separately in addition to code for primary procedure)), we believe a work RVU of 3.00 accurately reflects the work associated with this service compared to other related services. The AMA RUC reviewed the survey results, compared the code to other services, and recommended the survey 25th percentile work RVU of 3.78. We believe that the work associated with this service is similar to the work of CPT code 32506 and should be valued the same. Accordingly, we are assigning a work RVU of 3.00 to CPT code 32507 on an interim final basis for CY 2012.

For CPT code 32663 (Thoracoscopy, surgical; with lobectomy (single lobe)), the AMA RUC recommended a work RVU of 24.64. Upon clinical review, we have determined that it is most appropriate to accept the AMA RUC recommended work RVU of 24.64 on a provisional basis, pending review of the open heart surgery analogs, in this case, CPT code 32480. We are requesting the AMA RUC look at the incremental difference in RVUs and times between the open and laparoscopic surgeries and recommend a consistent valuation of RVUs and time for CPT code 32663 and other services within this family with this same issue. Accordingly, we are assigning a work RVU of 24.64 for CPT code 32663 on an interim basis for CY 2012.

After clinical review of CPT code 32668 (Thoracoscopy, surgical; with diagnostic wedge resection followed by anatomic lung resection (List separately in addition to code for primary procedure)), we believe a work RVU of 3.00 accurately reflects the work associated with this service compared to other related services. The AMA RUC reviewed the survey results, compared the code to other services, and recommended the survey 25th percentile work RVU of 4.00. We believe that the work associated with this service is similar to the work of CPT code 32506, which we have valued at a work RVU of 3.00. Accordingly, we are assigning a work RVU of 3.00 to CPT code 32668 on an interim basis for CY 2012.

For CPT code 32669 (Thoracoscopy, surgical; with removal of a single lung segment (segmentectomy)), the AMA RUC recommended a work RVU of 23.53. Upon clinical review, we have determined that it is most appropriate to accept the AMA RUC recommended work RVU of 23.53 on a provisional basis, pending review of the open heart surgery analogs, in this case CPT code 32480. We are requesting the AMA RUC look at the incremental difference in RVUs and times between the open and laparoscopic surgeries and recommend a consistent valuation for CPT 32669 and other services within this family with this same issue. Accordingly, we are assigning a work RVU of 23.53 to CPT code 32669 on an interim basis for CY 2012.

For CPT code 32670 (Thoracoscopy, surgical; with removal of two lobes (bilobectomy)) the AMA RUC recommended a work RVU of 28.52. Upon clinical review, we have determined that it is most appropriate to accept the AMA RUC recommended work RVU of 28.52 on a provisional basis, pending review of the open heart surgery analogs, in this case CPT code 32482. We are requesting the AMA RUC look at the incremental difference in RVUs and times between the open and laparoscopic surgeries and recommend a consistent valuation for CPT 32670 and other services within this family with this same issue. Accordingly, we are assigning a work RVU of 28.52 to CPT code 32670 on an interim basis for CY 2012.

For CPT code 32671 (Thoracoscopy, surgical; with removal of lung (pneumonectomy)), the AMA RUC recommended a work RVU of 31.92. Upon clinical review, we have determined that it is most appropriate to accept the AMA RUC recommended work RVU of 31.92 on a provisional basis, pending review of the open heart surgery analogs, in this case CPT code 32440. We are requesting the AMA RUC look at the incremental difference in RVUs and times between the open and laparoscopic surgeries and recommend a consistent valuation for CPT 32671 and other services within this family with this same issue. Accordingly, we are assigning a work RVU of 31.92 to CPT code 32671 on an interim basis for CY 2012.

For CPT code 32672 (Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed), the AMA RUC recommended a work RVU of 27.00. Upon clinical review, we have determined that it is most appropriate to accept the AMA RUC recommended work RVU of 27.00 on a provisional basis, pending review of the open heart surgery analogs, in this case CPT code 32491. We are requesting the AMA RUC look at the incremental difference in RVUs and times between the open and laparoscopic surgeries and recommend a consistent valuation for CPT 32672 and other services within this family with this same issue. Accordingly, we are assigning a work RVU of 27.00 to CPT code 32672 on an interim basis for CY 2012.

For CPT code 32673 (Thoracoscopy, surgical; with resection of thymus, unilateral or bilateral), the AMA RUC recommended a work RVU of 21.13. Upon clinical review, we have determined that it is most appropriate to accept the AMA RUC recommended work RVU of 21.13 on a provisional basis, pending review of related CPT codes 60520 (Thymectomy, partial or total; transcervical approach (separate procedure)), 60521 (Thymectomy, partial or total; sternal split or transthoracic approach, without radical mediastinal dissection (separate procedure)), and 60522 (Thymectomy, partial or total; sternal split or transthoracic approach, with radical mediastinal dissection (separate procedure)). At this time, we have concerns about appropriate relativity between the times and RVUs of these services. We are assigning a work RVU of 21.13 to CPT code 32673 on an interim basis for CY 2012.

For the CY 2012 new, revised, and potentially misvalued CPT codes reviewed in this family of services and not specifically discussed here, we agree with the AMA RUC/HCPAC-recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

(8) Cardiovascular: Heart and Pericardium

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
33212	Insert pulse gen sngl lead	5.52	5.26	5.26	Agree	No
33213	Insert pulse gen dual leads	6.37	5.53	5.53	Agree	No
33221	Insert pulse gen mult leads	New	5.80	5.80	Agree	No
33227	Remove&replace pm gen singl	New	5.50	5.50	Agree	No
33228	Remv&replc pm gen dual lead	New	5.77	5.77	Agree	No
33229	Remv&replc pm gen mult leads	New	6.04	6.04	Agree	No
33230	Insrt pulse gen w/dual leads	New	6.32	6.32	Agree	No
33231	Insrt pulse gen w/mult leads	New	6.59	6.59	Agree	No
33240	Insrt pulse gen w/singl lead	7.64	6.05	6.05	Agree	No
33262	Remv&replc cvd gen sing lead	New	6.06	6.06	Agree	No
33263	Remv&replc cvd gen dual lead	New	6.33	6.33	Agree	No
33264	Remv&replc cvd gen mult lead	New	6.60	6.60	Agree	No
36000	Place needle in vein	0.18	0.00	0.00	N/A	N/A
36251	Ins cath ren art 1st unilat	New	5.45	5.35	Disagree	No
36252	Ins cath ren art 1st bilat	New	7.38	6.99	Disagree	No
36253	Ins cath ren art 2nd+ unilat	New	7.55	7.55	Agree	No
36254	Ins cath ren art 2nd+ bilat	New	8.15	8.15	Agree	No
37191	Ins endovas vena cava filtr	New	4.71	4.71	Agree	No
37192	Redo endovas vena cava filtr	New	8.00	7.35	Disagree	Yes
37193	Rem endovas vena cava filter	New	8.00	7.35	Disagree	Yes
37619	Ligation of inf vena cava	New	37.60	30.00	Disagree	No

(A) Pediatric Cardiovascular Code (CPT Code 36000)

The AMA RUC recommended that CMS consider a bundled status for CPT code 36000, (Introduction of needle or intracatheter, vein) because the AMA RUC and many specialty societies believe CPT code 36000 always is a component of other services. We agree with the AMA RUC recommendation and for CY 2012, CPT code 36000 will have a status code of B (bundled). We are publishing the RVUs for CPT code 36000 in the CY 2012 PFS, but Medicare will no longer make separate payment for this service.

(B) Renal Angiography Codes (CPT Codes 36251–36254)

CPT codes 75722 and 75724 were identified through the Codes Reported Together 75 percent or More screen. These supervision and interpretation codes were commonly billed with the catheter placement code 36245. For CY 2012, the specialties submitted a code change proposal to the CPT Editorial Panel to bundle the services commonly reported together. The panel deleted CPT codes 75722 and 75724 and created 4 bundled services (CPT codes 36251, 36252, 36253, and 36254) for CY 2012.

After clinical review of CPT code 36251 (Selective catheter placement (first-order), main renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture and catheter placement(s), fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiologic supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; unilateral), we believe a work RVU of 5.35 accurately reflects the work associated with this service. The AMA RUC reviewed the survey results, compared the code to other services, and concluded that the work value for CPT code 36251 should be directly crosswalked to CPT code 31267 (Nasal/ sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus) (work RVU = 5.45). The AMA RUC recommended a work RVU of 5.45 for CPT code 36251. We determined that the work associated with CPT code 36251 is closely aligned in terms of physician time and intensity with CPT code 52341 (Cystourethroscopy; with treatment of ureteral stricture (*e.g.,* balloon dilation, laser, electrocautery, and incision) (work RVU=5.35). We believe crosswalking to the work RVU of CPT code 52341 appropriately accounts for the work associated with CPT code 36251. Therefore, we are assigning a work RVU of 5.35 to CPT code 36251 on an interim final basis for CY 2012.

After clinical review of CPT code 36252 (Selective catheter placement (first-order), main renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture and catheter placement(s), fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiologic supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; bilateral), we believe a work RVU of 6.99 accurately reflects the work associated with this service. The AMA RUC reviewed the survey results, compared the code to other services, and concluded that the work value for CPT code 36252 should be directly crosswalked to CPT code 43272 (Endoscopic retrograde cholangiopancreatography (ERCP); with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique) (work RVU = 7.38). While the AMA RUC recommended a work RVU of 7.38 for CPT code 36252. We believe the intensity of this service is akin to CPT code 58560 (Hysteroscopy, surgical; with division or resection of intrauterine septum (any method)) (work RVU = 6.99). Accordingly, we are assigning a work RVU of 6.99 to CPT code 36252 on an interim final basis for CY 2012.

For the CY 2012 new, revised, and potentially misvalued CPT codes reviewed in this family of services and not specifically discussed here, we agree

with the AMA RUC/HCPAC-recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

(C) IVC Transcatheter Procedures (CPT Codes 37191–37193)

After clinical review of CPT code 37192 (Repositioning of intravascular vena cava filter, endovascular approach inclusive of vascular access, vessel selection, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy)), we believe a work RVU of 7.35 accurately reflects the work associated with this service. The AMA RUC reviewed the survey results, compared the code to other services, and concluded that the survey 75th percentile intra-service time of 60 minutes and the 25th percentile of work RVU of 8.00 accurately describes the physician work involved in the service. We determined that the work associated with CPT code 37192 is similar to CPT code 93460 (Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed), which has a work RVU of 7.35 and has the following times: 48 minutes pre-service, 50 minutes intra-service, and 30 minutes post-service. As such, we believe that the survey median intra-service time of 45 minutes appropriately accounts for the time required to furnish the intra-service work of this procedure. Therefore, we are assigning a work RVU of 7.35 to CPT code 37192, with a refinement to 45 minutes of intra-service time, on an interim final basis for CY 2012. A complete listing of the times associated with this code is available on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

After clinical review of CPT code 37193 (Retrieval (removal) of intravascular vena cava filter, endovascular approach inclusive of vascular access, vessel selection, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy)), we believe a work RVU of 7.35 accurately reflects the work associated with this service. The AMA RUC reviewed the survey results, compared the code to other services, and concluded that the survey 75th percentile intra-service time of 60 minutes and the 25th percentile of work RVU of 8.00 accurately describes the physician work involved in the service. We believe that the work associated with CPT code 37193 is similiar to CPT code 93460 (Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed), which has a work RVU of 7.35 and the following times: 48 minutes pre-service, 50 minutes intra-service, and 30 minutes post-service. As such, we believe that the survey median intra-service time of 45 minutes appropriately accounts for the time required to furnish the intra-service work associated with this procedure. Therefore, we are assigning a work RVU of 7.35 to CPT code 37193, with a refinement to 45 minutes of intra-service time, on an interim final basis for CY 2012. A complete listing of the times associated with this code is available on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

After clinical review of CPT code 37619 (Ligation of inferior vena cava), we believe a work RVU of 30.00 accurately reflects the work associated with this service. The AMA RUC reviewed the survey results, compared the code to other services, and concluded that the survey respondents underestimated the total physician work for this rarely performed service, by underestimating the significant post-operative work. The AMA RUC recommended a work RVU of 37.60 for CPT code 37619. We determined that the work associated with this service is more aligned with reference CPT code 37617 (Ligation, major artery (*e.g.,* post-traumatic, rupture); abdomen) (work RVU = 23.97), therefore we believe the survey median work RVU of 30.00 is more appropriate. Accordingly, we are assigning a work RVU of 30.00 to CPT code 37619 on an interim final basis for CY 2012.

For the CY 2012 new, revised, and potentially misvalued CPT codes reviewed in this family of services and not specifically discussed here, we agree with the AMA RUC/HCPAC-recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

(9) Hemic and Lymphatic Systems: General, Bone Marrow or Stem Cell Services/Procedures (CPT Codes 38230 and 38232)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
38230	Bone marrow harvest allogen	4.85	4.00	3.09	Disagree	No
38232	Bone marrow harvest autolog	New	3.50	3.09	Disagree	No

For CY 2012, the CPT Editorial Panel split CPT code 38230 into two separate codes: 38230 (Bone marrow harvesting for transplantation; allogeneic), and 38232 (Bone marrow harvesting for transplantation; autologous) to more accurately reflect current practice. For CY 2012, we changed the global period from 010 to 000 for CPT code 38230, and also assigned a global period of 000 to CPT code 38232, as these services rarely require overnight hospitalization and physician follow-up in the days following the procedure.

After clinical review of CPT codes 38230 and 38232, we believe that a work RVU of 3.09 appropriately accounts for the work associated with these services. The AMA RUC reviewed the specialty society survey results and, after comparison to similar CPT codes, the AMA RUC recommended the survey median work RVU of 4.00 for CPT code 38230, and the survey median work RVU of 3.50 for CPT code 38232. We believe that the work for these services is very similar and should be valued the same. CPT code 38230 currently (CY 2011) has a work RVU of 4.85 with a ten-day global period that includes 1 CPT code 99213 level 3 office or outpatient visit, and 1 CPT code 99238 discharge day management service. To

convert CPT code 38230 from a 10-day global period to a 0-day global period, one could subtract out the work RVUs for CPT code 99213 (work RVU = 0.97) and CPT code 99238 (work RVU = 1.28), resulting in a work RVU of 2.60. However, we believe that a work RVU of 2.60 would place these services too low compared to similar services. We believe that the CPT code 32830 survey 25th percentile work RVU of 3.09 accurately captures the intensity of these two services. Therefore, we are assigning a work RVU of 3.09 to CPT codes 32830 and 32832 on an interim final basis for CY 2012.

(10) Digestive: Liver (CPT Code 47000)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
47000	Needle biopsy of liver	1.90	1.90	1.90	Agree	No

We identified CPT code 47000 (Biopsy of liver, needle; percutaneous) as potentially misvalued through the Harvard-Valued—Utilization > 30,000 screen.

After clinical review of CPT code 47000, we believe that the current (CY 2011) work RVU of 1.90 be maintained. The AMA RUC reviewed the specialty society survey data, and also concluded that a work RVU of 1.90 be maintained. We request that the AMA RUC and CPT Editorial Panel consider reviewing all the percutaneous biopsy CPT codes to incorporate imaging guidance into the RVU and descriptor where appropriate. We are assigning a work RVU of 1.90 to CPT code 47000 on an interim final basis for CY 2012.

(11) Digestive: Abdomen, Peritoneum, and Omentum (CPT Codes 49082–49084)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
49082	Abd paracentesis	New	1.35	1.24	Disagree	Yes
49083	Abd paracentesis w/imaging	New	2.00	2.00	Agree	No
49084	Peritoneal lavage	New	2.50	2.00	Disagree	No

The AMA RUC identified CPT codes 49080 and 49081 through the Harvard-Valued—Utilization > 100,000 screen. The related specialty societies noted that the services have evolved since the codes were initially established and need separate codes that distinguish paracentesis performed without imaging guidance and paracentesis performed with imaging guidance. For CY 2012, the CPT Editorial Panel deleted CPT codes 49080 and 49081 and created 3 new CPT codes, 49082, 49083, and 49084, to more accurately describe the current medical practice.

After clinical review of CPT code 49082 (Abdominal paracentesis (diagnostic or therapeutic); without imaging guidance), we believe that a work RVU of 1.24 accurately accounts for the work associated with this service. The AMA RUC recommended a work RVU of 1.35 for CPT code 49082, which corresponds to the current (CY 2011) work RVU for CPT code 49080 (CY 2011 descriptor: Peritoneocentesis, abdominal paracentesis, or peritoneal lavage (diagnostic or therapeutic); initial). For CPT code 49082 we believe that the survey response rate (9 of 517) is too low to produce a reliable estimate. We believe that CPT code 49082 is similar in time and intensity to CPT code 32562 (Instillation(s), via chest tube/catheter, agent for fibrinolysis (*e.g.,* fibrinolytic agent for break up of multiloculated effusion); subsequent day) which has a work RVU of 1.24 and 10 minutes of intra-service time. Therefore, we are assigning a work RVU of 1.24, with a refinement to 10 minutes of intra-service time, to CPT code 49082 for CY 2012. A complete listing of the times associated with this CPT code is available on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

After clinical review of CPT codes 49083 (Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance) and 49084 (Peritoneal lavage, including imaging guidance, when performed), we believe that a work RVU of 2.00 accurately accounts for the work associated with these services. After comparison to similar CPT codes, the AMA RUC recommended a work RVU of 2.00 for CPT code 49083 and a work RVU of 2.50 for CPT code 49084. We agree with the AMA RUC-recommended work RVU of 2.00 for CPT code 49083, and believe that CPT code 49084 requires similar work and should be valued the same. Therefore, we are assigning a work RVU of 2.00 to CPT codes 49083 and 49084 on an interim final basis for CY 2012.

(12) Nervous: Spine and Spinal Cord (CPT Codes 62367–62370)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
62367	Analyze spine infus pump	0.48	0.48	0.48	Agree	No
62368	Analyze sp inf pump w/reprog	0.75	0.67	0.67	Agree	No
62369	Anal sp inf pmp w/reprg&fill	New	0.67	0.67	Agree	No
62370	Anl sp inf pmp w/mdreprg&fil	New	1.10	0.90	Disagree	No

For CY 2012 the AMA RUC Relativity Assessment Workgroup identified CPT codes 62367, 62368, 95990, and 95991 as part of the Codes Reported Together 75 percent or More screen. For CY 2012, the CPT Editorial Panel created 2 new CPT codes, 62369 and 62370, to report electronic analysis of programmable implanted pump for intrathecal or epidural drug infusion with reprogramming and refill requiring and not requiring physician's skill and editorially revised 3 existing CPT codes, CPT code 62367 to report without reprogramming or refill and CPT codes 95990 and 95991 to report refilling and maintenance of implantable pump or reservoir for drug delivery requiring and not requiring physician skill. The changes to CPT code 95990 and 95991 were editorial only and did not require a review of the physician work or practice expense.

After clinical review of CPT code 62370 (Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring physician's skill)), we believe that a work RVU of 0.90 accurately accounts for the work associated with this service. After a comparison to similar services, the AMA RUC recommended a work RVU of 1.10 for CPT code 62370 based on a crosswalk to CPT code 56605 (Biopsy of vulva or perineum (separate procedure); 1 lesion). We believe that a work RVU of 1.10 for CPT code 62370 is too high compared to similar services in this family. We find CPT code 62370 to be similar in intensity and complexity to CPT code 93281 (Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; multiple lead pacemaker system) (work RVU = 0.90). We believe that a work RVU of 0.90, which is between the specialty society survey 25th percentile and median work RVU, appropriately reflects the work of CPT code 62370. Therefore, we are assigning a work RVU of 0.90 to CPT code 62370 on an interim final basis for CY 2012.

For the CY 2012 new, revised, and potentially misvalued CPT codes reviewed in this family of services and not specifically discussed here, we agree with the AMA RUC/HCPAC-recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

(13) Nervous: Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System (CPT Codes 64633–64636)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
64633	Destroy cerv/thor facet jnt	New	3.84	3.84	Agree	No
64634	Destroy c/th facet jnt addl	New	1.32	1.32	Agree	No
64635	Destroy lumb/sac facet jnt	New	3.78	3.78	Agree	Yes
64636	Destroy l/s facet jnt addl	New	1.16	1.16	Agree	Yes

CPT code 64626 was identified by the AMA RUC's Five-Year Review Identification Workgroup as potentially misvalued through the Site-of-Service Anomaly screen. The specialty society requested and the AMA RUC agreed that CPT codes 64622, 64623, 64626, 64627 be referred to CPT to clarify that imaging is required. For CY 2012, the CPT Editorial Panel deleted four CPT codes (64622–64623, and 64626–64627) and created four new CPT codes (64633–64636) to describe neurolysis reported per joint (2 nerves per each joint) instead of per nerve, under image guidance.

After clinical review of CPT codes 64633 (Destruction by neurolytic agent, paravertebral facet joint nerve(s); cervical or thoracic, with image guidance (fluoroscopy or CT), single facet joint), 64634 (Destruction by neurolytic agent, paravertebral facet joint nerve(s); cervical or thoracic, with image guidance (fluoroscopy or CT), each additional facet joint (List separately in addition to code for primary procedure)), 64635 (Destruction by neurolytic agent, paravertebral facet joint nerve(s); lumbar or sacral, with image guidance (fluoroscopy or CT), single facet joint), and 64636 (Destruction by neurolytic agent, paravertebral facet joint nerve(s); lumbar or sacral, with image guidance (fluoroscopy or CT), each additional facet joint (List separately in addition to code for primary procedure)), we believe that the specialty society survey 25th percentile work RVUs of 3.84, 1.32, 3.78, and 1.16 (respectively) accurately reflect the work associated with these services. These are also the AMA RUC-recommended work RVUs for these services. For CPT codes 64635 and 64636, we believe that the survey median intra-service times of 28 minutes and 15 minutes (respectively) appropriately allow for the intra-service work associated with furnishing these services. The AMA RUC recommended an intra-service time of 30 minutes for CPT code 64635, and an intra-service time of 20 minutes for CPT code 64636.

In sum, on an interim final basis for CY 2012 we are finalizing a work RVU of 3.84 for CPT code 64633 and a work RVU of 1.32 for CPT code 64634, without refinement to the AMA RUC-recommended time. On an interim final basis for CY 2012 we are finalizing a work RVU of 3.78 for CPT code 64635 and a work RVU of 1.16 for CPT code 64636, with refinement to the AMA RUC-recommended time. A complete listing of the times associated with these procedures is available on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.* Additionally, we request that the AMA RUC review CPT code 64681 (Destruction by neurolytic agent, with or without radiologic monitoring; superior hypogastric plexus) which was the reference service for CPT codes 64633 and 64635.

(14) Diagnostic Radiology: Abdomen (CPT Code 74174)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
74174	Ct angio abd&pelv w/o&w/dye	New	2.20	2.20	Agree	No

CPT codes 74175 and 72191 were identified by the AMA RUC Relativity Assessment Workgroup's Codes Reported Together 75 percent or More screen, with both services reported over 95 percent of the time together. For CY 2012, the CPT Editorial Panel created CPT code 74174 which bundles the work of CPT codes 74175 and 72191 when reported together on the same date of service.

We reviewed CPT code 74174 (Computed tomographic angiography, abdomen and pelvis; with contrast material(s), including noncontrast images, if performed, and image postprocessing), and are accepting the AMA RUC-recommended work RVUs and times on an interim basis for CY 2012. We request that the AMA RUC review the component CPT codes: 74175 (Computed tomographic angiography, abdomen, with contrast material(s), including noncontrast images, if performed, and image postprocessing) and 72191 (Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing). On an interim basis for CY 2012 we are assigning a work RVU of 2.20 to CPT code 74174.

(15) Pathology and Laboratory: Cytopathology (CPT Codes 88104, 88106, and 88108)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
88104	Cytopath fl nongyn smears	0.56	0.56	0.56	Agree	No
88106	Cytopath fl nongyn filter	0.56	0.56	0.37	Disagree	No
88108	Cytopath concentrate tech	0.56	0.56	0.44	Disagree	No

CPT code 88104 was identified through the AMA RUC Relativity Assessment Workgroup by the Harvard-Valued—Utilization > 100,000. Additionally, CPT codes 88106–88108 were identified as part of the Cytopathology family for AMA RUC review.

After clinical review of CPT code 88104 (Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation), we believe that the current (CY 2011) work RVU of 0.56 accurately reflects the work associated with this service. We also believe that 24 minutes of intra-service time, the survey median, and no pre- or post-service time is appropriate for this service. That AMA RUC also recommended a work RVU of 0.56 for CPT code 88104 and 24 minutes of intra-service time with no pre- or post-service time. Therefore, we are maintaining the current work RVU of 0.56 and 24 minutes of intra service time for CPT code 88104 on an interim final basis for CY 2012.

After clinical review of CPT code 88106 (Cytopathology, fluids, washings or brushings, except cervical or vaginal; simple filter method with interpretation) we believe that a work RVU of 0.37 accurately reflects the work associated with this service. The AMA RUC reviewed the survey results for CPT code 88106 and recommended a work RVU of 0.56. However, we believe that this value overstates the work of this service when compared to the CPT code 88104. We believe that CPT code 88106 is similar in intensity to CPT code 88104, and that the primary factor distinguishing the work of the two services is the intra-service time. As previously, CPT code 88104 has a work RVU of 0.56, and 24 minutes of intra-service time. For CPT code 88106, we believe 16 minutes of intra-service time, the survey median, is appropriate for this service. Therefore, we believe that the work RVU for CPT code 88106 should be reduced proportionately to reflect the lower intra-service time in order to maintain relativity with the CPT code 88104.

In calculating the RVU for CPT code 88106, we determined the RVU per minute (0.56/24 = 0.023) for the CPT code 88104. Then we multiplied the RVU per minute (0.023) of CPT code 88104 by the intra-service minutes for CPT code 88106 (0.023*16 = 0.37). We believe a work RVU of 0.37 appropriately maintains relativity with CPT code 88104. Therefore, we are assigning a work RVU of 0.37 for CPT code 88106 and an intra-service time of 16 minutes on an interim final basis for CY 2012. The times assigned to this CPT code are available on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

After clinical review of CPT code 88108 (Cytopathology, concentration technique, smears and interpretation

(*e.g.,* Saccomanno technique)), we believe that a work RVU of 0.44 accurately reflects the work associated with this service. The AMA RUC reviewed the survey results for CPT code 88106 and recommended a work RVU of 0.56. However, we believe that this value overstates the work of this service when compared to CPT code 88104. We believe that CPT code 88108 is similar in intensity to CPT code 88104, and that the primary factor distinguishing the work of the two services is the intra-service time. CPT code 88104 has a work RVU of 0.56, and 24 minutes of intra-service time. For CPT code 88108, we believe 19 minutes of intra-service time, the survey median, is appropriate for this service. Therefore, we believe that the work RVU for CPT code 88108 should be reduced proportionately to reflect the lower intra-service time in order to maintain relativity with CPT code 88104.

In calculating the RVU for CPT code 88108, we determined the RVU per minute (0.56/24 = 0.023) for the CPT code 88104. Then we multiplied the RVU per minute (0.023) of CPT code 88104 by the intra-service minutes for CPT code 88108 (0.023*19 = 0.44). We believe a work RVU of 0.44 appropriately maintains relativity with CPT code 88104. Therefore we are assigning a work RVU of 0.44 and an intra-service time of 19 minutes to CPT code 88108 on an interim final basis for CY 2012. The times assigned to this CPT code are available on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

(16) Psychiatry: Psychiatric Therapeutic Procedures (CPT Code 90845, 90867–90869)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
90845	Psychoanalysis	1.79	2.10	1.79	Disagree	Yes
90867	Tcranial magn stim tx plan	0.00	3.52	3.52	Agree	Yes
90868	Tcranial magn stim tx deli	0.00	0.48	0.48	Agree	No
90869	Tcran magn stim redetemine	New	3.20	3.00	Disagree	No

CPT code 90845 was first considered as part of the Fourth Five-Year Review. However, in that review process, the related specialty societies referred the family of services to the CPT Editorial Panel to consider a revision to the code descriptors. During the CPT review process, CPT recommended removing CPT code 90845 from the list of codes for revision, as CPT believed revisions to the descriptor were unnecessary because the work inherent in providing this service was the same regardless of provider.

After clinical review of CPT code 90845 (Psychoanalysis), including a review of the information provided by the specialty societies and the AMA RUC, we believe that the current (2011) work RVU of 1.79 and the current times should be maintained for this code until the other codes in the family are revised by CPT and reviewed by the AMA RUC. The AMA RUC recommended a work RVU of 2.10 for CPT code 90845. We would like to refrain from establishing a new interim final value for CPT code 90845 until we can view this CPT code relative to the revised codes in the family, which we anticipate reviewing for CY 2013. Therefore, we are maintaining the current work RVU of 1.79 and current times for CPT code 90845 on an interim basis for CY 2012. A complete listing of the times associated with CPT code 90845 is available on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

For CY 2011 the CPT Editorial Panel converted Category III codes 0160T and 0161T to Category I status CPT codes 90867 and 90868, which were contractor priced on the Physician Fee Schedule. For CY 2012, the CPT Editorial Panel modified CPT codes 90867 and 90868, and created CPT code 90869. These three CPT codes are priced on the Physician Fee Schedule for CY 2012.

After clinical review of CPT code 90867 (Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management), we believe that the AMA RUC-recommended survey median work RVU of 3.52 appropriately reflects the work associated with this service. However, we believe that the survey 75th percentile intra-service time of 60 minutes appropriately accounts for the time required to furnish the intra-service work of this procedure. The AMA RUC recommended 65 minutes of intra-service time for CPT code 90867. We are assigning a work RVU of 3.52, with refinement to 60 minutes of intra-service time, to CPT code 90867 on an interim final basis for CY 2012. A complete listing of the times associated with CPT code 90867 is available on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

After clinical review of CPT code 90869 (Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management), we believe that a work RVU of 3.00 appropriately accounts for the work associated with this service. The original specialty society recommendation to the AMA RUC for CPT code 90869 was for a work RVU of 3.00, and the AMA RUC recommended to us a work RVU of 3.20, the survey median. We believe that CPT code 90869 is similar in time and intensity to CPT code 95974 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour) (work RVU = 3.00), and the work should be valued the same. Therefore, we are assigning a work RVU of 3.00 to CPT code 90869 on an interim final basis for CY 2012.

For the CY 2012 new, revised, and potentially misvalued CPT codes reviewed in this family of services and

not specifically discussed here, we agree with the AMA RUC/HCPAC-recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

(17) Ophthalmology: Special Ophthalmological Services (92071 and 92072)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
92071	Contact lens fitting for tx	New	0.70	0.61	Disagree	Yes
92072	Fit contac lens for managmnt	New	1.97	1.97	Agree	No

For the Fourth Five-Year Review, we identified CPT code 92070 through the Harvard-Valued—Utilization > 30,000 screen. Upon review of this service, the specialty societies agreed that there are two distinct uses for CPT code 92070 that have substantially different levels of work. For CY 2012, the CPT Editorial Panel agreed and deleted CPT code 92070 and created two new CPT codes (92071 and 92072) to distinguish reporting of fitting of contact lens for treatment of ocular surface disease and fitting of contact lens for management of keratoconus.

CPT code 92070 (Fitting of contact lens for treatment of disease, including supply of lens) is being deleted for CY 2012 and the utilization from CPT code 92070 is expected to be captured by new CPT code 92071(Fitting of contact lens for treatment of ocular surface disease). As CPT code 92070 was typically billed with an E/M service on the same day, we believe that CPT code 92071 will also be billed typically with an E/m service on the same day. We believe some of the activities conducted during the pre- and post-service times of the procedure code and the E/M visit overlap and, therefore, should not be counted twice in developing the procedure's work value. As described earlier in section III.A. of this final rule with comment period, to account for this overlap, we reduced the pre-service evaluation and post-service time by one-third. For CPT code 92071 we reduced the pre-service evaluation time and the post service time from 5 minutes to 3 minutes.

In order to determine the appropriate work RVU for CPT code 92071, given the time change, we calculated the value of the extracted time and subtracted it from the AMA RUC-recommended work RVU. For CPT code 92071, we removed a total of 4 minutes at an intensity of 0.0224 per minute, which amounts to the removal of 0.09 of a work RVU. The AMA RUC recommended a work RVU of 0.70, the current (CY 2011) work RVU for CPT code 92070. Therefore, we are assigning an interim final work RVU of 0.61, with refinement to time, to CPT code 92071 for CY 2012. A complete listing of the times assigned to CPT code 92071 is available on the CMS Web site at: *https://www.cms.gov/PhysicianFeeSched/.*

For the CY 2012 new, revised, and potentially misvalued CPT codes reviewed in this family of services and not specifically discussed here, we agree with the AMA RUC/HCPAC-recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

(18) Special Otorhinolaryngologic Services: Audiologic Function Tests (CPT Codes 92558, 92587 and 92588)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
92558	Evoked auditory test qual	New	0.17	0.00	N/A	N/A
92587	Evoked auditory test limited	0.13	0.45	0.35	Disagree	No
92588	Evoked auditory tst complete	0.36	0.60	0.55	Disagree	No

We identified CPT code 92587 through the CMS Fastest Growing screen. For CY 2011, the specialty society surveyed this service, however, after reviewing the survey data, they concluded that more than one service is being represented under this code and requested the service be referred back to the CPT Editorial Panel for further clarification. For CY 2012, the CPT Editorial Panel created CPT code 92558 to describe evoked otoacoustic emissions screening and revised CPT codes 92587 and 92588 clarify the otoaucoustic emissions evaluations.

New CPT code 92558 (Evoked otoacoustic emissions; screening (qualitative measurement of distortion product or transient evoked otoacoustic emissions), automated analysis) describes a screening service that does not fall within the statutory definition of a physicians' service, per section 1848 of the Act. As such, CPT code 92558 will have procedure status of X on the PFS for CY 2012, which indicates that this service is not within the statutory definition of ''physicians' service'' for PFS payment purposes. We will not pay for CPT code 92558 under the PFS. We note that the HCPAC recommended a work RVU of 0.17, with 5 minutes of intra-service time and 2 minutes of immediate post-service time, for CPT code 92558.

After clinical review of CPT code 92587 (Distortion product evoked otoacoustic emissions; limited evaluation (to confirm the presence or absence of hearing disorder, 3–6 frequencies) or transient evoked otoacoustic emissions, with interpretation and report), we believe that the survey 25th percentile work RVU of 0.35 accurately describes the work associated with this service. The HCPAC reviewed the survey results, and

after a comparison to similar CPT codes, recommended a work RVU of 0.45 for CPT code 92587, which is between the survey 25th percentile and median values. We believe that CPT code 92587 is similar in time and intensity to CPT code 97124 (Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)) (work RVU = 0.35), and that the survey 25th percentile value appropriately reflects the relativity of this service. Therefore, we are assigning a work RVU of 0.35 to CPT code 92587 on an interim final basis for CY 2012.

After clinical review of CPT code 92588 (Distortion product evoked otoacoustic emissions; comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report), we believe that the survey 25th percentile work RVU of 0.55 accurately describes the work associated with this service. The HCPAC reviewed the survey results, and after a comparison to similar CPT codes, recommended the survey median work RVU of 0.62 for CPT code 92588. We believe that CPT code 92588 is similar in work to CPT code 92570 (Acoustic immittance testing, includes tympanometry (impedance testing), acoustic reflex threshold testing, and acoustic reflex decay testing) (work RVU = 0.55), and that the survey 25th percentile work RVU of 0.55 appropriately reflects the relativity of this service. Therefore, we are assigning a work RVU of 0.55 to CPT code 92588 on an interim final basis for CY 2012.

(19) Special Otorhinolaryngologic Services: Evaluative and Therapeutic Services (CPT Codes 92605 and 92618)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
92605	Ex for nonspeech device rx	0.00	1.75	0.00	N/A	N/A
92618	Ex for nonspeech dev rx add	New	0.65	0.00	N/A	N/A

As a result of the Medicare Improvements for Patients and Providers Act of 2008, starting in July 2009, speech-language pathologists were able to bill Medicare independently as private practitioners. The American Speech-Language-Hearing Association (ASHA) requested that we, in light of the legislation, base speech-language pathology services on professional work values and not through the practice expense component. As a result, we requested that the AMA RUC review the speech-language pathology codes for professional work as requested by ASHA. After reviewing the survey data for CPT code 92605, the specialty society indicated and the HCPAC agreed that CPT code 92605 would be better captured as a ''per hour'' code. For CY 2012, the CPT Editorial Panel revised CPT code 92605 to indicate ''first hour'' and created a new add-on code (CPT code 92618) to capture each additional 30 minutes.

Revised CPT code 92605 (CY 2012 long descriptor: Evaluation for prescription of non-speech-generating augmentative and alternative communication device, face-to-face with the patient; first hour) currently (CY 2011) has a procedure status indicator of B on the PFS, which indicates that payment for the service is always bundled into payment for other services not specified. We continue to believe that payment for this service is included in other services and, therefore, that CPT code 92605 should maintain the procedure status indicator of B on the PFS. As new CPT code 92618 (Evaluation for prescription of non-speech-generating augmentative and alternative communication device, face-to-face with the patient; each additional 30 minutes (List separately in addition to code for primary procedure)) is the add-on procedure code to CPT code 92605, we believe that payment for that service should also be considered bundled into payment for other services, and therefore, should also have a procedure status indicator of B on the PFS. For CPT code 92605 the HCPAC recommended the survey 25th percentile work RVU of 1.75. For CPT code 92618 the HCPAC recommended the survey 25th percentile work RVU of 0.65. We are publishing these RVUs in the CY 2012 PFS, however, as stated previously, both codes will have a procedure status indicator of B and will not be separately payable on the PFS.

(20) Cardiovascular: Cardiac Catheterization (93451–93568)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
93451	Right heart cath	2.72	3.02	2.72	Disagree	No
93452	Left hrt cath w/ventrclgrphy	4.75	4.32	4.75	Disagree	No
93453	R&l hrt cath w/ventriclgrphy	6.24	5.98	6.24	Disagree	No
93454	Coronary artery angio s&i	4.79	4.95	4.79	Disagree	No
93455	Coronary art/grft angio s&i	5.54	6.15	5.54	Disagree	No
93456	R hrt coronary artery angio	6.15	6.00	6.15	Disagree	No
93457	R hrt art/grft angio	6.89	7.66	6.89	Disagree	No
93458	L hrt artery/ventricle angio	5.85	6.51	5.85	Disagree	No
93459	L hrt art/grft angio	6.60	7.34	6.60	Disagree	No
93460	R&l hrt art/ventricle angio	7.35	7.88	7.35	Disagree	No
93461	R&l hrt art/ventricle angio	8.10	9.00	8.10	Disagree	No
93462	L hrt cath trnsptl puncture	3.73	3.73	3.73	Agree	No
93463	Drug admin & hemodynmic meas	2.00	2.00	2.00	Agree	No
93464	Exercise w/hemodynamic meas	1.80	1.80	1.80	Agree	No
93563	Inject congenital card cath	1.11	2.00	1.11	Disagree	No
93564	Inject hrt congntl art/grft	1.13	2.10	1.13	Disagree	No
93565	Inject l ventr/atrial angio	0.86	1.90	0.86	Disagree	No
93566	Inject r ventr/atrial angio	0.86	0.96	0.86	Disagree	No
93567	Inject suprvlv aortography	0.97	0.97	0.97	Agree	No
93568	Inject pulm art hrt cath	0.88	0.98	0.88	Disagree	No

In the CY 2012 final rule with comment period (75 FR 73334 through 73337), we discussed generally the concept of bundling services and specifically, new CY 2011 CPT codes that describe the bundling of two or more existing component services performed together 95 percent or more of the time. As we noted in that rule, we expect this bundling of component services to continue over the next several years as the work efficiencies for services commonly furnished together are recognized. Stakeholders should expect that increased bundling of services into fewer codes will result in reduced PFS payment for a comprehensive service. Specifically, the decrease in RVUs assigned to the comprehensive service, as compared to the total RVUs of the sum of the individual component services, reflects the efficiencies in work and/or PE that occur when component services are furnished together.

For CY 2011, the AMA RUC provided CMS with recommendations for several categories of new comprehensive services that historically have been reported under multiple component codes. These services fell into the three major clinical categories of: Endovascular revascularization, computed tomography (CT), and diagnostic cardiac catheterization. In the CY 2011 final rule with comment period, we acknowledged that while each category of services is unique, since bundling of component services is likely to occur more often in the coming years, we believe a consistent approach is especially important when valuing bundled services to ensure that RVUs reflect work efficiencies.

As discussed in the CY 2011 final rule with comment period, the AMA RUC used a variety of methodologies in developing RVUs for comprehensive codes in these three categories of bundled services. To develop the RVUs for the comprehensive endovascular revascularization services, the AMA RUC generally recommended the median work RVUs from the physician survey performed by the specialty society. The recommended values for the comprehensive services are an average of 27 percent lower than the summed RVUs of the component services (taking into consideration any MPPR that would currently apply) included in the bundle. To develop the RVUs for comprehensive CT services, the AMA RUC recommended taking the sum of 100 percent of the current work RVUs for the code with the highest RVUs and 50 percent for the second code. Under this methodology, the recommended work RVUs for the comprehensive CT codes are consistently approximately 25 percent lower than the sum of the RVUs for the component services (75 FR 7335 through 7336). We agreed in the CY 2011 final rule with comment period that the decreased work RVUs that the AMA RUC recommended for comprehensive services in these two categories reflected a reasonable estimation of the work efficiencies created by the bundling of the component services. Therefore, for CY 2011, we accepted as interim final work RVUs the AMA RUC-recommended values for endovascular revascularization and CT services, and we are finalizing our interim final work RVUs without modification for CY 2012 (Table 15) see section III.B.1. of this final rule with comment period.

In contrast to the endovascular revascularization and CT codes, the AMA RUC recommended values for the comprehensive diagnostic cardiac catheterization codes did not appear to reflect the efficiencies in work and/or PE that occur when component services are furnished together. To develop the RVUs for comprehensive diagnostic cardiac catheterization services, the AMA RUC generally recommended the lower of either the sum of the current RVUs for the component services or the physician survey 25th percentile value. In most cases, the AMA RUC's recommendation for the comprehensive service was actually the sum of the current work RVUs for the component services, and we stated in the CY 2011 final rule with comment period that we were unsure how this approach is resource-based with respect to physician work. We also were concerned that the results of the physician survey overstated the work for these well-established procedures because the 25th percentile work RVU value was usually higher than the sum of the current RVUs for the component services. Finally, we noted that, in

contrast to the RVU survey results, survey physician times for the comprehensive codes were significantly reduced as compared to the summed minutes of the component codes.

In contrast to the result of combining the component codes into comprehensive endovascular revascularization and CT bundles where efficiencies were reflected through significant reductions in the RVUs (average of 27 percent and 25 percent respectively), the AMA RUC-recommended RVUs for the comprehensive codes for diagnostic cardiac catheterization were an average of only one percent lower. We noted that if we were to accept the AMA RUC's recommended values for these cardiac catheterization codes, we essentially would be agreeing with the presumption that there are negligible work efficiencies gained in the bundling of these services. On the contrary, we believed that the AMA RUC did not fully consider or account for the efficiency gains when the component services are furnished together, which was also supported by the significant reduction in reported service time on the survey. Therefore, in the CY 2011 final rule with comment period, we requested that the AMA RUC reexamine the cardiac catheterization codes as quickly as possible, given the significant PFS utilization and spending for these services, and put forward an alternative approach to valuing these services that would produce relative values that are resource-based and account for efficiencies inherent in bundling.

For CY 2011, we also stated that we believed the new comprehensive diagnostic cardiac catheterization codes would be overvalued under the AMA RUC's CY 2011 recommendations. To address this potential overvaluation, we employed an interim methodology to approximate the efficiencies garnered through the bundling of the component codes to determine alternative CY 2011 interim values for the cardiac catheterization codes based on the information that we had at the time. Given that the AMA RUC recommendations for the bundling of endovascular revascularization and CT codes resulted in average reductions in the RVUs of 27 percent and 25 percent respectively, we believed an approximation of work efficiencies garnered through the bundling of the component codes could be up to 27 percent. Since we were referring the cardiac catheterization codes back to the AMA RUC, requesting that the AMA RUC provide CMS with a better estimate of the work efficiencies, we believed at the time that applying a conservative estimate of the work efficiencies was appropriate as an interim measure. Accordingly, to account for efficiencies inherent in bundling, we set the work RVUs for all of the bundled CY 2011 cardiac catheterization codes for which we received AMA RUC recommendations to 10 percent less than the sum of the current work RVUs for the component codes, taking into consideration any MPPR that would apply under current PFS policy.

At our request, the AMA RUC reviewed these codes again for CY 2012 and reiterated its previous recommendations, maintaining that there are negligible work efficiencies gained in the bundling of these services. The AMA RUC noted that over the 20 years that cardiac catheterization services have been available to patients, several of the codes being bundled have been bundled and unbundled a number of times in the past and that in each instance, the CMS has retained the RVUs of component codes. In response to CMS' observation that the recently surveyed physician times of the new CY 2011 comprehensive codes were significantly reduced, the AMA RUC stated that the new times were correct and that the previous times were grossly overstated. That is, the previous times originating from the Harvard valuation process rather than the survey process were inaccurate. The AMA RUC explained that the specialty societies have not previously addressed inaccurate physician times in any of the previous bundling/unbundling opportunities, because the societies deemed physician time unimportant and stakeholders focused on the work RVUs of the services instead. Stakeholders also strongly argued that no one had previously validated the physician time for the services in place for 20 years, although they continued to urge CMS to accept that the RVUs developed through the same process remain unchanged.

Comments: The commenters believed that cardiac catheterization codes were already under-valued, and therefore the AMA RUC could not find any additional efficiencies in its recommendation to CMS regarding the bundling of these codes. Commenters noted some of the component catheterization codes were reviewed by the AMA RUC in 2007 for PE which has already resulted in reduced payments for those services. Commenters also asserted that catheterization codes were developed and intended to be used in conjunction with one another and that each code represents a distinct portion of the catheterization procedure. The commenters surmised that there is no duplication in service time, equipment or supplies. Finally, commenters believed CMS did not base its 10-percent reduction of cardiac catheterization RVUs on any data analysis.

Response: We disagree with the AMA RUC's recommendation that there are negligible efficiencies in physician work when the component services of diagnostic cardiac catheterization are performed together. Although the AMA RUC did not revise their estimate of physician work for these newly bundled services, we find it difficult to accept that there are no efficiencies in the 20 year evolution of cardiac catheterization services. Improvements in technologies associated with cardiac catheterization and the increased familiarity with performing these high frequency services support some reduction in both the physician times and the RVUs. We do not believe that the AMA RUC recommendations for CY 2012 fully considered these areas for additional efficiencies. Given the AMA RUC's valuation of newly bundled services for endovascular revascularization and CT codes, we were reasonably assured that the approximation of work efficiencies through bundling could be up to 27 percent. We ultimately used a very conservative estimate of 10 percent for the work efficiencies we would expect to be present when multiple component cardiac catheterization services are bundled together into a single comprehensive service for valuing these services for CY 2011.

In lieu of a more specific estimate from the AMA RUC, and using the best information available to us at this time, we believe it is appropriate to assign as interim final for CY 2012 our CY 2011 interim values with a 10 percent reduction in work efficiencies. Specifically, for CY 2012, we are assigning the following interim final work RVUs for the following CPT codes: 2.72 for CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed), 4.75 for CPT code 93452 (Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed), 6.24 for CPT code 93453 (Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed), 4.79 for CPT code 93454 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation),

5.54 for CPT code 93455 (with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography), 6.15 for CPT code 93456 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with right heart catheterization), 6.89 for CPT code 93457 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization), 5.85 for CPT code 93458 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed), 6.60 for CPT code 93459 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography), 7.35 for CPT code 93460 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed), 8.10 for CPT code 93461 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography), 1.11 for CPT code 93563 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization), 1.13 for CPT code 93564 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization for selective opacification of aortocoronary venous or arterial bypass graft(s) (*e.g.,* aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (*e.g.,* internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization, when performed), 0.86 for CPT code 93565 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization for selective left ventricular or left arterial angiography), 0.86 for CPT code 93566 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization for selective right ventricular or right atrial angiography), 0.97 for CPT code 93567 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization for supravalvular aortography), and 0.88 for CPT code 93568 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization for pulmonary angiography).

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
94060	Evaluation of wheezing	0.31	0.31	0.26	Disagree	No
94726	Pulm funct tst plethysmograp	New	0.31	0.26	Disagree	No
94727	Pulm function test by gas	New	0.31	0.26	Disagree	No
94728	Pulm funct test oscillometry	New	0.31	0.26	Disagree	No
94729	C02/membane diffuse capacity	New	0.19	0.17	Disagree	No
94780	Car seat/bed test 60 min	New	0.48	0.48	Agree	No
94781	Car seat/bed test + 30 min	New	0.17	0.17	Agree	No

For the CY 2012 new, revised, and potentially misvalued CPT codes reviewed in this family of services and not specifically discussed here, we agree with the AMA RUC/HCPAC-recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

(21) Pulmonary: Other Procedures (CPT Codes 94060, 94726–94729, 94780 and 94781)

We identified CPT code 94060 through the MPC List screen. The AMA RUC Relativity Assessment Workgroup identified CPT codes 94240, 94260, 94350, 94360, 94370, and 94725 through the Codes Reported Together 75 percent or More screen. These codes are commonly billed together with CPT code 94720, 94360, 94240, and 94350. For CY 2012, the specialty society submitted a codes change proposal to the CPT Editorial Panel to bundle the services commonly reported together. As a result, CPT created CPT codes 94726, 94727, 94728, and 94729. For CY 2012, CPT also created CPT codes 94780 and 94781 to report car seat testing administered to the patient in the private physician's office.

After clinical review, we determined that CPT codes 94060 (Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator

administration), 94726 (Plethysmography for determination of lung volumes and, when performed, airway resistance), 94727 (Gas dilution or washout for determination of lung volumes and, when performed, distribution of ventilation and closing volumes), and 94728 (Airway resistance by impulse oscillometry), involve very similar work and should have the same work RVU. CPT code 94240 (Functional residual capacity or residual volume: helium method, nitrogen open circuit method, or other method) (work RVU=0.26) is being deleted for CY 2012 and the utilization associated with that service is expected to be captured under new CPT codes 94726 and 92727. We believe that a work RVU of 0.26 appropriately reflects the work associated with CPT codes 94060, 94726, 94727, and 94728. We believe this value is further supported by CPT code 97012 (Application of a modality to 1 or more areas; traction, mechanical) (work RVU=0.25) which has similar time and intensity. The AMA RUC recommended a work RVU of 0.31 for CPT codes 94060, 94726, 94727, and 94728, which corresponded to each surveys 25th percentile work RVU. We are assigning a work RVU of 0.26 to CPT codes 94060, 94726, 94727, and 94728 on an interim final basis for CY 2012.

After clinical review of CPT code 94729 (Diffusing capacity (*e.g.,* carbon monoxide, membrane) (List separately in addition to code for primary procedure)), we believe that a work RVU of 0.17 accurately reflects the work associated with this service. Based on comparison to similar services, the AMA RUC recommended a work RVU of 0.19 for CPT code 94729. We believe that CPT code 94010 (Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation) (work RVU=0.17) is similar in time and intensity to CPT code 94729, and that the codes should have the same work RVU. Therefore, we are assigning a work RVU of 0.17 to CPT code 94729 on an interim final basis for CY 2012.

For the CY 2012 new, revised, and potentially misvalued CPT codes reviewed in this family of services and not specifically discussed here, we agree with the AMA RUC/HCPAC-recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

(22) Neurology and Neuromuscular Procedures: Nerve Conduction Tests (CPT Codes 95885–95887)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
95885	Musc tst done w/nerv tst lim	New	0.35	0.35	Agree	No
95886	Musc test done w/n test comp	New	0.92	0.92	Agree	No
95887	Musc tst done w/n tst nonext	New	0.73	0.73	Agree	No

CPT codes 95860, 95861, 95863 and 95864 were identified by the AMA RUC Relativity Assessment Workgroup through the Codes Reported Together 75 percent or More screen. These codes are billed commonly with CPT code 95904. The specialty societies submitted a code change proposal to the CPT Editorial Panel to bundle the services commonly reported together. For CY 2012, the CPT Editorial Panel created 3 new add-on procedure codes: CPT codes 95885, 95886, and 95887. The CPT Editorial Panel noted, and the AMA RUC agreed, that these 3 new codes were approved with the intent that the specialties will take additional time and bring forward a more comprehensive coding solution which bundles services commonly performed together for CY 2013.

We reviewed CPT codes 95885 (Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; limited), 95886 (Needle electromyography, each extremity with related paraspinal areas when performed, done with nerve conduction, amplitude and latency/velocity study; complete, five or more muscles studied, innervated by three or more nerves or four or more spinal levels), 95887 (Needle electromyography, non-extremity (cranial nerve supplied or axial) muscle(s) done with nerve conduction, amplitude and latency/velocity study), and are accepting the AMA RUC-recommended work RVUs and times on an interim basis, pending review of the other electromyography services for CY 2012. On an interim basis for CY 2012 we are assigning a work RVU of 0.35 to CPT code 95885, a work RVU of 0.92 to CPT code 95886, and a work RVU of 0.73 to CPT code 95887.

(23) Neurology and Neuromuscular Procedures: Autonomic Function Tests (CPT Codes 95938 and 95939)

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2012 Interim/Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
95938	Somatosensory testing	New	0.86	0.86	Agree	No
95939	C motor evoked upr&lwr limbs	New	2.25	2.25	Agree	No

CPT code pairs 95925/95926 and 95928/95929 were identified by the AMA RUC Relativity Assessment Workgroup Codes Reported Together 75 percent or More screen. For CY 2012, the CPT Editorial Panel created CPT code 95938 to capture the reporting of CPT codes 95925 and 95926 together, and CPT codes 95939 to capture the reporting CPT codes 95928 and 95929 together. The specialty society had obtained valid survey results for CPT code 95938 but not for 95939, as only 31 percent of the respondents indicated the vignette was typical. The AMA RUC and specialty societies agreed that a new survey should be conducted for CY 2013.

We reviewed CPT codes 95938 (Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs) and 95939 (Motor evoked potential study; in upper and lower limbs), and are accepting the AMA RUC-recommended work RVUs and times on an interim basis, pending resurvey of CPT code 95939. We also request that the AMA RUC review the component CPT codes 95925, 95926, 95928, and 95929. On an interim basis for CY 2012 we are assigning a work RVU of 0.86 to CPT code 95938, and a work RVU of 2.25 to CPT code 95939.

(24) Other CY 2012 New, Revised, and Potentially Misvalued CPT Codes Not Specifically Discussed Previously

For all other CY 2012 new, revised, and potentially misvalued CPT codes not specifically discussed previously, we agree with the AMA RUC/HCPAC recommended work RVUs and are setting as interim final the work RVUs listed in Table 19.

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TABLE 19: CY 2012 NEW, REVISED, AND POTENTIALLY MISVALUED CODE DECISIONS

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2012 Interim/ Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
10060	Drainage of skin abscess	1.22	1.50	1.22	Disagree	No
10061	Drainage of skin abscess	2.45	2.45	2.45	Agree	No
11056	Trim skin lesions 2 to 4	0.61	0.50	0.50	Agree	No
11719	Trim nail(s)	0.17	0.17	0.17	N/A	N/A
11720	Debride nail 1-5	0.32	0.32	0.32	Agree	No
11721	Debride nail 6 or more	0.54	0.54	0.54	Agree	No
15271	Skin sub graft trnk/arm/leg	New	1.50	1.50	Agree	No
15272	Skin sub graft t/a/l add-on	New	0.59	0.33	Disagree	No
15273	Skin sub grft t/arm/lg child	New	3.50	3.50	Agree	No
15274	Skn sub grft t/a/l child add	New	0.80	0.80	Agree	No
15275	Skin sub graft face/nk/hf/g	New	1.83	1.83	Agree	No
15276	Skin sub graft f/n/hf/g addl	New	0.59	0.50	Disagree	No
15277	Skn sub grft f/n/hf/g child	New	4.00	4.00	Agree	No
15278	Skn sub grft f/n/hf/g ch add	New	1.00	1.00	Agree	No
15777	Acellular derm matrix implt	New	3.65	3.65	Agree	No
16020	Dress/debrid p-thick burn s	0.80	0.80	0.71	Disagree	Yes
16025	Dress/debrid p-thick burn m	1.85	1.85	1.74	Disagree	Yes
20527	Inj dupuytren cord w/enzyme	New	1.00	1.00	Agree	No
20600	Drain/inject joint/bursa	0.66	0.66	0.66	Agree	No
20605	Drain/inject joint/bursa	0.68	0.68	0.68	Agree	No
20610	Drain/inject joint/bursa	0.79	0.79	0.79	Agree	No
22633	Lumbar spine fusion combined	New	27.75	27.75	Agree	No
22634	Spine fusion extra segment	New	8.16	8.16	Agree	No
26341	Manipulat palm cord post inj	New	1.66	0.91	Disagree	No
27096	Inject sacroiliac joint	1.40	1.48	1.48	Agree	No
29581	Apply multlay comprs lwr leg	0.60	0.60	0.25	Disagree	No
29582	Apply multlay comprs upr leg	New	0.35	0.35	Agree	No
29583	Apply multlay comprs upr arm	New	0.25	0.25	Agree	No
29584	Appl multlay comprs arm/hand	New	0.35	0.35	Agree	No
29826	Shoulder arthroscopy/surgery	9.16	3.00	3.00	Agree	No
29880	Knee arthroscopy/surgery	9.45	7.39	7.39	Agree	No
29881	Knee arthroscopy/surgery	8.71	7.03	7.03	Agree	No
32096	Open wedge/bx lung infiltr	New	17.00	13.75	Disagree	No
32097	Open wedge/bx lung nodule	New	17.00	13.75	Disagree	No
32098	Open biopsy of lung pleura	New	14.99	12.91	Disagree	No
32100	Exploration of chest	16.16	17.00	13.75	Disagree	No
32505	Wedge resect of lung initial	New	18.79	15.75	Disagree	No
32506	Wedge resect of lung add-on	New	3.00	3.00	Agree	No
32507	Wedge resect of lung diag	New	3.78	3.00	Disagree	No
32601	Thoracoscopy diagnostic	5.45	5.50	5.50	Agree	No
32607	Thoracoscopy w/bx infiltrate	New	5.50	5.50	Agree	No
32608	Thoracoscopy w/bx nodule	New	6.84	6.84	Agree	No
32609	Thoracoscopy w/bx pleura	New	4.58	4.58	Agree	No
32663	Thoracoscopy w/lobectomy	24.64	24.64	24.64	Agree	No
32666	Thoracoscopy w/wedge resect	New	14.50	14.50	Agree	No
32667	Thoracoscopy w/w resect addl	New	3.00	3.00	Agree	No
32668	Thoracoscopy w/w resect diag	New	4.00	3.00	Disagree	No
32669	Thoracoscopy remove segment	New	23.53	23.53	Agree	No
32670	Thoracoscopy bilobectomy	New	28.52	28.52	Agree	No
32671	Thoracoscopy pneumonectomy	New	31.92	31.92	Agree	No
32672	Thoracoscopy for lvrs	New	27.00	27.00	Agree	No
32673	Thoracoscopy w/thymus resect	New	21.13	21.13	Agree	No

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2012 Interim/ Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
32674	Thoracoscopy lymph node exc	New	4.12	4.12	Agree	No
33212	Insert pulse gen sngl lead	5.52	5.26	5.26	Agree	No
33213	Insert pulse gen dual leads	6.37	5.53	5.53	Agree	No
33221	Insert pulse gen mult leads	New	5.80	5.80	Agree	No
33227	Remove&replace pm gen singl	New	5.50	5.50	Agree	No
33228	Remv&replc pm gen dual lead	New	5.77	5.77	Agree	No
33229	Remv&replc pm gen mult leads	New	6.04	6.04	Agree	No
33230	Insrt pulse gen w/dual leads	New	6.32	6.32	Agree	No
33231	Insrt pulse gen w/mult leads	New	6.59	6.59	Agree	No
33240	Insrt pulse gen w/singl lead	7.64	6.05	6.05	Agree	No
33262	Remv&replc cvd gen sing lead	New	6.06	6.06	Agree	No
33263	Remv&replc cvd gen dual lead	New	6.33	6.33	Agree	No
33264	Remv&replc cvd gen mult lead	New	6.60	6.60	Agree	No
36000	Place needle in vein	0.18	0.00	0.00	N/A	N/A
36251	Ins cath ren art 1st unilat	New	5.45	5.35	Disagree	No
36252	Ins cath ren art 1st bilat	New	7.38	6.99	Disagree	No
36253	Ins cath ren art 2nd+ unilat	New	7.55	7.55	Agree	No
36254	Ins cath ren art 2nd+ bilat	New	8.15	8.15	Agree	No
37191	Ins endovas vena cava filtr	New	4.71	4.71	Agree	No
37192	Redo endovas vena cava filtr	New	8.00	7.35	Disagree	Yes
37193	Rem endovas vena cava filter	New	8.00	7.35	Disagree	Yes
37619	Ligation of inf vena cava	New	37.60	30.00	Disagree	No
38230	Bone marrow harvest allogen	4.85	4.00	3.09	Disagree	No
38232	Bone marrow harvest autolog	New	3.50	3.09	Disagree	No
38746	Remove thoracic lymph nodes	4.88	4.12	4.12	Agree	No
47000	Needle biopsy of liver	1.90	1.90	1.90	Agree	No
49082	Abd paracentesis	New	1.35	1.24	Disagree	Yes
49083	Abd paracentesis w/imaging	New	2.00	2.00	Agree	No
49084	Peritoneal lavage	New	2.50	2.00	Disagree	No
62367	Analyze spine infus pump	0.48	0.48	0.48	Agree	No
62368	Analyze sp inf pump w/reprog	0.75	0.67	0.67	Agree	No
62369	Anal sp inf pmp w/reprg&fill	New	0.67	0.67	Agree	No
62370	Anl sp inf pmp w/mdreprg&fil	New	1.10	0.90	Disagree	No
64633	Destroy cerv/thor facet jnt	New	3.84	3.84	Agree	No
64634	Destroy c/th facet jnt addl	New	1.32	1.32	Agree	No
64635	Destroy lumb/sac facet jnt	New	3.78	3.78	Agree	Yes
64636	Destroy l/s facet jnt addl	New	1.16	1.16	Agree	Yes
67210	Treatment of retinal lesion	9.45	6.36	6.36	Agree	No
67220	Treatment of choroid lesion	14.39	6.36	6.36	Agree	No
70470	Ct head/brain w/o & w/dye	1.27	1.27	1.27	Agree	No
72100	X-ray exam of lower spine	0.22	0.22	0.22	Agree	No
72110	X-ray exam of lower spine	0.31	0.31	0.31	Agree	No
72114	X-ray exam of lower spine	0.36	0.32	0.32	Agree	No
72120	X-ray exam of lower spine	0.22	0.22	0.22	Agree	No
72170	X-ray exam of pelvis	0.17	0.17	0.17	Agree	No
73030	X-ray exam of shoulder	0.18	0.18	0.18	Agree	No
73620	X-ray exam of foot	0.16	0.16	0.16	Agree	No
74174	Ct angio abd&pelv w/o&w/dye	New	2.20	2.20	Agree	No
77435	Sbrt management	13.00	11.87	11.87	Agree	No
77469	Io radiation tx management	New	5.75	5.75	Agree	No
78226	Hepatobiliary system imaging	New	0.74	0.74	Agree	No
78227	Hepatobil syst image w/drug	New	0.90	0.90	Agree	No
78579	Lung ventilation imaging	New	0.49	0.49	Agree	No
78580	Lung perfusion imaging	0.74	0.74	0.74	Agree	No
78582	Lung ventilat&perfus imaging	New	1.07	1.07	Agree	No

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2012 Interim/ Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
78597	Lung perfusion differential	New	0.75	0.75	Agree	No
78598	Lung perf&ventilat diferentl	New	0.85	0.85	Agree	No
88104	Cytopath fl nongyn smears	0.56	0.56	0.56	Agree	No
88106	Cytopath fl nongyn filter	0.56	0.56	0.37	Disagree	No
88108	Cytopath concentrate tech	0.56	0.56	0.44	Disagree	No
88312	Special stains group 1	0.54	0.54	0.54	Agree	No
88313	Special stains group 2	0.24	0.24	0.24	Agree	No
88314	Histochemical stains add-on	0.45	0.45	0.45	Agree	No
88319	Enzyme histochemistry	0.53	0.53	0.53	Agree	No
88329	Path consult introp	0.67	0.67	0.67	Agree	No
88331	Path consult intraop 1 bloc	1.19	1.19	1.19	Agree	No
88332	Path consult intraop addl	0.59	0.59	0.59	Agree	No
90845	Psychoanalysis	1.79	2.10	1.79	Disagree	Yes
90867	Tcranial magn stim tx plan	0.00	3.52	3.52	Agree	Yes
90868	Tcranial magn stim tx deli	0.00	0.48	0.48	Agree	No
90869	Tcran magn stim redetemine	New	3.20	3.00	Disagree	No
92071	Contact lens fitting for tx	New	0.70	0.61	Disagree	Yes
92072	Fit contac lens for managmnt	New	1.97	1.97	Agree	No
92558	Evoked auditory test qual	New	0.17	0.00	N/A	N/A
92587	Evoked auditory test limited	0.13	0.45	0.35	Disagree	No
92588	Evoked auditory tst complete	0.36	0.60	0.55	Disagree	No
92605	Ex for nonspeech device rx	0.00	1.75	0.00	N/A	N/A
92618	Ex for nonspeech dev rx add	New	0.65	0.00	N/A	N/A
92960	Cardioversion electric ext	2.25	2.25	2.25	Agree	No
93451	Right heart cath	2.72	3.02	2.72	Disagree	No
93452	Left hrt cath w/ventrclgrphy	4.75	4.32	4.75	Disagree	No
93453	R&l hrt cath w/ventriclgrphy	6.24	5.98	6.24	Disagree	No
93454	Coronary artery angio s&i	4.79	4.95	4.79	Disagree	No
93455	Coronary art/grft angio s&i	5.54	6.15	5.54	Disagree	No
93456	R hrt coronary artery angio	6.15	6.00	6.15	Disagree	No
93457	R hrt art/grft angio	6.89	7.66	6.89	Disagree	No
93458	L hrt artery/ventricle angio	5.85	6.51	5.85	Disagree	No
93459	L hrt art/grft angio	6.60	7.34	6.60	Disagree	No
93460	R&l hrt art/ventricle angio	7.35	7.88	7.35	Disagree	No
93461	R&l hrt art/ventricle angio	8.10	9.00	8.10	Disagree	No
93462	L hrt cath trnsptl puncture	3.73	3.73	3.73	Agree	No
93463	Drug admin & hemodynmic meas	2.00	2.00	2.00	Agree	No
93464	Exercise w/hemodynamic meas	1.80	1.80	1.80	Agree	No
93563	Inject congenital card cath	1.11	2.00	1.11	Disagree	No
93564	Inject hrt congntl art/grft	1.13	2.10	1.13	Disagree	No
93565	Inject l ventr/atrial angio	0.86	1.90	0.86	Disagree	No
93566	Inject r ventr/atrial angio	0.86	0.96	0.86	Disagree	No
93567	Inject suprvlv aortography	0.97	0.97	0.97	Agree	No
93568	Inject pulm art hrt cath	0.88	0.98	0.88	Disagree	No
93971	Extremity study	0.45	0.45	0.45	Agree	No
94060	Evaluation of wheezing	0.31	0.31	0.26	Disagree	No
94726	Pulm funct tst plethysmograp	New	0.31	0.26	Disagree	No
94727	Pulm function test by gas	New	0.31	0.26	Disagree	No
94728	Pulm funct test oscillometry	New	0.31	0.26	Disagree	No
94729	C02/membane diffuse capacity	New	0.19	0.17	Disagree	No
94780	Car seat/bed test 60 min	New	0.48	0.48	Agree	No
94781	Car seat/bed test + 30 min	New	0.17	0.17	Agree	No
95010	Percut allergy titrate test	0.15	0.11	0.11	Agree	No
95015	Id allergy titrate-drug/bug	0.15	0.06	0.06	Agree	No
95885	Musc tst done w/nerv tst lim	New	0.35	0.35	Agree	No

CPT/ HCPCS Code	Descriptor	CY 2011 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2012 Interim/ Interim Final Work RVU	Agree/ Disagree with AMA RUC/HCPAC Recommendation	CMS Refinement to AMA RUC/HCPAC Recommended Time
95886	Musc test done w/n test comp	New	0.92	0.92	Agree	No
95887	Musc tst done w/n tst nonext	New	0.73	0.73	Agree	No
95900	Motor nerve conduction test	0.42	0.42	0.42	Agree	No
95903	Motor nerve conduction test	0.60	0.60	0.60	Agree	No
95904	Sense nerve conduction test	0.34	0.34	0.34	Agree	No
95938	Somatosensory testing	New	0.86	0.86	Agree	No
95939	C motor evoked upr&lwr limbs	New	2.25	2.25	Agree	No

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2. Establishing Interim Final Direct PE RVUs for CY 2012

a. Background

The AMA RUC provides CMS with recommendations regarding direct PE inputs, including clinical labor, supplies, and equipment, for new, revised, and potentially misvalued codes. We review the AMA RUC-recommended direct PE inputs on a code-by-code basis, including the recommended facility PE inputs and/or nonfacility PE inputs, as clinically appropriate for the code. We determine whether we agree with the AMA RUC's recommended direct PE inputs for a service or, if we disagree, we refine the PE inputs to represent inputs that better reflect our estimate of the PE resources required for the service in the facility and/or nonfacility settings. We also confirm that CPT codes should have facility and/or nonfacility direct PE inputs and make changes based on our clinical judgment and any PFS payment policies that would apply to the code.

b. Methodology

We have accepted for CY 2012, as interim final and without refinement, the direct PE inputs based on the recommendations submitted by the AMA RUC for the codes listed in Table 20. For the remainder of the AMA RUC's direct PE recommendations, we have accepted the PE recommendations submitted by the AMA RUC as interim final, but with refinements. These codes and the refinements to their direct PE inputs are listed in Table 21.

Generally, we only establish interim final direct PE inputs for services when the RUC has provided a new recommendation. For CY 2012, we are establishing interim final direct PE inputs for several codes for which the RUC did not provide direct PE recommendations. In the case of these codes, we believe it is necessary to establish new interim final direct PE inputs for codes not recently reviewed by the RUC for the same reasons we explain in greater detail in section II.B (''Potentially Misvalued Services Under the Physician Fee Schedule'') of this final rule with comment period: In order to maintain appropriate relativity among those codes and other related codes or between the PE and work components of PFS payment. There are two situations that have prompted us to establish interim final direct PE inputs for particular codes without a corresponding direct PE recommendation from the RUC.

The first situation occurs when the direct PE inputs of new, combined codes are developed without parallel review of the direct PE inputs of the component codes that describe the same services. For CY 2012, this situation applies to three sets of codes. CPT has created a new code, 74174, to describe CTA of the abdomen and pelvis. Prior to CY 2012, practitioners would have reported the combined service using two separate codes (74175 to describe CTA of the abdomen and 72191 to describe CTA of the pelvis). CPT similarly created a new combined code to describe short latency somatosensory evoked potential studies of the upper and lower limbs (95938). This combined service would have been previously reported using CPT codes 95925 (short latency somatosensory evoked potential studies of the upper limbs) and 95926 (short latency somatosensory evoked potential studies of the lower limbs). Finally, CPT created 95939 to describe central motor evoked potential study of the upper and lower limbs. This combined service would have been previously reported using component CPT codes 95928 (central motor evoked potential study of the upper limbs) and 95929 (central motor evoked potential study of the lower limbs).

Since each of these sets of component and combined codes is used to report the same service, we believe that it is important to maintain relativity among the associated practice expense values. We received direct PE recommendations from the RUC for the new codes describing combined services, but we did not receive corresponding recommendations regarding the existing codes describing the component services. The new direct PE inputs for the combined services are not fully congruent with the current direct PE inputs for the component codes. Therefore, maintaining the direct PE inputs for the existing component codes until we receive a RUC recommendation would result in at least one year of incongruent practice expense values. Therefore, we believe that it would be inappropriate to develop PE values for these sets of codes based on these inputs. Since we do not have corresponding recommendations regarding the existing component codes, we cannot maintain appropriate relativity among the codes without either refining the direct PE inputs of the new combined codes to conform to the existing component codes or refining the direct PE inputs of the existing component codes to conform to the direct PE inputs of the new combined codes. The direct PE inputs for each of the existing component codes were developed over 5 years ago. Since the direct PE inputs for the new combined codes were developed more recently, we believe that they better reflect current typical practice. Therefore, in order to maintain appropriate relativity among these sets of codes that describe the same services and in order to use the most accurate information available, we used the direct PE inputs for the new, combined codes in order to develop appropriate refinements to the direct PE inputs for the existing, component codes. The refinements to the current PE inputs for these codes are included in Table 21 and they will be considered interim final for CY 2012. In conjunction with our request for comprehensive review of code families as described in section II.B. of this final rule with comment period, we encourage the RUC to review component codes when developing recommendations regarding combined codes.

The second situation arises when the physician work values of particular codes are reviewed as part of the potentially misvalued code initiative without parallel review of the

corresponding direct PE inputs. In these cases, we have reviewed the existing direct PE inputs of the services in the context of the new physician work and time recommendations and, when appropriate, established refined interim final direct PE inputs consistent with existing policies. These codes are: 70470 (Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections), 73030 (Radiologic examination, pelvis; 1 or 2 views), 73030 (Radiologic examination, shoulder; complete, minimum of 2 views), 73620 (Radiologic examination, foot; 2 views), and 93971 (Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study). We are adopting on an interim final basis for CY 2012 the refinements to the current direct PE inputs for these codes as shown in Table 21, and these values are reflected in the CY 2012 PFS direct PE database. That database is available under downloads for the CY 2012 PFS final rule with comment period on the CMS Web site at: *http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage.*

c. Common and Code-Specific Refinements

While Table 21 details the CY 2012 refinements of the AMA RUC's direct PE recommendations at the code-specific level, we discuss the general nature of some common refinements and the reasons for particular refinements in the following section.

(1) Changes in Physician Time

Some direct PE inputs are directly affected by revisions in physician time described in section III.B.1 of this final rule with comment period. Specifically, changes in the intra-service portions of the physician time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs.

Changes in Intra-service Physician Time in the Nonfacility Setting. For most codes valued in the nonfacility setting, a portion of the clinical labor time allocated to the intra-service period reflects minutes assigned for assisting the physician with the procedure. To the extent that we are refining the times associated with the intra-service portion of such procedures, we have adjusted the corresponding intra-service clinical labor minutes in the nonfacility setting.

For equipment associated with the intra-service period in the nonfacility setting, we generally allocate time based on the typical number of minutes a piece of equipment is being used and, therefore, not available for use with another patient during that period. In general, we allocate these minutes based on the description of typical clinical labor activities. To the extent that we are making changes in the clinical labor times associated with the intra-service portion of procedures, we have adjusted the corresponding equipment minutes associated with the codes.

Changes in the Number or Level of Postoperative Office Visits in the Global Period. For codes valued with post-service physician office visits during a global period, most of the clinical labor time allocated to the post-service period reflects a standard number of minutes allocated for each of those visits. To the extent that we are refining the number or level of postoperative visits, we have modified the clinical staff time in the post-service period to reflect the change. For codes valued with post-service physician office visits during a global period, we allocate standard equipment for each of those visits. To the extent that we are making a change in the number or level of postoperative visits associated with a code, we have adjusted the corresponding equipment minutes. For codes valued with post-service physician office visits during a global period, a certain number of supply items are allocated for each of those office visits. To the extent that we are making a change in the number of postoperative visits, we have adjusted the corresponding supply item quantities associated with the codes. We note that many supply items associated with post-service physician office visits are allocated for each office visit (for example, a minimum multi-specialty visit pack (SA048) in the CY 2012 direct PE database). For these supply items, the quantities in the direct PE database should reflect the number of office visits associated with the code's global period. However, some supply items are associated with post-service physician office visits but are only allocated once during the global period because they are typically used during only one of the post-service office visits (for example, pack, post-op incision care (suture) (SA054) in the direct PE database). For these supply items, the quantities in the proposed notice direct PE database reflect that single quantity.

These refinements are reflected in the final CY 2011 PFS direct PE database and detailed in Table 21.

(2) Equipment Minutes

In general, the equipment time inputs correspond to the intra-service portion of the clinical labor times. Certain highly technical pieces of equipment and equipment rooms are less likely to be used by a clinician over the full course of a procedure and are typically available for other patients during time that may still be in the intra-service portion of the service. We adjust those equipment times accordingly. We refer interested stakeholders to our extensive discussion of these policies in the context of our CY 2011 interim final direct PE inputs in section III.B.2 of this final rule with comment period. We are refining the CY 2012 AMA RUC direct PE recommendations to conform to these equipment time policies. These refinements are reflected in the final CY 2011 PFS direct PE database and detailed in Table 21.

(3) Moderate Sedation Inputs

In section II.A.3 of this final rule with commenter period, we finalized a standard package of direct PE inputs for services where moderate sedation is considered inherent in the procedure. We refer interested parties to our extensive discussion of these policies as proposed and finalized in section III.A.3 of this final rule with comment period. We are refining the CY 2012 AMA RUC direct PE recommendations to conform to these policies. These refinements are reflected in the final CY 2012 PFS direct PE database and detailed in Table 21.

(4) Standard Minutes for Clinical Labor Tasks

In general, the minutes associated with certain clinical labor tasks are standardized depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. In the case of some services, the RUC has recommended a numbers of minutes either greater or lesser than time typically allotted for certain tasks. In those cases, CMS clinical staff has reviewed the deviations from the standards to determine their clinical appropriateness. Where the recommended exceptions have not been accepted, we have refined the interim final direct PE inputs to match the standard times for those tasks and each of those refinements appears in Table 21.

(5) Supply and Equipment Invoices

When clinically appropriate, the AMA RUC generally recommends the use of supply and equipment items that already exist in the direct PE database for new, revised, and potentially misvalued codes. Some recommendations include supply or equipment items that are not currently in the direct PE database. In these cases, the AMA RUC has historically

recommended a new item be created and has facilitated CMS' pricing of that item by working with the specialty societies to provide sales invoices to us. We appreciate the contributions of the AMA RUC in that process.

We received invoices for several new supply and equipment items for CY 2012. We have accepted each of these items and added them to the direct PE database. In general, the prices listed on the submitted invoices match the items listed in the RUC direct PE recommendations. However, in some cases, the relationship between submitted invoices and the items listed on the direct PE recommendations is not clear. For example, some submitted invoices only list total charges that include all of the line items on the invoice, including charges for costs other than the price of the equipment listed on the recommendation. When the price for all of those line items is apparent, we subtract that amount from the total charges to determine the appropriate price of the equipment. For example, equipment item invoices often include line items reflecting a limited quantity of disposable supplies for use during procedures. When these supplies are built into the overall price of the equipment and they also appear as direct PE inputs, we subtract the price of the supplies from the overall price of the equipment since we have an empirical basis for determining the price of the excluded line item and the price of those supplies is built into the payment rate for the service. When we have no way of determining how much of the total price listed on the invoice includes amounts attributed to excluded line items, we cannot accept the invoice as acceptable information to establish or update a price input. In terms of the CY 2012 direct PE recommendations, we point out that while we have accepted the RUC's recommendation for direct PE inputs for SBRT treatment delivery, we could not accept the accompanying invoices to update the price of the ''SRS system, SBRT, six systems, average'' equipment (ER083). Each of these invoices included line items that we would not accept as part of the cost of the equipment, such as costs for training technologists to use the equipment, and the price for these items were not separately identifiable. Therefore, we did not update the equipment price for ER083 in establishing interim final direct PE inputs for CY 2012.

(6) Application of Casts and Strapping (CPT codes 29581–29584)

The RUC recommended establishing a new supply input for CPT codes 29582 (Application of multi-layer venous wound compression system, below knee; thigh and leg, including ankle and foot, when performed), 29583 (Application of multi-layer venous wound compression system, below knee; upper arm and forearm), and 29584 (Application of multi-layer venous wound compression system, below knee; upper arm, forearm, hand, and fingers). Accompanying the RUC recommendations, we received an invoice that reflected a price of $16.39 per system when purchased as part of case of eight. In response to this recommendation, we have created a supply item called ''multi-layer compression system bandages'' (SG096) with a price input of $16.39. As discussed in section III.B.1.b. of this final rule for comment period, for CY 2012 the CPT Editorial Panel revised the descriptor for CPT code 29581 (Application of multi-layer compression system; leg (below knee), including ankle and foot), and also created CPT codes 29582, 29583, and 29584 to describe the application of multi-layer compression to the upper and lower extremities. The CPT Editorial Panel and AMA RUC concluded that the revisions to the descriptor for CPT code 29581 were editorial only, and the specialty society believed that resurveying CPT code 29581 was not necessary. As such, the AMA RUC did not review the direct PE inputs for CPT code 29581. After clinical review, we believe that CPT codes 29581, 29582, 29583, and 29584 all describe similar services from a resource perspective. In line with this determination, we are treating all four codes as physical therapy services and replacing the supply input called ''dressing, multi layer system, venous ulcer'' (SG093) in 29581 with the new supply item ''multi-layer compression system bandages'' (SG096) on an interim basis for CY 2012.In section III.B.1.b (Establishing Interim final RVUs for CY 2012) of this CY 2012 PFS final rule, we believe that a survey that addresses all 4 CPT codes together as a family and gathers responses from all clinicians who furnish the services described by CPT codes 29581 through 29584 would help assure the appropriate gradation in valuation of these 4 services Therefore, for CY 2012 we are holding the work, practice expense, and malpractice values interim.

(7) Image Guidance for Biopsies

The RUC submitted direct PE inputs for CPT codes CPT codes 47000 (Biopsy of liver, needle; percutaneous) and 32405 (Biopsy, lung or mediastinum, percutaneous needle) including minutes allocated to a CT room. As reflected in Table 21, we refined both recommendations to exclude the CT room. For 47000, CPT instructs practitioners to report separate codes when image guidance is used to furnish the service. Therefore, it would be inappropriate to include the equipment used for image guidance as a direct PE input for 47000. For 32405, we note that the recommendations for the new nonfacility direct PE inputs for the code were developed using the direct PE inputs for recently CPT code 49083 (Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance) and that code does not include use of a CT room as a typically used resource. These refinements are reflected in the final CY 2012 PFS direct PE database.

(8) Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System

For CY 2012, CPT created CPT Editorial Panel deleted four codes and created four new codes to describe neurolysis reported per joint (2 nerves per each joint) instead of per nerve under image guidance. The new codes are: 64633 (Destruction by neurolytic agent, paravertebral facet joint nerve(s); cervical or thoracic, with image guidance (fluoroscopy or CT), single facet joint); 64634 (Destruction by neurolytic agent, paravertebral facet joint nerve(s); cervical or thoracic, with image guidance (fluoroscopy or CT), each additional facet joint (List separately in addition to code for primary procedure)); 64635 (Destruction by neurolytic agent, paravertebral facet joint nerve(s); lumbar or sacral, with image guidance (fluoroscopy or CT), single facet joint); and 64636 (Destruction by neurolytic agent, paravertebral facet joint nerve(s); lumbar or sacral, with image guidance (fluoroscopy or CT), each additional facet joint (List separately in addition to code for primary procedure)).

The RUC submitted direct practice expense inputs for these new codes that describe existing services. For codes 64633 and 64635, in addition to the cannula (SD011), the radiofrequency generator (EQ214), and other inputs, the direct PE input recommendation included a very expensive supply item called ''kit, probe, radiofrequency, XIi-enhanced RF probe'' (SA100). The recommendation did not provide a rationale as to why this highly priced kit should be included as a direct PE input for these existing services when the four predecessor codes that described the services prior to CY 2012 included neither this item nor any similarly priced disposable supply. Therefore, we are refining the RUC recommendation by removing the supply item SA100

from both 64633 and 64635. We note that the direct PE inputs for these codes are interim for CY 2012, and we will consider any submitted information regarding the use of this supply in furnishing these services prior to finalizing the direct PE inputs for CY 2013.

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Table 20. CPT Codes with Accepted AMA RUC Direct PE Recommendations for CY 2012 New, Revised, and Potentially Misvalued Codes

CPT Code	CPT Code Description
15272	Skin sub graft t/a/l add-on
15274	Skn sub grft t/a/l child add
15276	Skin sub graft f/n/hf/g addl
15278	Skn sub grft f/n/hf/g ch add
22634	Spine fusion extra segment
29826	Shoulder arthroscopy/surgery
29880	Knee arthroscopy/surgery
29881	Knee arthroscopy/surgery
32096	Open wedge/bx lung infiltr
32097	Open wedge/bx lung nodule
32098	Open biopsy of lung pleura
32100	Exploration of chest
32505	Wedge resect of lung initial
32506	Wedge resect of lung add-on
32507	Wedge resect of lung diag
32663	Thoracoscopy w/lobectomy
32666	Thoracoscopy w/wedge resect
32667	Thoracoscopy w/w resect addl
32668	Thoracoscopy w/w resect diag
32669	Thoracoscopy remove segment
32670	Thoracoscopy bilobectomy
32671	Thoracoscopy pneumonectomy

CPT Code	CPT Code Description
32672	Thoracoscopy for lvrs
32673	Thoracoscopy w/thymus resect
32674	Thoracoscopy lymph node exc
33212	Insert pulse gen sngl lead
33213	Insert pulse gen dual leads
33221	Insert pulse gen mult leads
33227	Remove&replace pm gen singl
33228	Remv&replc pm gen dual lead
33229	Remv&replc pm gen mult leads
33230	Insrt pulse gen w/dual leads
33231	Insrt pulse gen w/mult leads
33240	Insrt pulse gen w/singl lead
33262	Remv&replc cvd gen sing lead
33263	Remv&replc cvd gen dual lead
33264	Remv&replc cvd gen mult lead
38208	Thaw preserved stem cells
38209	Wash harvest stem cells
38230	Bone marrow harvest allogen
38232	Bone marrow harvest autolog
38240	Bn marrow/stm transplt allo
38746	Remove thoracic lymph nodes
49084	Peritoneal lavage
62367	Analyze spine infus pump
62368	Analyze sp inf pump w/reprog

CPT Code	CPT Code Description
76950	Echo guidance radiotherapy
77373	Sbrt delivery
77418	Radiation tx delivery imrt
77421	Stereoscopic x-ray guidance
77435	Sbrt management
77469	Io radiation tx management
88312	Special stains group 1
88313	Special stains group 2
88314	Histochemical stains add-on
88319	Enzyme histochemistry
92072	Fit contac lens for managmnt
92558	Evoked auditory test qual
92587	Evoked auditory test limited
92605	Ex for nonspeech device rx
92618	Ex for nonspeech dev rx add
94780	Car seat/bed test 60 min
95010	Percut allergy titrate test
95015	Id allergy titrate-drug/bug
95024	Id allergy test drug/bug
95900	Motor nerve conduction test
95903	Motor nerve conduction test
95904	Sense nerve conduction test
98925	Osteopathic manipulation
98926	Osteopathic manipulation

CPT Code	CPT Code Description
98927	Osteopathic manipulation
98928	Osteopathic manipulation
98929	Osteopathic manipulation

Table 21. CPT Codes with Refined AMA RUC Direct PE Recommendations for CY 2012 New, Revised, and Potentially Misvalued Codes

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
11056	Trim skin lesions 2 to 4	EF031	table, power	NF		30	35	Refined equipment time to reflect typical use exclusive to patient
		EQ168	light, exam	NF		30	35	Refined equipment time to reflect typical use exclusive to patient
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	30	35	Conforming to physician time
11721	Debride nail 6 or more	EF031	table, power	NF		23	26	Refined equipment time to reflect typical use exclusive to patient
		EQ109	dust extractor			23	26	Refined equipment time to reflect typical use exclusive to patient
		EQ168	light, exam	NF		23	26	Refined equipment time to reflect typical use exclusive to patient
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	23	26	Conforming to physician time
15271	Skin sub graft trnk/arm/leg	EQ137	instrument pack, basic ($500-$1499)	NF		43	40	Refined equipment time to reflect typical use exclusive to patient
15273	Skin sub grft t/arm/lg child	EQ137	instrument pack, basic ($500-$1499)	NF		48	45	Refined equipment time to reflect typical use exclusive to patient
		SA054	pack, post-op incision care (suture)	NF		1	0	Changed quantity to reflect typical use
15275	Skin sub graft face/nk/hf/g	EQ137	instrument pack, basic ($500-$1499)	NF		43	40	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
15277	Skn sub grft f/n/hf/g child	EQ137	instrument pack, basic ($500-$1499)	NF		53	50	Refined equipment time to reflect typical use exclusive to patient
		SA054	pack, post-op incision care (suture)	NF		1	0	Changed quantity to reflect typical use
20527	Inj dupuytren cord w/enzyme	SA048	pack, minimum multi-specialty visit	NF		0	1	Missing quantity
22523	Percut kyphoplasty thor	EF018	stretcher	NF		60	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		0	120	Standard input for Moderate Sedation
		EQ010	ECG, 3-channel	NF		131	0	Non-standard input for Moderate Sedation
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		0	120	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		131	120	Refined equipment time to reflect typical use exclusive to patient
		EQ138	instrument pack, medium ($1500 and up)	NF		71	83	Refined equipment time to reflect typical use exclusive to patient
		EQ211	pulse oximeter w-printer	NF		131	0	Non-standard input for Moderate Sedation
		SA053	pack, post-op incision care (suture & staple)	NF		0	1	Missing quantity
22524	Percut kyphoplasty lumbar	EF018	stretcher	NF		60	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		0	117	Standard input for Moderate Sedation
		EQ010	ECG, 3-channel	NF		128	0	Non-standard input for Moderate Sedation

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		0	117	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		128	117	Refined equipment time to reflect typical use exclusive to patient
		EQ138	instrument pack, medium ($1500 and up)	NF		68	80	Refined equipment time to reflect typical use exclusive to patient
		EQ211	pulse oximeter w-printer	NF		128	0	Non-standard input for Moderate Sedation
		SA053	pack, post-op incision care (suture & staple)	NF		0	1	Missing quantity
22525	Percut kyphoplasty add-on	EL014	room, radiographic-fluoroscopic	NF		42	40	Refined equipment time to reflect typical use exclusive to patient
		EQ138	instrument pack, medium ($1500 and up)	NF		42	40	Refined equipment time to reflect typical use exclusive to patient
		L037D	RN/LPN/MTA	NF	Prepare room, equipment, supplies	2	0	Add-on code - Time is accounted for in base code
22633	Lumbar spine fusion combined	L037D	RN/LPN/MTA	NF	Other Clinical Activity (please specify)	15	0	CMS clinical review
26341	Manipulat palm cord post inj	SA048	pack, minimum multi-specialty visit	NF		0	2	Missing quantity
		SA048	pack, minimum multi-specialty visit	F		0	1	Missing quantity
27096	Inject sacroiliac joint	ED032	printer, laser, paper	NF		18	0	CMS clinical review
		EF018	stretcher	NF		60	38	Refined equipment time to reflect typical use exclusive to patient
		L037D	RN/LPN/MTA	NF	Prepare room, equipment, supplies	2	0	Time accounted for elsewhere

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
29581	Apply multlay comprs lwr leg	SG095	Hemostatic patch	NF		1	0	Incorrect CMS Code
		SG096	Multi-layer compression system bandages	NF		0	1	CMS Code correction
29582	Apply multlay comprs upr leg	EF028	table, mat, hi-lo, 6 x 8 platform	NF		0	20	Missing time
		SA020	kit, loop snare (Microvena)	NF		1	0	Incorrect CMS Code
		SM020	lotion, antibacterial	NF		0	1	CMS Code correction
29583	Apply multlay comprs upr arm	EF028	table, mat, hi-lo, 6 x 8 platform	NF		0	20	Missing time
		SA020	kit, loop snare (Microvena)	NF		1	0	Incorrect CMS Code
		SM020	lotion, antibacterial	NF		0	1	CMS Code correction
29584	Appl multlay comprs arm/hand	EF028	table, mat, hi-lo, 6 x 8 platform	NF		0	20	Missing time
		SA020	kit, loop snare (Microvena)	NF		1	0	Incorrect CMS Code
		SM020	lotion, antibacterial	NF		0	1	CMS Code correction
32405	Percut bx lung/mediastinum	EF019	stretcher chair	NF		272	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		0	277	Standard input for Moderate Sedation
		EL007	room, CT	NF		44	0	CMS clinical review
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		272	277	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EQ032	IV infusion pump	NF		272	277	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	30	35	Conforming to physician time
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	1	0	Standardized time input
		L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	1	0	Standardized time input
		L037D	RN/LPN/MTA	NF	Monitor patient during Moderate Sedation	30	35	CMS clinical review
		L037D	RN/LPN/MTA	NF	Prepare and position patient/ monitor patient/ set up IV	3	2	Standardized time input
32601	Thoracoscopy diagnostic	L051A	RN	F	Coordinate pre-surgery services	20	10	Standardized time input
		L051A	RN	F	Follow-up phone calls & prescriptions	7	3	Standardized time input
		L051A	RN	F	Provide pre-service education/obtain consent	20	7	Standardized time input
		L051A	RN	F	Schedule space and equipment in facility	8	5	Standardized time input
32607	Thoracoscopy w/bx infiltrate	L051A	RN	F	Coordinate pre-surgery services	20	10	Standardized time input
		L051A	RN	F	Follow-up phone calls & prescriptions	7	3	Standardized time input
		L051A	RN	F	Provide pre-service education/obtain consent	20	7	Standardized time input
		L051A	RN	F	Schedule space and equipment in facility	8	5	Standardized time input
32608	Thoracoscopy w/bx nodule	L051A	RN	F	Coordinate pre-surgery services	20	10	Standardized time input
		L051A	RN	F	Follow-up phone calls & prescriptions	7	3	Standardized time input
		L051A	RN	F	Provide pre-service education/obtain consent	20	7	Standardized time input
		L051A	RN	F	Schedule space and equipment in facility	8	5	Standardized time input

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
32609	Thoracoscopy w/bx pleura	L051A	RN	F	Coordinate pre-surgery services	20	10	Standardized time input
		L051A	RN	F	Follow-up phone calls & prescriptions	7	3	Standardized time input
		L051A	RN	F	Provide pre-service education/obtain consent	20	7	Standardized time input
		L051A	RN	F	Schedule space and equipment in facility	8	5	Standardized time input
36200	Place catheter in aorta	EF019	stretcher chair	NF		101	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		41	272	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EL011	room, angiography	NF		41	40	Refined equipment time to reflect typical use exclusive to patient
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		101	272	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ032	IV infusion pump	NF		41	272	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ168	light, exam	NF		101	40	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EQ212	pulse oxymetry recording software (prolonged monitoring)	NF		101	0	Non-standard input for Moderate Sedation
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	0	30	CMS Code correction
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	3	0	Standardized time input
		L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	4	3	Standardized time input
		L051A	RN	NF	Assist physician in performing procedure	30	0	CMS Code correction
		L051A	RN	NF	Monitor patient during Moderate Sedation	0	30	Standard input for Moderate Sedation
		SA044	pack, moderate sedation	NF		0	1	Missing quantity
		SB001	cap, surgical	NF		0	2	CMS Code correction
36245	Ins cath abd/l-ext art 1st	EF019	stretcher chair	NF		144	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		84	315	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EL011	room, angiography	NF		84	83	Refined equipment time to reflect typical use exclusive to patient
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		144	315	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EQ032	IV infusion pump	NF		84	315	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ168	light, exam	NF		144	83	Refined equipment time to reflect typical use exclusive to patient
		EQ212	pulse oxymetry recording software (prolonged monitoring)	NF		144	0	Non-standard input for Moderate Sedation
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	0	73	CMS Code correction
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	3	0	Standardized time input
		L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	4	3	Standardized time input
		L051A	RN	NF	Assist physician in performing procedure	73	0	CMS Code correction
		L051A	RN	NF	Monitor patient during Moderate Sedation	0	73	Standard input for Moderate Sedation
		SA044	pack, moderate sedation	NF		0	1	Missing quantity
		SB001	cap, surgical	NF		0	2	CMS Code correction
36246	Ins cath abd/l-ext art 2nd	EF019	stretcher chair	NF		116	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		56	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EL011	room, angiography	NF		56	55	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		116	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ032	IV infusion pump	NF		56	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ168	light, exam	NF		116	55	Refined equipment time to reflect typical use exclusive to patient
		EQ212	pulse oxymetry recording software (prolonged monitoring)	NF		116	0	Non-standard input for Moderate Sedation
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	0	45	CMS Code correction
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	3	0	Standardized time input
		L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	4	3	Standardized time input
		L051A	RN	NF	Assist physician in performing procedure	45	0	CMS Code correction
		L051A	RN	NF	Monitor patient during Moderate Sedation	0	45	CMS Code correction
		SA044	pack, moderate sedation	NF		0	1	Missing quantity
		SB001	cap, surgical	NF		0	2	CMS Code correction
36247	Ins cath abd/l-ext art 3rd	EF019	stretcher chair	NF		131	0	Non-standard input for Moderate Sedation

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EF027	table, instrument, mobile	NF		71	302	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EL011	room, angiography	NF		71	70	Refined equipment time to reflect typical use exclusive to patient
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		131	302	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ032	IV infusion pump	NF		71	302	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ168	light, exam	NF		131	70	Refined equipment time to reflect typical use exclusive to patient
		EQ212	pulse oxymetry recording software (prolonged monitoring)	NF		131	0	Non-standard input for Moderate Sedation
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	0	60	CMS Code correction
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	3	0	Standardized time input
		L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	4	3	Standardized time input
		L051A	RN	NF	Assist physician in performing procedure	60	0	CMS Code correction
		L051A	RN	NF	Monitor patient during Moderate Sedation	0	60	Standard input for Moderate Sedation

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		SA044	pack, moderate sedation	NF		0	1	Missing quantity
		SB001	cap, surgical	NF		0	2	CMS Code correction
36251	Ins cath ren art 1st unilat	EF018	stretcher	NF		322	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		322	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		322	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ032	IV infusion pump	NF		322	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available	5	3	Standardized time input
36252	Ins cath ren art 1st bilat	EF018	stretcher	NF		322	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		322	295	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		322	295	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ032	IV infusion pump	NF		322	295	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available	5	3	Standardized time input
36253	Ins cath ren art 2nd+ unilat	EF018	stretcher	NF		322	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		322	302	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		322	302	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ032	IV infusion pump	NF		322	302	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available	5	3	Standardized time input
36254	Ins cath ren art 2nd+ bilat	EF018	stretcher	NF		322	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		322	310	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		322	310	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ032	IV infusion pump	NF		322	310	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available	5	3	Standardized time input
37191	Ins endovas vena cava filtr	EF018	stretcher	NF		332	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		0	272	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		332	272	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ032	IV infusion pump	NF		332	272	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		SB024	gloves, sterile	NF		2	4	Changed quantity to reflect typical use
		SB028	gown, surgical, sterile	NF		2	4	Changed quantity to reflect typical use
37192	Redo endovas vena cava filtr	EF018	stretcher	NF		332	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		0	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		332	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ032	IV infusion pump	NF		332	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		SB024	gloves, sterile	NF		2	4	Changed quantity to reflect typical use
		SB028	gown, surgical, sterile	NF		2	4	Changed quantity to reflect typical use
37193	Rem endovas vena cava filter	EF018	stretcher	NF		332	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		0	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		332	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		EQ032	IV infusion pump	NF		332	287	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
47000	Needle biopsy of liver	EF019	stretcher chair	NF		262	0	Non-standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		0	268	Standard input for Moderate Sedation
		EL007	room, CT	NF		35	0	CMS clinical review
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		252	268	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EQ032	IV infusion pump	NF		252	268	Moderate Sedation equipment - Time includes administering anesthesia, procedure time, and monitoring patient
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	20	26	Conforming to physician time
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	1	0	Standardized time input
		L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	1	0	Standardized time input
		L037D	RN/LPN/MTA	NF	Monitor patient during Moderate Sedation	20	26	CMS clinical review
		L037D	RN/LPN/MTA	NF	Prepare and position patient/ monitor patient/ set up IV	3	2	Standardized time input
49082	Abd paracentesis	EF015	mayo stand	NF		62	36	Refined equipment time to reflect typical use exclusive to patient
		EF031	table, power	NF		62	36	Refined equipment time to reflect typical use exclusive to patient
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		62	36	Refined equipment time to reflect typical use exclusive to patient
		EQ168	light, exam	NF		62	36	Refined equipment time to reflect typical use exclusive to patient
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	20	10	Conforming to physician time
		L037D	RN/LPN/MTA	NF	Montior drainage of fluid	25	10	CMS clinical review
		L037D	RN/LPN/MTA	NF	Prepare and position patient/ monitor patient/ set up IV	3	2	Standardized time input

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
49083	Abd paracentesis w/imaging	EF015	mayo stand	NF		86	39	Refined equipment time to reflect typical use exclusive to patient
		EF031	table, power	NF		86	39	Refined equipment time to reflect typical use exclusive to patient
		EL015	room, ultrasound, general	NF		86	39	Refined equipment time to reflect typical use exclusive to patient
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		86	39	Refined equipment time to reflect typical use exclusive to patient
		EQ168	light, exam	NF		86	39	Refined equipment time to reflect typical use exclusive to patient
		ER029	film alternator (motorized film viewbox)	NF		86	39	Refined equipment time to reflect typical use exclusive to patient
		L051B	RN/Diagnostic Medical Sonographer	NF	Assist physician in performing procedure	25	20	Conforming to physician time
		L051B	RN/Diagnostic Medical Sonographer	NF	Clean room/equipment by physician staff	6	3	Standardized time input
		L051B	RN/Diagnostic Medical Sonographer	NF	Prepare and position patient/ monitor patient/ set up IV	6	2	Standard input for Moderate Sedation
		L051B	RN/Diagnostic Medical Sonographer	NF	Prepare room, equipment, supplies	5	2	Standard input for Moderate Sedation
		No Code	film jacket	NF		1	0	Non-standard direct practice expense input
			processor chemicals	NF		1	0	Non-standard direct practice expense input
51736	Urine flow measurement	EQ259	uroflowmeter, digital, w-chair	NF		10	9	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		SK082	towel, paper (Bounty) (per sheet)	NF		0	4	Changed quantity to reflect typical use
		SM012	disinfectant spray (Transeptic)	NF		0	1	Changed quantity to reflect typical use
		SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		0	1	Changed quantity to reflect typical use
51741	Electro-uroflowmetry first	EQ259	uroflowmeter, digital, w-chair	NF		1	9	Refined equipment time to reflect typical use exclusive to patient
62369	Anal sp inf pmp w/reprg&fill	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	20	15	Conforming to physician time
62370	Anl sp inf pmp w/mdreprg &fil	L037D	RN/LPN/MTA	NF	Interval history obtained by pain medicine nurse regarding course of treatment and pain related medical history	3	0	CMS clinical review
64633	Destroy cerv/thor facet jnt	EF018	stretcher	NF		116	59	Refined equipment time to reflect typical use exclusive to patient
64633	Destroy cerv/thor facet jnt	EF023	table, exam	NF		0	36	Missing time
		EF023	table, exam	F		0	36	Missing time
		EQ168	light, exam	NF		0	36	Missing time
		EQ168	light, exam	F		0	36	Missing time
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package	10	0	CMS clinical review
		SA100	kit, probe, radiofrequency, Xli-enhanced RF probe	NF		1	0	CMS clinical review
64634	Destroy c/th facet jnt addl	ED025	film processor, wet	NF		30	20	Refined equipment time to reflect typical use exclusive to patient
		ED031	printer, dye sublimation (photo, color)	NF		30	20	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EF018	stretcher	NF		30	20	Refined equipment time to reflect typical use exclusive to patient
		EL018	room, mobile c-ARM	NF		30	20	Refined equipment time to reflect typical use exclusive to patient
		EQ211	pulse oximeter w-printer	NF		30	20	Refined equipment time to reflect typical use exclusive to patient
		EQ214	radiofrequency generator (NEURO)	NF		30	20	Refined equipment time to reflect typical use exclusive to patient
		ER029	film alternator (motorized film viewbox)	NF		30	20	Refined equipment time to reflect typical use exclusive to patient
		ER067	x-ray view box, 4 panel	NF		30	20	Refined equipment time to reflect typical use exclusive to patient
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	30	20	Conforming to physician time
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	30	20	Conforming to physician time
64635	Destroy lumb/sac facet jnt	ED025	film processor, wet	NF		38	36	Refined equipment time to reflect typical use exclusive to patient
		ED031	printer, dye sublimation (photo, color)	NF		38	36	Refined equipment time to reflect typical use exclusive to patient
		EF018	stretcher	NF		116	59	Refined equipment time to reflect typical use exclusive to patient
		EF023	table, exam	NF		0	36	Missing time

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EF023	table, exam	F		0	36	Missing time
		EL018	room, mobile c-ARM	NF		38	36	Refined equipment time to reflect typical use exclusive to patient
		EQ168	light, exam	NF		0	36	Missing time
		EQ168	light, exam	F		0	36	Missing time
		EQ211	pulse oximeter w-printer	NF		38	36	Refined equipment time to reflect typical use exclusive to patient
		EQ214	radiofrequency generator (NEURO)	NF		38	36	Refined equipment time to reflect typical use exclusive to patient
		ER029	film alternator (motorized film viewbox)	NF		38	36	Refined equipment time to reflect typical use exclusive to patient
		ER067	x-ray view box, 4 panel	NF		38	36	Refined equipment time to reflect typical use exclusive to patient
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	30	28	Conforming to physician time
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package	10	0	CMS clinical review
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	30	28	Conforming to physician time
		SA100	kit, probe, radiofrequency, Xli-enhanced RF probe	NF		1	0	CMS clinical review
64636	Destroy l/s facet jnt addl	ED025	film processor, wet	NF		30	15	Refined equipment time to reflect typical use exclusive to patient
		ED031	printer, dye sublimation (photo, color)	NF		30	15	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EF018	stretcher	NF		30	15	Refined equipment time to reflect typical use exclusive to patient
		EL018	room, mobile c-ARM	NF		30	15	Refined equipment time to reflect typical use exclusive to patient
		EQ211	pulse oximeter w-printer	NF		30	15	Refined equipment time to reflect typical use exclusive to patient
		EQ214	radiofrequency generator (NEURO)	NF		30	15	Refined equipment time to reflect typical use exclusive to patient
		ER029	film alternator (motorized film viewbox)	NF		30	15	Refined equipment time to reflect typical use exclusive to patient
		ER067	x-ray view box, 4 panel	NF		30	15	Refined equipment time to reflect typical use exclusive to patient
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	30	15	Conforming to physician time
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	30	15	Conforming to physician time
70470	Ct head/brain w/o & w/dye	EL007	room, CT	NF		42	30	Refined equipment time to reflect typical use exclusive to patient
72100	X-ray exam of lower spine	ED025	film processor, wet	NF		17	4	Refined equipment time to reflect typical use exclusive to patient
		EL012	room, basic radiology	NF		17	13	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		ER029	film alternator (motorized film viewbox)	NF		0	4	Missing time
		ED025	film processor, wet	NF		28	6	Refined equipment time to reflect typical use exclusive to patient
		EL012	room, basic radiology	NF		25	19	Refined equipment time to reflect typical use exclusive to patient
		ER029	film alternator (motorized film viewbox)	NF		0	6	Missing time
72114	X-ray exam of lower spine	ED025	film processor, wet	NF		36	8	Refined equipment time to reflect typical use exclusive to patient
		EL012	room, basic radiology	NF		33	25	Refined equipment time to reflect typical use exclusive to patient
		ER029	film alternator (motorized film viewbox)	NF		0	8	Missing time
72120	X-ray exam of lower spine	ED025	film processor, wet	NF		22	4	Refined equipment time to reflect typical use exclusive to patient
		EL012	room, basic radiology	NF		19	15	Refined equipment time to reflect typical use exclusive to patient
		ER029	film alternator (motorized film viewbox)	NF		0	4	Missing time
		EL012	room, basic radiology	NF		12	10	Refined equipment time to reflect typical use exclusive to patient
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	2	1	CMS clinical review

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L041B	Radiologic Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	1	2	Standardized time input
		L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	1	2	Standardized time input
72170	X-ray exam of lower spine	EL012	room, basic radiology	NF		12	10	Refined equipment time to reflect typical use exclusive to patient
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	2	1	CMS clinical review
		L041B	Radiologic Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	1	2	Standardized time input
		L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	1	2	Standardized time input
72191	Ct angiograph pelv w/o&w/dye	ED014	computer workstation, 3D reconstruction CT-MR	NF		0	15	Refined equipment time to reflect typical use exclusive to patient
		ED024	film processor, dry, laser	NF		10	15	Refined equipment time to reflect typical use exclusive to patient
		ED032	printer, laser, paper	NF		0	10	Refined equipment time to reflect typical use exclusive to patient
		EL007	room, CT	NF		55	40	Refined equipment time to reflect typical use exclusive to patient
		ER029	film alternator (motorized film viewbox)	NF		0	15	Refined equipment time to reflect typical use exclusive to patient
		L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	0	4	CMS clinical review
		L041B	Radiologic Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	0	5	CMS clinical review
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	0	33	Conforming to physician time

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	0	3	Standardized time input
		L041B	Radiologic Technologist	NF	Other Clinical Activity (please specify)	0	15	CMS clinical review
		SA019	kit, iv starter	NF		0	1	Changed quantity to reflect typical use
		SB014	drape, sterile, three-quarter sheet	NF		0	1	Changed quantity to reflect typical use
		SB022	gloves, non-sterile	NF		0	1	Changed quantity to reflect typical use
		SB024	gloves, sterile	NF		1	0	Changed quantity to reflect typical use
		SB036	paper, exam table	NF		0	7	Changed quantity to reflect typical use
		SC001	angiocatheter 14g-24g	NF		1	0	Changed quantity to reflect typical use
		SC002	angiocatheter set	NF		0	1	Changed quantity to reflect typical use
		SC012	heparin lock	NF		0	1	Changed quantity to reflect typical use
		SC019	iv tubing (extension)	NF		1	3	Changed quantity to reflect typical use
		SD212	tubing, sterile, connecting (fluid administration)	NF		0	1	Changed quantity to reflect typical use
		SG050	gauze, non-sterile 2in x 2in	NF		0	1	Changed quantity to reflect typical use
		SG053	gauze, sterile 2in x 2in	NF		0	1	Changed quantity to reflect typical use
		SG075	tape, elastic, 1in (Elastoplast, Elasticon) (5yd uou)	NF		0	6	Changed quantity to reflect typical use

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		SG079	tape, surgical paper 1in (Micropore)	NF		6	0	Changed quantity to reflect typical use
		SH065	sodium chloride 0.9% flush syringe	NF		0	15	Changed quantity to reflect typical use
		SH068	sodium chloride 0.9% inj bacteriostatic (30ml uou)	NF		0.34	0	Changed quantity to reflect typical use
		SJ043	povidone swabsticks (3 pack uou)	NF		0	0	Changed quantity to reflect typical use
		SK016	computer media, optical disk 2.6gb	NF		0	0	Changed quantity to reflect typical use
		SK034	film, x-ray 14in x 17in	NF		12	8	Changed quantity to reflect typical use
		SK089	x-ray developer solution	NF		0	8	Changed quantity to reflect typical use
		SK091	x-ray envelope	NF		1	0	Changed quantity to reflect typical use
		SK092	x-ray fixer solution	NF		0	8	Changed quantity to reflect typical use
		SK098	film, x-ray, laser print	NF		0	11	Changed quantity to reflect typical use
73030	X-ray exam of shoulder	EL012	room, basic radiology	NF		14	11	Refined equipment time to reflect typical use exclusive to patient
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	2	3	Standardized time input
		L041B	Radiologic Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	1	2	Standardized time input
		L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	1	2	Standardized time input
73620	X-ray exam of foot	EL012	room, basic radiology	NF		14	11	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	2	3	Standardized time input
		L041B	Radiologic Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	1	2	Standardized time input
		L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	1	2	Standardized time input
74174	Ct angio abd&pelv w/o&w/dye	73405	film jacket	NF		1	0	Non-standard direct practice expense input
		ED014	computer workstation, 3D reconstruction CT-MR	NF		38	20	Refined equipment time to reflect typical use exclusive to patient
		ED024	film processor, dry, laser	NF		82	20	Refined equipment time to reflect typical use exclusive to patient
		EL007	room, CT	NF		82	57	Refined equipment time to reflect typical use exclusive to patient
		ER029	film alternator (motorized film viewbox)	NF		82	20	Refined equipment time to reflect typical use exclusive to patient
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	0	33	CMS Code correction
		L041B	Radiologic Technologist	NF	Other Clinical Activity (please specify)	0	20	CMS Code correction
		L041B	Radiologic Technologist	NF	Provide pre-service education/obtain consent	3	2	Standardized time input
		L046A	CT Technologist	NF	Assist physician in performing procedure	33	0	Incorrect CMS Code
		L046A	CT Technologist	NF	Other Clinical Activity (please specify)	25	0	Incorrect CMS Code
		SC019	iv tubing (extension)	NF		1	3	Changed quantity to reflect typical use
		SC025	needle, 14-20g, biopsy	NF		1	0	Changed quantity to reflect typical use

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		SC029	needle, 18-27g	NF		0	1	Changed quantity to reflect typical use
		SC050	stop cock, 4-way	NF		0	1	Changed quantity to reflect typical use
		SC053	syringe 20ml	NF		1	0	Changed quantity to reflect typical use
		SC060	syringe, pressure (radiology)	NF		0	1	Changed quantity to reflect typical use
		SD212	tubing, sterile, connecting (fluid administration)	NF		0	1	Changed quantity to reflect typical use
		SD260	Y-set connection tubing	NF		1	0	Changed quantity to reflect typical use
74175	Ct angio abdom w/o & w/dye	ED014	computer workstation, 3D reconstruction CT-MR	NF		0	15	Refined equipment time to reflect typical use exclusive to patient
		ED024	film processor, dry, laser	NF		10	15	Refined equipment time to reflect typical use exclusive to patient
		ED032	printer, laser, paper	NF		0	10	Refined equipment time to reflect typical use exclusive to patient
		EL007	room, CT	NF		61	40	Refined equipment time to reflect typical use exclusive to patient
		ER029	film alternator (motorized film viewbox)	NF		0	15	Refined equipment time to reflect typical use exclusive to patient
		L046A	CT Technologist	NF	Prepare room, equipment, supplies	5	4	CMS clinical review
		L046A	CT Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	12	5	CMS clinical review

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L046A	CT Technologist	NF	Assist physician in performing procedure	57	33	Conforming to physician time
		L046A	CT Technologist	NF	Clean room/equipment by physician staff	5	3	Standardized time input
		L046A	CT Technologist	NF	Other Clinical Activity (please specify)	5	15	CMS clinical review
		SA019	kit, iv starter	NF		0	1	Changed quantity to reflect typical use
		SB014	drape, sterile, three-quarter sheet	NF		0	1	Changed quantity to reflect typical use
		SB022	gloves, non-sterile	NF		0	1	Changed quantity to reflect typical use
		SB024	gloves, sterile	NF		1	0	Changed quantity to reflect typical use
		SB036	paper, exam table	NF		0	7	Changed quantity to reflect typical use
		SC001	angiocatheter 14g-24g	NF		1	0	Changed quantity to reflect typical use
		SC002	angiocatheter set	NF		0	1	Changed quantity to reflect typical use
		SC012	heparin lock	NF		0	1	Changed quantity to reflect typical use
		SC019	iv tubing (extension)	NF		1	3	Changed quantity to reflect typical use
		SD212	tubing, sterile, connecting (fluid administration)	NF		0	1	Changed quantity to reflect typical use
		SG050	gauze, non-sterile 2in x 2in	NF		0	1	Changed quantity to reflect typical use
		SG053	gauze, sterile 2in x 2in	NF		0	1	Changed quantity to reflect typical use

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		SG075	tape, elastic, 1in (Elastoplast, Elasticon) (5yd uou)	NF		0	6	Changed quantity to reflect typical use
		SG079	tape, surgical paper 1in (Micropore)	NF		6	0	Changed quantity to reflect typical use
		SH065	sodium chloride 0.9% flush syringe	NF		0	15	Changed quantity to reflect typical use
		SH068	sodium chloride 0.9% inj bacteriostatic (30ml uou)	NF		0.34	0	Changed quantity to reflect typical use
		SJ043	povidone swabsticks (3 pack uou)	NF		0	0	Changed quantity to reflect typical use
		SK016	computer media, optical disk 2.6gb	NF		0	0	Changed quantity to reflect typical use
		SK034	film, x-ray 14in x 17in	NF		12	8	Changed quantity to reflect typical use
		SK089	x-ray developer solution	NF		0	8	Changed quantity to reflect typical use
		SK091	x-ray envelope	NF		1	0	Changed quantity to reflect typical use
		SK092	x-ray fixer solution	NF		0	8	Changed quantity to reflect typical use
		SK098	film, x-ray, laser print	NF		0	11	Changed quantity to reflect typical use
77014	Ct scan for therapy guide	EL007	room, CT	NF		18	14	Refined equipment time to reflect typical use exclusive to patient
		ER029	film alternator (motorized film viewbox)	NF		4	4	CMS Code correction
		SK091	x-ray envelope	NF		1	1	CMS Code correction

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
78226	Hepatobiliary system imaging	ER032	gamma camera system, single-dual head	NF		85	75	Refined equipment time to reflect typical use exclusive to patient
		L049A	Nuclear Medicine Technologist	NF	Instruction/Counseling as patient is taken back to waiting area after each scanning session	3	0	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	5	2	Standardized time input
		L049A	Nuclear Medicine Technologist	NF	Prepare room, equipment, supplies	3	4	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Provide pre-service education/obtain consent	3	4	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Regulatory compliance - NRC required wipe tests and survey areas used including regulatory documentation.	5	3	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Specific room clean up of RP injection areas with defacement of labels	5	4	CMS clinical review
78227	Hepatobil syst image w/drug	ER032	gamma camera system, single-dual head	NF		117	107	Refined equipment time to reflect typical use exclusive to patient
		L049A	Nuclear Medicine Technologist	NF	Instruction/Counseling as patient is taken back to waiting area after each scanning session	3	0	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	7	2	Standardized time input
		L049A	Nuclear Medicine Technologist	NF	Prepare room, equipment, supplies	3	4	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Provide pre-service education/obtain consent	3	4	CMS clinical review

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L049A	Nuclear Medicine Technologist	NF	Regulatory compliance - NRC required wipe tests and survey areas used including regulatory documentation.	5	3	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Specific room clean up of RP injection areas with defacement of labels	5	4	CMS clinical review
78579	Lung ventilation imaging	ER032	gamma camera system, single-dual head	NF		38	35	Refined equipment time to reflect typical use exclusive to patient
		L049A	Nuclear Medicine Technologist	NF	Instruction/Counseling as patient is taken back to waiting area after each scanning session	3	0	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	5	2	Standardized time input
		L049A	Nuclear Medicine Technologist	NF	Prepare room, equipment, supplies	3	2	Standardized time input
		L049A	Nuclear Medicine Technologist	NF	Regulatory compliance - NRC required wipe tests and survey areas used including regulatory documentation.	5	3	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Specific room clean up of RP injection areas with defacement of labels	5	4	CMS clinical review
78580	Lung perfusion imaging	ER032	gamma camera system, single-dual head	NF		48	45	Refined equipment time to reflect typical use exclusive to patient
		L049A	Nuclear Medicine Technologist	NF	Instruction/Counseling as patient is taken back to waiting area after each scanning session	3	0	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	5	2	Standardized time input

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L049A	Nuclear Medicine Technologist	NF	Prepare room, equipment, supplies	3	2	Standardized time input
		L049A	Nuclear Medicine Technologist	NF	Regulatory compliance - NRC required wipe tests and survey areas used including regulatory documentation.	5	3	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Specific room clean up of RP injection areas with defacement of labels	5	4	CMS clinical review
78582	Lung ventilat&perfus imaging	ER032	gamma camera system, single-dual head	NF		71	68	Refined equipment time to reflect typical use exclusive to patient
		L049A	Nuclear Medicine Technologist	NF	Instruction/Counseling as patient is taken back to waiting area after each scanning session	3	0	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	7	2	Standardized time input
		L049A	Nuclear Medicine Technologist	NF	Prepare room, equipment, supplies	3	2	Standardized time input
		L049A	Nuclear Medicine Technologist	NF	Regulatory compliance - NRC required wipe tests and survey areas used including regulatory documentation.	5	3	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Specific room clean up of RP injection areas with defacement of labels	5	4	CMS clinical review
78597	Lung perfusion differential	ER032	gamma camera system, single-dual head	NF		38	35	Refined equipment time to reflect typical use exclusive to patient
		L049A	Nuclear Medicine Technologist	NF	Instruction/Counseling as patient is taken back to waiting area after each scanning session	3	0	CMS clinical review

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L049A	Nuclear Medicine Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	5	2	Standardized time input
		L049A	Nuclear Medicine Technologist	NF	Prepare room, equipment, supplies	3	2	Standardized time input
		L049A	Nuclear Medicine Technologist	NF	Regulatory compliance - NRC required wipe tests and survey areas used including regulatory documentation.	5	3	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Specific room clean up of RP injection areas with defacement of labels	5	4	CMS clinical review
78598	Lung perf&ventila t diferentl	ER032	gamma camera system, single-dual head	NF		68	62	Refined equipment time to reflect typical use exclusive to patient
		L049A	Nuclear Medicine Technologist	NF	Instruction/Coun seling as patient is taken back to waiting area after each scanning session	3	0	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	7	2	Standardized time input
		L049A	Nuclear Medicine Technologist	NF	Prepare room, equipment, supplies	3	2	Standardized time input
		L049A	Nuclear Medicine Technologist	NF	Regulatory compliance - NRC required wipe tests and survey areas used including regulatory documentation.	5	3	CMS clinical review
		L049A	Nuclear Medicine Technologist	NF	Specific room clean up of RP injection areas with defacement of labels	5	4	CMS clinical review
90867	Tcranial magn stim tx plan	EQ342	NeuroStar TMS Therapy System	NF		104	94	Refined equipment time to reflect typical use exclusive to patient
		L037D	RN/LPN/MT A	NF	Assist physician in performing procedure	99	60	Conforming to physician time

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L037D	RN/LPN/MTA	NF	Prepare and position patient/ monitor patient/ set up IV	0	15	Missing time
90868	Tcranial magn stim tx deli	EQ342	NeuroStar TMS Therapy System	NF		47	37	Refined equipment time to reflect typical use exclusive to patient
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	42	10	Conforming to physician time
		L037D	RN/LPN/MTA	NF	Prepare and position patient/ monitor patient/ set up IV	0	15	Missing time
90869	Tcran magn stim redetemine	EQ342	NeuroStar TMS Therapy System	NF		82	72	Refined equipment time to reflect typical use exclusive to patient
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	77	45	Conforming to physician time
		L037D	RN/LPN/MTA	NF	Prepare and position patient/ monitor patient/ set up IV	0	15	Missing time
92071	Contact lens fitting for tx	EL006	lane, screening (oph)	NF		15	11	Refined equipment time to reflect typical use exclusive to patient
92588	Evoked auditory tst complete	EF008	chair with headrest, exam, reclining	NF		25	16.5	Refined equipment time to reflect typical use exclusive to patient
		EQ034	OAE-otoacoustic emission system	NF		25	16.5	Refined equipment time to reflect typical use exclusive to patient
		EQ054	audiometric soundproof booth (exam and control rooms)	NF		25	16.5	Refined equipment time to reflect typical use exclusive to patient
93971	Evoked auditory tst complete	ED021	computer, desktop, w-monitor	NF		48	38	Refined equipment time to reflect typical use exclusive to patient

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		ED034	video SVHS VCR (medical grade)	NF		48	38	Refined equipment time to reflect typical use exclusive to patient
		EF018	stretcher	NF		48	38	Refined equipment time to reflect typical use exclusive to patient
		EL016	room, ultrasound, vascular	NF		48	38	Refined equipment time to reflect typical use exclusive to patient
94726	Pulm funct tst plethysmograp	EQ039	Vmax 229 (PFT equip, computer system)	NF		50	47	Refined equipment time to reflect typical use exclusive to patient
		EQ211	pulse oximeter w-printer	NF		0	47	Missing time
94727	Pulm function test by gas	EQ039	Vmax 229 (PFT equip, computer system)	NF		35	32	Refined equipment time to reflect typical use exclusive to patient
		EQ211	pulse oximeter w-printer	NF		35	32	Refined equipment time to reflect typical use exclusive to patient
94728	Pulm funct test oscillometry	EQ044	Vmax 62j (body plethysmograph autobox)	NF		0	31	Missing time
		EQ341	Oscillometry	NF		34	31	Refined equipment time to reflect typical use exclusive to patient
94729	C02/membane diffuse capacity	EQ211	pulse oximeter w-printer	NF		0	30	Missing time
94781	Car seat/bed test + 30 min	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		0	30	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
95885	Musc tst done w/nerv tst lim	EF023	table, exam	NF		21	15	Refined equipment time to reflect typical use exclusive to patient
		EQ024	EMG-NCV-EP system, 8 channel	NF		21	15	Refined equipment time to reflect typical use exclusive to patient
		L037A	Electrodiagnostic Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	2	0	Add-on code - Time is accounted for in base code
		L037A	Electrodiagnostic Technologist	NF	Prepare room, equipment, supplies	1	0	Add-on code - Time is accounted for in base code
		L037A	Electrodiagnostic Technologist	NF	Prepare skin - clean each insertion site with alcohol	1	0	Add-on code - Time is accounted for in base code
		L037A	Electrodiagnostic Technologist	NF	Set up machine	1	0	Add-on code - Time is accounted for in base code
95886	Musc test done w/n test comp	EF023	table, exam	NF		36	30	Refined equipment time to reflect typical use exclusive to patient
		EQ130	hydrocollator, hot	NF		36	30	Refined equipment time to reflect typical use exclusive to patient
		L037A	Electrodiagnostic Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	2	0	Add-on code - Time is accounted for in base code
		L037A	Electrodiagnostic Technologist	NF	Prepare room, equipment, supplies	1	0	Add-on code - Time is accounted for in base code
		L037A	Electrodiagnostic Technologist	NF	Prepare skin - clean each insertion site with alcohol	1	0	Add-on code - Time is accounted for in base code
		L037A	Electrodiagnostic Technologist	NF	Set up machine	1	0	Add-on code - Time is accounted for in base code
95887	Musc tst done w/n tst nonext	EF023	table, exam	NF		26	20	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EQ024	EMG-NCV-EP system, 8 channel	NF		26	20	Refined equipment time to reflect typical use exclusive to patient
		L037A	Electrodiagnostic Technologist	NF	Prepare and position patient/ monitor patient/ set up IV	2	0	Add-on code - Time is accounted for in base code
		L037A	Electrodiagnostic Technologist	NF	Prepare room, equipment, supplies	1	0	Add-on code - Time is accounted for in base code
		L037A	Electrodiagnostic Technologist	NF	Prepare skin - clean each insertion site with alcohol	1	0	Add-on code - Time is accounted for in base code
		L037A	Electrodiagnostic Technologist	NF	Set up machine	1	0	Add-on code - Time is accounted for in base code
95925	Somatosensory testing	EF023	table, exam	NF		92	76	Refined equipment time to reflect typical use exclusive to patient
		EQ024	EMG-NCV-EP system, 8 channel	NF		92	76	Refined equipment time to reflect typical use exclusive to patient
		EQ047	air compressor, safety	NF		92	76	Refined equipment time to reflect typical use exclusive to patient
		L047B	REEGT	NF	Complete pre-service diagnostic & referral forms	2	0	CMS clinical review
		L047B	REEGT	NF	Coordinate pre-surgery services	2	0	CMS clinical review
		L047B	REEGT	NF	Provide pre-service education/obtain consent	7	0	CMS clinical review
		L047B	REEGT	NF	Follow-up phone calls & prescriptions	3	0	CMS clinical review
		L047B	REEGT	NF	Review requisition. Assess for special needs	0	5	CMS clinical review

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L047B	REEGT	NF	Give patient instruction for test preparation (e.g. hair lotion) and what to expect on the day of testing	0	3	CMS clinical review
		L047B	REEGT	NF	Greet patient, provide gowning, assure appropriate medical records are available	6	3	CMS clinical review
		L047B	REEGT	NF	Obtain vital signs	3	0	CMS clinical review
		L047B	REEGT	NF	Prepare room, equipment, supplies	5	2	CMS clinical review
		L047B	REEGT	NF	Prepare and position patient/ monitor patient/ set up IV	2	0	CMS clinical review
		L047B	REEGT	NF	Measure and mak head and peripheral locations for electrode. Aplly and secure electrodes	12	6	CMS clinical review
		L047B	REEGT	NF	Check impedances, reapply as necessary	0	4	CMS clinical review
		L047B	REEGT	NF	Sedate/apply anesthesia	2	0	CMS clinical review
		L047B	REEGT	NF	Assist physician in performing procedure	45	42	Conforming to physician time
		L047B	REEGT	NF	Complete worksheets	0	3	CMS clinical review
		L047B	REEGT	NF	Remove electrodes and cleanup patient	4	5	CMS clinical review
		L047B	REEGT	NF	Release patient and give discharge instructions	0	3	CMS clinical review
		L047B	REEGT	NF	Monitor pt. following service/check tubes, monitors, drains	5	0	CMS clinical review
		L047B	REEGT	NF	Clean room/equipment by physician staff	5	3	CMS clinical review
		L047B	REEGT	NF	Complete medical record, and archive data	0	5	CMS clinical review
		L047B	REEGT	NF	Review/read X-ray, lab, and pathology reports	3	0	CMS clinical review

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		SD165	electrode, EEG (single)	NF		0	8	Changed quantity to reflect typical use
		SD166	electrode, EGG (single)	NF		4	0	Changed quantity to reflect typical use
95926	Somatosensory testing	EF023	table, exam	NF		92	76	Refined equipment time to reflect typical use exclusive to patient
		EQ024	EMG-NCV-EP system, 8 channel	NF		92	76	Refined equipment time to reflect typical use exclusive to patient
		EQ047	air compressor, safety	NF		92	76	Refined equipment time to reflect typical use exclusive to patient
		L047B	REEGT	NF	Complete pre-service diagnostic & referral forms	2	0	CMS clinical review
		L047B	REEGT	NF	Coordinate pre-surgery services	2	0	CMS clinical review
		L047B	REEGT	NF	Provide pre-service education/obtain consent	7	0	CMS clinical review
		L047B	REEGT	NF	Follow-up phone calls & prescriptions	3	0	CMS clinical review
		L047B	REEGT	NF	Review requisition. Assess for special needs	0	5	CMS clinical review
		L047B	REEGT	NF	Give patient instruction for test preparation (e.g. hair lotion) and what to expect on the day of testing	0	3	CMS clinical review
		L047B	REEGT	NF	Greet patient, provide gowning, assure appropriate medical records are available	6	3	CMS clinical review
		L047B	REEGT	NF	Obtain vital signs	3	0	CMS clinical review
		L047B	REEGT	NF	Prepare room, equipment, supplies	5	2	CMS clinical review

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L047B	REEGT	NF	Prepare and position patient/ monitor patient/ set up IV	2	0	CMS clinical review
		L047B	REEGT	NF	Measure and mak head and peripheral locations for electrode. Aplly and secure electrodes	12	6	CMS clinical review
		L047B	REEGT	NF	Check impedances, reapply as necessary	0	4	CMS clinical review
		L047B	REEGT	NF	Sedate/apply anesthesia	2	0	CMS clinical review
		L047B	REEGT	NF	Assist physician in performing procedure	45	42	Conforming to physician time
		L047B	REEGT	NF	Complete worksheets	0	3	CMS clinical review
		L047B	REEGT	NF	Remove electrodes and cleanup patient	4	5	CMS clinical review
		L047B	REEGT	NF	Release patient and give discharge instructions	0	3	CMS clinical review
		L047B	REEGT	NF	Monitor pt. following service/check tubes, monitors, drains	5	0	CMS clinical review
		L047B	REEGT	NF	Clean room/equipment by physician staff	5	3	CMS clinical review
		L047B	REEGT	NF	Complete medical record, and archive data	0	5	CMS clinical review
		L047B	REEGT	NF	Review/read X-ray, lab, and pathology reports	3	0	CMS clinical review
		SD165	electrode, EEG (single)	NF		0	8	Changed quantity to reflect typical use
		SD166	electrode, EGG (single)	NF		4	0	Changed quantity to reflect typical use
95928	C motor evoked uppr limbs	ED032	printer, laser, paper	NF		60	10	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EF008	chair with headrest, exam, reclining	NF		105	0	Refined equipment time to reflect typical use exclusive to patient
		EF023	table, exam	NF		0	84.5	Refined equipment time to reflect typical use exclusive to patient
		EQ024	EMG-NCV-EP system, 8 channel	NF		105	84.5	Refined equipment time to reflect typical use exclusive to patient
		EQ178	magnetic stimulator hand coil (70-90mm)	NF		105	84.5	Refined equipment time to reflect typical use exclusive to patient
		EQ180	magnetic stimulator system (BiStim)	NF		105	84.5	Refined equipment time to reflect typical use exclusive to patient
		L047B	REEGT	NF	Complete pre-service diagnostic & referral forms	2	0	CMS clinical review
		L047B	REEGT	NF	Coordinate pre-surgery services	2	0	CMS clinical review
		L047B	REEGT	NF	Provide pre-service education/obtain consent	7	0	CMS clinical review
		L047B	REEGT	NF	Follow-up phone calls & prescriptions	3	0	CMS clinical review
		L047B	REEGT	NF	Review requisition. Assess for special needs	0	5	CMS clinical review
		L047B	REEGT	NF	Give patient instruction for test preparation (e.g. hair lotion) and what to expect on the day of testing	0	3	CMS clinical review
		L047B	REEGT	NF	Greet patient, provide gowning, assure appropriate medical records are available	6	3	CMS clinical review
		L047B	REEGT	NF	Obtain vital signs	3	0	CMS clinical review

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L047B	REEGT	NF	Prepare and position patient/ monitor patient/ set up IV	2	0	CMS clinical review
		L047B	REEGT	NF	Measure and mak head and peripheral locations for electrode. Aplly and secure electrodes	12	6	CMS clinical review
		L047B	REEGT	NF	Initiate baseline nerve conduction study	8	0	CMS clinical review
		L047B	REEGT	NF	Assist physician in performing procedure	60	54.5	Conforming to physician time
		L047B	REEGT	NF	Complete worksheets	0	3	CMS clinical review
		L047B	REEGT	NF	Remove electrodes and cleanup patient	4	5	CMS clinical review
		L047B	REEGT	NF	Release patient and give discharge instructions	0	3	CMS clinical review
		L047B	REEGT	NF	Monitor pt. following service/check tubes, monitors, drains	5	0	CMS clinical review
		L047B	REEGT	NF	Complete medical record, and archive data	0	5	CMS clinical review
		SD062	electrode, surface	NF		8	0	Changed quantity to reflect typical use
		SD165	electrode, EEG (single)	NF		0	12	Changed quantity to reflect typical use
		SG051	gauze, non-sterile 4in x 4in	NF		1	0	Changed quantity to reflect typical use
		SG056	gauze, sterile 4in x 4in (10 pack uou)	NF		0	1	Changed quantity to reflect typical use
		SK057	paper, laser printing (each sheet)	NF		15	0	Changed quantity to reflect typical use
		SK059	paper, recording (per sheet)	NF		0	6	Changed quantity to reflect typical use
		SL001	acetone	NF		0	15	Changed quantity to reflect typical use

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		SM018	glutaraldehyde 3.4% (Cidex, Maxicide, Wavicide)	NF		0	0.34	Changed quantity to reflect typical use
95929	C motor evoked lwr limbs	ED032	printer, laser, paper	NF		55	10	Refined equipment time to reflect typical use exclusive to patient
		EF008	chair with headrest, exam, reclining	NF		115	0	Refined equipment time to reflect typical use exclusive to patient
		EF023	table, exam	NF		0	84.5	Refined equipment time to reflect typical use exclusive to patient
		EQ024	EMG-NCV-EP system, 8 channel	NF		105	84.5	Refined equipment time to reflect typical use exclusive to patient
		EQ178	magnetic stimulator hand coil (70-90mm)	NF		105	84.5	Refined equipment time to reflect typical use exclusive to patient
		EQ179	magnetic stimulator leg coil (110mm)	NF		105	84.5	Refined equipment time to reflect typical use exclusive to patient
		EQ180	magnetic stimulator system (BiStim)	NF		105	84.5	Refined equipment time to reflect typical use exclusive to patient
		L047B	REEGT	NF	Complete pre-service diagnostic & referral forms	2	0	CMS clinical review
		L047B	REEGT	NF	Coordinate pre-surgery services	2	0	CMS clinical review
		L047B	REEGT	NF	Provide pre-service education/obtain consent	7	0	CMS clinical review
		L047B	REEGT	NF	Follow-up phone calls & prescriptions	3	0	CMS clinical review
		L047B	REEGT	NF	Review requisition. Assess for special needs	0	5	CMS clinical review

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		L047B	REEGT	NF	Give patient instruction for test preparation (e.g. hair lotion) and what to expect on the day of testing	0	3	CMS clinical review
		L047B	REEGT	NF	Greet patient, provide gowning, assure appropriate medical records are available	6	3	CMS clinical review
		L047B	REEGT	NF	Obtain vital signs	3	0	CMS clinical review
		L047B	REEGT	NF	Prepare and position patient/ monitor patient/ set up IV	2	0	CMS clinical review
		L047B	REEGT	NF	Measure and mak head and peripheral locations for electrode. Aplly and secure electrodes	12	6	CMS clinical review
		L047B	REEGT	NF	Initiate baseline nerve conduction study	23	0	CMS clinical review
		L047B	REEGT	NF	Assist physician in performing procedure	55	54.5	Conforming to physician time
		L047B	REEGT	NF	Complete worksheets	0	3	CMS clinical review
		L047B	REEGT	NF	Remove electrodes and cleanup patient	4	5	CMS clinical review
		L047B	REEGT	NF	Release patient and give discharge instructions	0	3	CMS clinical review
		L047B	REEGT	NF	Monitor pt. following service/check tubes, monitors, drains	5	0	CMS clinical review
		L047B	REEGT	NF	Complete medical record, and archive data	0	5	CMS clinical review
		SD062	electrode, surface	NF		8	0	Changed quantity to reflect typical use
		SD165	electrode, EEG (single)	NF		0	12	Changed quantity to reflect typical use
		SG051	gauze, non-sterile 4in x 4in	NF		1	0	Changed quantity to reflect typical use

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		SG056	gauze, sterile 4in x 4in (10 pack uou)	NF		0	1	Changed quantity to reflect typical use
		SK057	paper, laser printing (each sheet)	NF		15	0	Changed quantity to reflect typical use
		SK059	paper, recording (per sheet)	NF		0	6	Changed quantity to reflect typical use
		SL001	acetone	NF		0	15	Changed quantity to reflect typical use
		SM018	glutaraldehyde 3.4% (Cidex, Maxicide, Wavicide)	NF		0	0.34	Changed quantity to reflect typical use
95938	Somatosensory testing	EF023	table, exam	NF		1	129	Refined equipment time to reflect typical use exclusive to patient
		EQ024	EMG-NCV-EP system, 8 channel	NF		1	129	Refined equipment time to reflect typical use exclusive to patient
		EQ047	air compressor, safety	NF		1	129	Refined equipment time to reflect typical use exclusive to patient
95939	C motor evoked upr&lwr limbs	ED032	printer, laser, paper	NF		0	10	Missing time
		SJ020	electrode conductive gel	NF		0	2	Missing quantity
		SL001	acetone	NF		0	15	Missing quantity
96413	Chemo iv infusion 1 hr	EF009	chair, medical recliner	NF		83	87	Refined equipment time to reflect typical use exclusive to patient
		EP016	hood, biohazard	NF		22	20	Refined equipment time to reflect typical use exclusive to patient

CPT Code	CPT Code Description	CMS Code	CMS Code Description	NonFac / Fac	Labor Activity (if applicable)	RUC Recommendation (min or qty)	CMS Refinement (min or qty)	Comment
		EQ032	IV infusion pump	NF		83	87	Refined equipment time to reflect typical use exclusive to patient
		L056A	RN/OCN	NF	Complete pre-service diagnostic & referral forms	3	0	Standardized time input
		L056A	RN/OCN	NF	Coordinate pre-surgery services	3	0	Standardized time input
96416	Chemo prolong infuse w/pump	EF009	chair, medical recliner	NF		100	72	Refined equipment time to reflect typical use exclusive to patient
		EP016	hood, biohazard	NF		31	28	Refined equipment time to reflect typical use exclusive to patient
		L056A	RN/OCN	NF	Assist physician in performing procedure	19	6	Conforming to physician time
		L056A	RN/OCN	NF	Monitor pt. following service/check tubes, monitors, drains	5	0	CMS clinical review
		L056A	RN/OCN	NF	Review charts by chemo nurse regarding course of treatment & obtain chemotherapy-related medical hx	4	0	CMS clinical review

3. Establishing Interim Final Malpractice RVUs for CY 2012

According to our malpractice methodology discussed in section II.C.1. of this final rule with comment period, we have assigned malpractice RVUs for CY 2012 new and revised codes by utilizing a crosswalk to a source code with a similar malpractice risk-of-service. We have reviewed the AMA RUC-recommended malpractice source code crosswalks for CY 2012 new and revised codes, and we are accepting nearly all of them on an interim final basis for CY 2012. For four CPT codes describing multi-layer compression systems, we are assigning a source code crosswalk different from the source code crosswalks recommended by the AMA RUC and HCPAC.

For CPT codes 29582 (Application of multi-layer venous wound compression system, below knee; thigh and leg, including ankle and foot, when performed), 29583 (Application of multi-layer venous wound compression system, below knee; upper arm and forearm), and 29584 (Application of multi-layer venous wound compression system, below knee; upper arm, forearm, hand, and fingers), the AMA RUC recommended a malpractice source code crosswalk to CPT code 29540 (Strapping; ankle and/or foot). For CPT codes 29582 and 29584 the HCPAC recommended a malpractice source code crosswalk to CPT code 97124 (Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)), and for CPT code 29583 the HCPAC recommended a malpractice source code crosswalk to CPT code 97762 (Checkout for orthotic/prosthetic use, established patient, each 15 minutes).

In addition to providing recommendations on malpractice source code crosswalks, the AMA RUC also provides recommendations to us on utilization crosswalks, which are largely used to estimate utilization shifts for budget neutrality. CPT codes 29582, 29583, and 29584 are new for CY 2012. The AMA RUC recommended, and we agreed, that the estimated utilization for CPT codes 29582, 29583, and 29584 would have previously been reported using CPT code 97140 (Manual therapy techniques (*e.g.,* mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes). After review, we believe that CPT code 97140 provides the most appropriate malpractice source code crosswalk for CPT codes 29582, 29583, and 29584. Therefore, we are assigning CPT code 97140 as the malpractice source code

crosswalk for CPT codes 29582, 29583, and 29584 on an interim basis for CY 2012.

As discussed in section III.B.1.b. of this final rule with comment period, for CY 2012 the CPT Editorial Panel revised the descriptor for CPT code 29581 (Application of multi-layer compression system; leg (below knee), including ankle and foot), and also created CPT codes 29582, 29583, and 29584 to describe the application of multi-layer compression to the upper and lower extremities. The CPT Editorial Panel and AMA RUC concluded that the revisions to the descriptor for CPT code 29581 were editorial only, and the specialty society believed that resurveying CPT code 29581 was not necessary. As such, the AMA RUC issued a recommendation of ''No Change'' to us for CPT code 29581. After clinical review, we believe that CPT codes 29581, 29582, 29583, and 29584 all describe similar services from a resource perspective. In line with this determination, we assigned CPT code 29581 the same interim work RVU as CPT code 29583. Because we find these services to be so similar, to we also believe that it is appropriate for CPT codes 29581 and 29583 to have the same malpractice source code crosswalk. Therefore, we are assigning CPT code 97140 as the malpractice source code crosswalk for CPT code 29581 on an interim basis for CY 2012. In section III.B.1.b. of this final rule with comment period, we requested that the layer compression systems family of services be surveyed together and that the AMA RUC and HCPAC review their recommendations to us for these services. For CY 2012 we are holding the work, practice expense, and malpractice values interim pending resurvey and review.

In addition to changes to the AMA RUC-recommended malpractice crosswalk mentioned previously, we also added HCPCS code G0451 to the malpractice crosswalk. As discussed in section III.B.1.b. of this final rule with comment period, for CY 2012 we created HCPCS code G0451 (Development testing, with interpretation and report, per standardized instrument form) to replace CPT code 96110 (Developmental screening, with interpretation and report, per standardized instrument form), as CPT code 96110 will be excluded from payment on the physician fee schedule effective January 1, 2012. We assigned CPT code 96110 as the malpractice source code crosswalk for HCPCS code G0451.

In accordance with our malpractice methodology, we have adjusted the malpractice RVUs of the CY 2012 new/revised codes for difference in work RVUs (or, if greater, the clinical labor portion of the fully implemented PE RVUs) between the source code and the new/revised code to reflect the specific risk-of-service for the new/revised codes. Table 22 lists the CY 2012 new/revised CPT codes and their respective source codes used to set the interim final CY 2012 malpractice RVUs. Revised CPT codes that are crosswalked to themselves (that is, CPT code 27096 to 27096) are not listed.

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TABLE 22: MALPRACTICE SOURCE CODES FOR CY 2012 NEW/REVISED CODES USED TO SET THE MALPRACTICE RVUs

New/ Revised HCPCS	Short Descriptor	Malpractice Source Code	Short Descriptor
15271	Skin sub graft trnk/arm/leg	16025	Dress/debrid p-thick burn m
15272	Skin sub graft t/a/l add-on	10160	Puncture drainage of lesion
15273	Skin sub grft t/arm/lg child	15002	Wound prep trk/arm/leg
15274	Skn sub grft t/a/l child add	10160	Puncture drainage of lesion
15275	Skin sub graft face/nk/hf/g	16025	Dress/debrid p-thick burn m
15276	Skin sub graft f/n/hf/g addl	10160	Puncture drainage of lesion
15277	Skn sub grft f/n/hf/g child	15004	Wound prep f/n/hf/g
15278	Skn sub grft f/n/hf/g ch add	10160	Puncture drainage of lesion
15777	Acellular derm matrix implt	49568	Hernia repair w/mesh
20527	Inj dupuytren cord w/enzyme	20526	Ther injection carp tunnel
22633	Lumbar spine fusion combined	22612	Lumbar spine fusion
22634	Spine fusion extra segment	22614	Spine fusion extra segment
26341	Manipulat palm cord post inj	20526	Ther injection carp tunnel
29581	Apply multlay comprs lwr leg	97140	Manual therapy
29582	Apply multlay comprs upr leg	97140	Manual therapy
29583	Apply multlay comprs upr arm	97140	Manual therapy
29584	Appl multlay comprs arm/hand	97140	Manual therapy
32096	Open wedge/bx lung infiltr	32151	Remove lung foreign body
32097	Open wedge/bx lung nodule	32151	Remove lung foreign body
32098	Open biopsy of lung pleura	32662	Thoracoscopy w/mediast exc
32100	Exploration of chest	32660	Thoracoscopy surgical
32505	Wedge resect of lung initial	32651	Thoracoscopy remove cortex
32506	Wedge resect of lung add-on	33517	Cabg artery-vein single
32507	Wedge resect of lung diag	33517	Cabg artery-vein single
32607	Thoracoscopy w/bx infiltrate	32601	Thoracoscopy diagnostic
32608	Thoracoscopy w/bx nodule	32605	Thoracoscopy diagnostic
32609	Thoracoscopy w/bx pleura	33572	Open coronary endarterectomy
32666	Thoracoscopy w/wedge resect	32662	Thoracoscopy w/mediast exc
32667	Thoracoscopy w/w resect addl	33517	Cabg artery-vein single
32668	Thoracoscopy w/w resect diag	33572	Open coronary endarterectomy
32669	Thoracoscopy remove segment	32663	Thoracoscopy w/lobectomy
32670	Thoracoscopy bilobectomy	32652	Thoracoscopy rem totl cortex
32671	Thoracoscopy pneumonectomy	32503	Resect apical lung tumor
32672	Thoracoscopy for lvrs	32141	Remove/treat lung lesions
32673	Thoracoscopy w/thymus resect	32665	Thoracoscop w/esoph musc exc
32674	Thoracoscopy lymph node exc	32501	Repair bronchus add-on
33221	Insert pulse gen mult leads	33223	Revise pocket for defib

New/ Revised HCPCS	Short Descriptor	Malpractice Source Code	Short Descriptor
33227	Remove&replace pm gen singl	33223	Revise pocket for defib
33228	Remv&replc pm gen dual lead	33223	Revise pocket for defib
33229	Remv&replc pm gen mult leads	33223	Revise pocket for defib
33230	Insrt pulse gen w/dual leads	33223	Revise pocket for defib
33231	Insrt pulse gen w/mult leads	33223	Revise pocket for defib
33240	Insrt pulse gen w/singl lead	33223	Revise pocket for defib
33262	Remv&replc cvd gen sing lead	33223	Revise pocket for defib
33263	Remv&replc cvd gen dual lead	33223	Revise pocket for defib
33264	Remv&replc cvd gen mult lead	33223	Revise pocket for defib
36251	Ins cath ren art 1st unilat	36245	Ins cath abd/l-ext art 1st
36252	Ins cath ren art 1st bilat	36245	Ins cath abd/l-ext art 1st
36253	Ins cath ren art 2nd+ unilat	36245	Ins cath abd/l-ext art 1st
36254	Ins cath ren art 2nd+ bilat	36245	Ins cath abd/l-ext art 1st
37191	Ins endovas vena cava filtr	37620	Revision of major vein
37192	Redo endovas vena cava filtr	37620	Revision of major vein
37193	Rem endovas vena cava filter	37620	Revision of major vein
37619	Ligation of inf vena cava	35082	Repair artery rupture aorta
38232	Bone marrow harvest autolog	38230	Bone marrow harvest allogen
49082	Abd paracentesis	49080	Puncture peritoneal cavity
49083	Abd paracentesis w/imaging	49080	Puncture peritoneal cavity
49084	Peritoneal lavage	49080	Puncture peritoneal cavity
62368	Analyze sp inf pump w/reprog	95991	Spin/brain pump refil & main
62369	Anal sp inf pmp w/reprg&fill	95991	Spin/brain pump refil & main
62370	Anl sp inf pmp w/mdreprg&fil	95991	Spin/brain pump refil & main
64633	Destroy cerv/thor facet jnt	64626	Destr paravertebrl nerve c/t
64634	Destroy c/th facet jnt addl	64627	Destr paravertebral n add-on
64635	Destroy lumb/sac facet jnt	64622	Destr paravertebrl nerve l/s
64636	Destroy l/s facet jnt addl	64623	Destr paravertebral n add-on
74174	Ct angio abd&pelv w/o&w/dye	74175	Ct angio abdom w/o & w/dye
77469	Io radiation tx management	41019	Place needles h&n for rt
78226	Hepatobiliary system imaging	78223	Hepatobiliary imaging
78227	Hepatobil syst image w/drug	78223	Hepatobiliary imaging
78579	Lung ventilation imaging	78593	Vent image 1 proj gas
78582	Lung ventilat&perfus imaging	78584	Lung V/Q image single breath
78597	Lung perfusion differential	78596	Lung differential function
78598	Lung perf&ventilat diferentl	78596	Lung differential function
90867	Tcranial magn stim tx plan	90870	Electroconvulsive therapy
90868	Tcranial magn stim tx deli	90870	Electroconvulsive therapy
90869	Tcran magn stim redetemine	90870	Electroconvulsive therapy
92071	Contact lens fitting for tx	92070	Fitting of contact lens

New/ Revised HCPCS	Short Descriptor	Malpractice Source Code	Short Descriptor
92072	Fit contac lens for managmnt	92070	Fitting of contact lens
92618	Ex for nonspeech dev rx add	92605	Ex for nonspeech device rx
94726	Pulm funct tst plethysmograp	93720	Total body plethysmography
94727	Pulm function test by gas	94240	Residual lung capacity
94728	Pulm funct test oscillometry	94375	Respiratory flow volume loop
94729	C02/membane diffuse capacity	94720	Monoxide diffusing capacity
94780	Car seat/bed test 60 min	99478	Ic lbw inf < 1500 gm subsq
94781	Car seat/bed test + 30 min	99478	Ic lbw inf < 1500 gm subsq
95885	Musc tst done w/nerv tst lim	95870	Muscle test nonparaspinal
95886	Musc test done w/n test comp	95860	Muscle test one limb
95887	Musc tst done w/n tst nonext	95860	Muscle test one limb
95938	Somatosensory testing	95929	C motor evoked lwr limbs
95939	C motor evoked upr&lwr limbs	95929	C motor evoked lwr limbs
G0451	Development test interpt & rep	96110	Developmental screen

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IV. Allowed Expenditures for Physicians' Services and the Sustainable Growth Rate

A. Medicare Sustainable Growth Rate (SGR)

The SGR is an annual growth rate that applies to physicians' services paid by Medicare. The use of the SGR is intended to control growth in aggregate Medicare expenditures for physicians' services. Payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted based on a comparison of allowed expenditures (determined using the SGR) and actual expenditures. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased.

Section 1848(f)(2) of the Act specifies that the SGR for a year (beginning with CY 2001) is equal to the product of the following four factors:

(1) The estimated change in fees for physicians' services;

(2) The estimated change in the average number of Medicare fee-for-service beneficiaries;

(3) The estimated projected growth in real GDP per capita; and

(4) The estimated change in expenditures due to changes in statute or regulations.

In general, section 1848(f)(3) of the Act requires us to publish SGRs for 3 different time periods, no later than November 1 of each year, using the best data available as of September 1 of each year. Under section 1848(f)(3)(C)(i) of the Act, the SGR is estimated and subsequently revised twice (beginning with the FY and CY 2000 SGRs) based on later data. (The Act also provides for adjustments to be made to the SGRs for FY 1998 and FY 1999. See the February 28, 2003 **Federal Register** (68 FR 9567) for a discussion of these SGRs). Under section 1848(f)(3)(C)(ii) of the Act, there are no further revisions to the SGR once it has been estimated and subsequently revised in each of the 2 years following the preliminary estimate. In this final rule with comment, we are making our preliminary estimate of the CY 2012 SGR, a revision to the CY 2011 SGR, and our final revision to the CY 2010 SGR.

1. Physicians' Services

Section 1848(f)(4)(A) of the Act defines the scope of physicians' services covered by the SGR. The statute indicates that ''the term physicians' services includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office, but does not include services furnished to a Medicare+Choice plan enrollee.''

We published a definition of physicians' services for use in the SGR in the November 1, 2001 **Federal Register** (66 FR 55316). We defined physicians' services to include many of the medical and other health services listed in section 1861(s) of the Act. Since that time, the statute has been amended to add new Medicare benefits. As the statute changed, we modified the definition of physicians' services for the SGR to include the additional benefits added to the statute that meet the criteria specified in section 1848(f)(4)(A).

As discussed in the CY 2010 PFS final rule with comment period (74 FR 61961), the statute provides the Secretary with clear discretion to decide whether physician-administered drugs should be included or excluded from the definition of ''physicians' services.'' Accordingly, we removed physician-administered drugs from the definition of ''physicians' services'' in section 1848(f)(4)(A) of the Act for purposes of computing the SGR and the levels of allowed expenditures and actual expenditures beginning with CY 2010, and for all subsequent years. Furthermore, in order to effectuate fully the Secretary's policy decision to remove drugs from the definition of ''physicians' services,'' we removed physician-administered drugs from the calculation of allowed and actual expenditures for all prior years.

Thus, for purposes of determining allowed expenditures, actual expenditures for all years, and SGRs beginning with CY 2010 and for all subsequent years, we are specifying that physicians' services include the following medical and other health services if bills for the items and services are processed and paid by Medicare carriers (and those paid through intermediaries where specified) or the equivalent services processed by

the Medicare Administrative Contractors:

- Physicians' services.
- Services and supplies furnished incident to physicians' services, except for the expenditures for drugs and biologicals which are not usually self-administered by the patient.
- Outpatient physical therapy services and outpatient occupational therapy services.
- Services of PAs, certified registered nurse anesthetists, certified nurse midwives, clinical psychologists, clinical social workers, nurse practitioners, and certified nurse specialists.
- Screening tests for prostate cancer, colorectal cancer, and glaucoma.
- Screening mammography, screening pap smears, and screening pelvic exams.
- Diabetes outpatient self-management training (DSMT) services.
- MNT services.
- Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests (including outpatient diagnostic laboratory tests paid through intermediaries).
- X-ray, radium, and radioactive isotope therapy.
- Surgical dressings, splints, casts, and other devices used for the reduction of fractures and dislocations.
- Bone mass measurements.
- An initial preventive physical exam.
- Cardiovascular screening blood tests.
- Diabetes screening tests.
- Telehealth services.
- Physician work and resources to establish and document the need for a power mobility device.
- Additional preventive services.
- Pulmonary rehabilitation.
- Cardiac rehabilitation.
- Intensive cardiac rehabilitation.
- Kidney disease education services.
- Personalized prevention plan services.

2. Preliminary Estimate of the SGR for 2012

Our preliminary estimate of the CY 2012 SGR is −16.9 percent. We first estimated the CY 2012 SGR in March 2011, and we made the estimate available to the MedPAC and on our Web site. Table 23 shows the March 2011 estimate and our current estimates of the factors included in the CY 2012 SGR. The majority of the difference between the March estimate and our current estimate of the CY 2012 SGR is explained by net adjustments that reflect higher physician fees and fee-for-service enrollment after our March estimate was prepared. Estimates of 2012 real per capita GDP are also lower than were included in our March, 2011 estimate of the SGR.

TABLE 23: CY 2012 SGR CALCULATION

Statutory Factors	March Estimate	Current Estimate
Fees	0.1 percent (1.001)	0.6 percent (1.006)
Enrollment	3.3 percent (1.033)	3.5 percent (1.035)
Real Per Capita GDP	0.9 percent (1.009)	0.6 percent (1.006)
Law and Regulation	-20.6 percent (0.794)	-20.7 percent (0.793)
Total	-17.2 percent (0.828)	-16.9 percent (0.831)

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, 1.006 x 1.035 x 1.006 x 0.793.= 0.831). A more detailed explanation of each figure is provided in section IV.A.5.b. of this final rule with comment period.

3. Revised Sustainable Growth Rate for CY 2011

Our current estimate of the CY 2011 SGR is 6.0 percent. Table 24 shows our preliminary estimate of the CY 2011 SGR that was published in the CY 2011 PFS final rule with comment period (75 FR 73278) and our current estimate. The majority of the difference between the preliminary estimate and our current estimate of the CY 2011 SGR is explained by adjustments to reflect two intervening legislative changes that have occurred since publication of the CY 2011 final rule with comment period.

TABLE 24: CY 2011 SGR CALCULATION

Statutory Factors	Estimate from CY 2011 Final Rule	Current Estimate
Fees	0.2 percent (1.002)	0.2 percent (1.002)
Enrollment	2.4 percent (1.024)	1.8 percent (1.018)
Real Per Capita GDP	0.7 percent (1.007)	0.6 percent (1.006)
Law and Regulation	-16.2 percent (0.838)	3.3 percent (1.033)
Total	-13.4 percent (0.866)	6 percent (1.060)

Note: A more detailed explanation of each figure is provided in section IV.A.5.b. of this final rule with comment period.

4. Final Sustainable Growth Rate for CY 2010

The SGR for CY 2010 is 8.9 percent. Table 25 shows our preliminary estimate of the CY 2010 SGR from the CY 2010 PFS final rule with comment period (74 FR 61965), our revised estimate from the CY 2011 PFS final rule with comment period (75 FR 73278), and the final figures determined using the best available data as of September 1, 2011.

TABLE 25: CY 2010 SGR CALCULATION

Statutory Factors	Estimate from CY 2010 Final Rule	Estimate from CY 2011 Final Rule	Final
Fees	0.9 percent (1.009)	0.9 percent (1.009)	0.9 percent (1.009)
Enrollment	1.2 percent (1.012)	1.6 percent (1.016)	1.1 percent (1.011)
Real Per Capita GDP	0.7 percent (1.007)	0.7 percent (1.007)	0.6 percent (1.006)
Law and Regulation	-11.3 percent (0.887)	4.9 percent (1.049)	6.1 percent (1.061)
Total	-8.8 percent (0.912)	8.3 percent (1.083)	8.9 percent (1.089)

Note: A more detailed explanation of each figure is provided in section IV.A.5.c. of this final rule with comment period.

5. Calculation of CYs 2012, 2011, and 2010 Sustainable Growth Rates

a. Detail on the CY 2012 SGR

All of the figures used to determine the CY 2012 SGR are estimates that will be revised based on subsequent data. Any differences between these estimates and the actual measurement of these figures will be included in future revisions of the SGR and allowed expenditures and incorporated into subsequent PFS updates.

(1) Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2012

This factor is calculated as a weighted average of the CY 2012 changes in fees for the different types of services included in the definition of physicians' services for the SGR. Medical and other health services paid using the PFS are estimated to account for approximately 89.4 percent of total allowed charges included in the SGR in CY 2012 and are updated using the percent change in the Medicare Economic Index (MEI). As discussed in section IV.C. of this final rule with comment period, the percent change in the MEI for CY 2012 is 0.6 percent. Diagnostic laboratory tests are estimated to represent approximately 10.6 percent of Medicare allowed charges included in the SGR for CY 2012. Medicare payments for these tests are updated by the Consumer Price Index for Urban Areas (CPI–U), which is 3.6 percent for CY 2012. Section 3401(l) of the Affordable Care Act requires the Secretary to reduce the CPI–U update applied to clinical laboratory tests under the clinical laboratory fee schedule be reduced by a multi-factor productivity adjustment (MFP adjustment) and, for each of years 2011 through 2015, by 1.75 percentage points (percentage adjustment). The MFP adjustment will not apply in a year where the CPI–U is zero or a percentage decrease for a year. Further, the application of the MFP adjustment shall not result in an adjustment to the fee schedule of less than zero for a year. However, the application of the percentage adjustment may result in an adjustment to the fee schedule being less than zero for a year and may result in payment rates for a year being less than such payment rates for the preceding year. The applicable productivity adjustment for CY 2012 is 1.2 percent. Adjusting the CPI–U update by the productivity adjustment results in a 2.4 percent (3.6 percent (CPI–U)– 1.2 percent (MFP adjustment) update for CY 2012. However, the percentage reduction of 1.75 percent is applied for CYs 2011 through 2015, as discussed previously. Therefore, for CY 2012, diagnostic laboratory tests will receive an update of 0.7 percent (rounded). Table 26 shows the weighted average of the MEI and laboratory price changes for CY 2012.

TABLE 26: WEIGHTED-AVERAGE OF THE MEI AND LABORATORY PRICE CHANGES FOR CY 2012

	Weight	Update
Physician	0.894	0.6
Laboratory	0.106	0.7
Weighted-average	1.000	0.6

We estimate that the weighted average increase in fees for physicians' services in CY 2012 under the SGR will be 0.6 percent.

(2) Factor 2—The Percentage Change in the Average Number of Part B Enrollees From CY 2011 to CY 2012

This factor is our estimate of the percent change in the average number of fee-for-service enrollees from CY 2011 to CY 2012. Services provided to Medicare Advantage (MA) plan enrollees are outside the scope of the SGR and are excluded from this estimate. We estimate that the average number of Medicare Part B fee-for-service enrollees will increase by 3.5 percent from CY 2011 to CY 2012. Table 27 illustrates how this figure was determined.

TABLE 27: AVERAGE NUMBER OF MEDICARE PART B FEE-FOR-SERVICE ENROLLEES FROM CY 2011 TO CY 2012 (EXCLUDING BENEFICIARIES ENROLLED IN MA PLANS)

	CY 2011	CY 2012
Overall	45.102 million	46.589 million
Medicare Advantage (MA)	12.380 million	12.726 million
Net	32.722 million	33.863 million
Percent Increase		3.5 percent

An important factor affecting fee-for-service enrollment is beneficiary enrollment in MA plans. Because it is difficult to estimate the size of the MA enrollee population before the start of a CY, at this time we do not know how actual enrollment in MA plans will compare to current estimates. For this reason, the estimate may change substantially as actual Medicare fee-for-service enrollment for CY 2012 becomes known.

(3) Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in CY 2012

We estimate that the growth in real GDP per capita from CY 2011 to CY 2012 will be 0.6 percent (based on the annual growth in the 10 year moving average of real GDP per capita (2003 through 2012)). Our past experience indicates that there have also been changes in estimates of real GDP per capita growth made before the year begins and the actual change in real GDP per capita growth computed after the year is complete. Thus, it is possible that this figure will change as actual information on economic performance becomes available to us in CY 2012.

(4) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2012 Compared With CY 2011

The statutory and regulatory provisions that will affect expenditures in CY 2012 relative to CY 2011 are estimated to have an impact on expenditures of −20.7 percent. The impact is primarily due to the expiration of the physician fee schedule update included in the Medicare and Medicaid Extenders Act (MMEA) which specified a physician fee schedule update for CY 2011 only. Additionally, section 3102 of the Affordable Care Act revised the methodology for calculating the PE GPCIs for CY 2010 and CY 2011 so that the employee compensation and rent components of the PE GPCIs reflect only one-half of the relative cost differences for each locality compared to the national average. This provision included a hold harmless so that no area's GPCI could decline and was not budget neutral. In addition, section 103 of the MMEA extended the floor of 1.0 on the work GPCI through the end of CY 2011. This provision was also not budget neutral. The expiration of the methodological changes to the PE GPCIs and the floor of the work GPCI in CY 2012 will cause a reduction in spending in CY 2012 compared to CY 2011.

b. Detail on the CY 2011 SGR

A more detailed discussion of our revised estimates of the four elements of the CY 2011 SGR follows.

(1) Factor 1—Changes in Fees for Physicians' Services for CY 2011

This factor was calculated as a weighted-average of the CY 2011 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2011.

We estimate that services paid using the PFS account for approximately 92.1 percent of total allowed charges included in the SGR in CY 2011. These services were updated using the CY 2011 percent change in the MEI of 0.4 percent. We estimate that diagnostic laboratory tests represent approximately 7.9 percent of total allowed charges included in the SGR in CY 2011. Medicare payments for these tests are updated by the CPI–U, which was 1.1 percent for CY 2011. However, section 3401(l)(2)(iv)(subclause I) of the Affordable Care Act requires the Secretary to reduce the CPI–U update applied to clinical laboratory tests by a productivity adjustment, but does not allow the productivity adjustment to result in a negative CLFS update. The result is that the CLFS update for CY 2011 was 0.0 percent. Additionally, section 3401(1)(2)(iv)(II) of the Affordable Care Act reduces the update applied to clinical laboratory tests by 1.75 percent for CYs 2011 through 2015. Therefore, for CY 2011, diagnostic laboratory tests received an update of −1.75 percent.

Table 28 shows the weighted-average of the MEI and laboratory price changes for CY 2011.

TABLE 28: WEIGHTED-AVERAGE OF THE MEI, AND LABORATORY PRICE CHANGES FOR CY 2011

	Weight	Update
Physician	0.921	0.4
Laboratory	0.079	-1.8
Weighted-average	1.000	0.2

After considering the elements described in Table 28, we estimate that the weighted-average increase in fees for physicians' services in CY 2011 under the SGR was 0.2 percent. Our estimate of this factor in the CY 2011 PFS final rule with comment period was 0.2 percent (75 FR 73279).

(2) Factor 2—The Percentage Change in the Average Number of Part B Enrollees From CY 2010 to CY 2011

We estimate that the average number of Medicare Part B fee-for-service enrollees (excluding beneficiaries enrolled in Medicare Advantage plans) increased by 1.8 percent in CY 2011. Table 29 illustrates how we determined this figure.

TABLE 29: AVERAGE NUMBER OF MEDICARE PART B FEE-FOR-SERVICE ENROLLEES FROM CY 2010 TO CY 2011 (EXCLUDING BENEFICIARIES ENROLLED IN MA PLANS)

	2010	2011
Overall	43.816	45.102
Medicare Advantage (MA)	11.688	12.380
Net	32.128	32.722
Percent Increase		1.8

Our estimate of the 1.8 percent change in the number of fee-for-service enrollees, net of Medicare Advantage enrollment for CY 2011 compared to CY 2010, is different than our original estimate of an increase of 2.4 percent in the CY 2011 PFS final rule with comment period (75 FR 73279). While our current projection based on data from 8 months of CY 2011 differs from our original estimate of 2.4 percent when we had no actual data, it is still possible that our final estimate of this figure will be different once we have complete information on CY 2011 fee-for-service enrollment.

(3) Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in CY 2011

We estimate that the growth in real GDP per capita will be 0.6 percent for CY 2011 (based on the annual growth in the 10-year moving average of real GDP per capita (2002 through 2011)). Our past experience indicates that there have also been differences between our estimates of real per capita GDP growth made prior to the year's end and the actual change in this factor. Thus, it is possible that this figure will change further as complete actual information on CY 2011 economic performance becomes available to us in CY 2012.

(4) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2011 Compared With CY 2010

The statutory and regulatory provisions that affected expenditures in CY 2011 relative to CY 2010 are estimated to have an impact on expenditures of 3.3 percent. These include the Department of Defense Appropriations Act (DODAA), the Temporary Extension Act (TEA), and the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act (PACMBPRA) which provided for physician fee schedule updates. Furthermore, the Affordable Care Act contained provisions regarding the policy on equipment utilization for imaging services, the multiple procedure payment reduction policy for imaging services, and the annual wellness visit providing personalized prevention plan services.

c. Detail on the CY 2010 SGR

A more detailed discussion of our final revised estimates of the four elements of the CY 2010 SGR follows.

(1) Factor 1—Changes in Fees for Physicians' Services for CY 2010

This factor was calculated as a weighted-average of the CY 2010 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2010.

We estimate that services paid under the PFS account for approximately 91.3 percent of total allowed charges included in the SGR in CY 2010. These services were updated using the CY 2010 percent change in the MEI of 1.2 percent. We estimate that diagnostic laboratory tests represent approximately 8.7 percent of total allowed charges included in the SGR in CY 2010. Medicare payments for these tests are updated by the CPI–U, which was −1.4 percent for CY 2010. However, section 145 of the Medicare Improvements for Patients and Providers Act (MIPPA), reduced the update applied to clinical laboratory tests by 0.5 percent for CY 2009 and CY 2010. Therefore, for CY 2010, diagnostic laboratory tests received an update of −1.9 percent. Since we removed physician-administered drugs from the definition of ''physicians' services'' for purposes of computing the SGR and the levels of allowed expenditures and actual

expenditures beginning with CY 2010, and for all subsequent years, drugs represent 0.0 percent of Medicare allowed charges included in the SGR in CY 2010 and later years.

Table 30 shows the weighted-average of the MEI and laboratory price changes for CY 2010.

TABLE 30: WEIGHTED-AVERAGE OF THE MEI, LABORATORY, AND DRUG PRICE CHANGES FOR CY 2010

	Weight	Update
Physician	0.913	1.2
Laboratory	0.087	-1.9
Weighted-average	1.00	0.9

After considering the elements described in Table 30, we estimate that the weighted-average increase in fees for physicians' services in CY 2010 under the SGR was 0.9 percent. This figure is a final one based on complete data for CY 2010.

(2) Factor 2—The Percentage Change in the Average Number of Part B Enrollees From CY 2009 to CY 2010

We estimate the change in the number of fee-for-service enrollees (excluding beneficiaries enrolled in MA plans) from CY 2009 to CY 2010 was 1.1 percent. Our calculation of this factor is based on complete data from CY 2010. Table 31 illustrates the calculation of this factor.

TABLE 31: AVERAGE NUMBER OF MEDICARE PART B FROM CY 2009 TO CY 2010 (EXCLUDING BENEFICIARIES ENROLLED IN MA PLANS)

	2009	2010
Overall	42.879	43.816
Medicare Advantage (MA)	11.101	11.688
Net	31.778	32.128
Percent Change		1.1

(3) Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in CY 2010

We estimate that the growth in real per capita GDP was 0.6 percent in CY 2010 (based on the annual growth in the 10-year moving average of real GDP per capita (CYs 2001 through 2010)). This figure is a final one based on complete data for CY 2010.

(d) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2010 Compared With CY 2009

Our final estimate for the net impact on expenditures from the statutory and regulatory provisions that affect expenditures in CY 2010 relative to CY 2009 is 6.1 percent. The statutory and regulatory provisions that affected expenditures in CY 2010 relative to CY 2009 include the DODAA, the TEA, and the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act (PACMBPRA) which provided for physician fee schedule updates. Also included are the MIPPA provisions regarding the physician fee schedule update, PQRI and E-prescribing incentives, the work GPCIs, and payment provisions related to certain pathology services. Additionally, the Affordable Care Act contained provisions regarding the work GPCIs, the policy on equipment utilization for imaging services, coverage of preventive services, and a physician enrollment requirement.

B. The Update Adjustment Factor (UAF)

Section 1848(d) of the Act provides that the PFS update is equal to the product of the the UAF and the MEI. The UAF is applied to make actual and target expenditures (referred to in the statute as ''allowed expenditures'') equal. As discussed previously, allowed expenditures are equal to actual expenditures in a base period updated each year by the SGR. The SGR sets the annual rate of growth in allowed expenditures and is determined by a formula specified in section 1848(f) of the Act.

1. Calculation Under Current Law

Under section 1848(d)(4)(B) of the Act, the UAF for a year beginning with CY 2001 is equal to the sum of the following—

- *Prior Year Adjustment Component.* An amount determined by—
  - ++ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (the year prior to the year for which the update is being determined) and the amount of the actual expenditures for those services for that year;
  - ++ Dividing that difference by the amount of the actual expenditures for those services for that year; and
  - ++ Multiplying that quotient by 0.75.
- *Cumulative Adjustment Component.* An amount determined by—
  - ++ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for those services during that period;

++ Dividing that difference by actual expenditures for those services for the prior year as increased by the SGR for the year for which the UAF is to be determined; and

++ Multiplying that quotient by 0.33.

Section 1848(d)(4)(E) of the Act requires the Secretary to recalculate allowed expenditures consistent with section 1848(f)(3) of the Act. As discussed previously, section 1848(f)(3) specifies that the SGR (and, in turn, allowed expenditures) for the upcoming CY (CY 2012 in this case), the current CY (that is, CY 2011) and the preceding CY (that is, CY 2010) are to be determined on the basis of the best data available as of September 1 of the current year. Allowed expenditures for a year generally are estimated initially and subsequently revised twice. The second revision occurs after the CY has ended (that is, we are making the second revision to CY 2010 allowed expenditures in this final rule with comment).

Table 32 shows the historical SGRs corresponding to each period through CY 2012.

TABLE 32: ANNUAL AND CUMULATIVE ALLOWED AND ACTUAL EXPENDITURES FOR PHYSICIANS' SERVICES FROM APRIL 1, 1996 THROUGH THE END OF THE CURRENT CALENDAR YEAR

Period	Annual Allowed Expenditures ($ in billions)	Annual Actual Expenditures ($ in billions)	Cumulative Allowed Expenditures ($ in billions)	Cumulative Actual Expenditures ($ in billions)	FY/CY SGR
4/1/96-3/31/97	$46.8[1]	$46.8	$46.8	$46.8	N/A
4/1/97-3/31/98	$48.3	$47.0	$95.2	$93.9	FY 1998=3.2%
4/1/98-3/31/99	$50.4	$47.8	$145.6	$141.7	FY 1999=4.2%
1/1/99-3/31/99	$12.7	$12.4	[2]	$141.7	FY 1999=4.2%
4/1/99-12/31/99	$40.3	$37.0	[3]	$178.8	FY 2000=6.9%
1/1/99-12/31/99	$53.0	$49.5	$185.8	$178.8	FY 1999/2000
1/1/00-12/31/00	$56.8	$54.1	$242.7	$232.9	CY 2000=7.3%
1/1/01-12/31/01	$59.4	$61.2	$302.1	$294.2	CY 2001=4.5%
1/1/02-12/31/02	$64.3	$64.6	$366.4	$358.7	CY 2002=8.3%
1/1/03-12/31/03	$69.0	$70.2	$435.4	$429.0	CY 2003=7.3%
1/1/04-12/31/04	$73.6	$78.3	$509.0	$507.2	CY 2004=6.6%
1/1/05-12/31/05	$76.7	$83.5	$585.7	$590.7	CY 2005=4.2%
1/1/06-12/31/06	$77.8	$84.6	$663.5	$675.3	CY 2006=1.5%
1/1/07-12/31/07	$80.5	$84.5	$744.0	$759.8	CY 2007=3.5%
1/1/08-12/31/08	$84.2	$86.7	$828.2	$846.4	CY 2008=4.5%
1/1/09-12/31/09	$89.6	$90.6	$917.8	$937.0	CY 2009=6.4%
1/1/10-12/31/10	$97.5	$95.4	$1,015.3	$1,032.2	CY 2010=8.9%
1/1/11-12/31/11	$103.4	$101.1	$1,118.7	$1,133.3	CY 2011=6.0%
1/1/12-12/31/12	$85.9	NA	$1,204.6	NA	CY 2011 = -16.9

[1] Allowed expenditures in the first year (April 1, 1996-March 31, 1997) are equal to actual expenditures. All subsequent figures are equal to quarterly allowed expenditure figures increased by the applicable SGR. Cumulative allowed expenditures are equal to the sum of annual allowed expenditures. We provide more detailed quarterly allowed and actual expenditure data on our Web site at the following address: http://www.cms.hhs.gov/SustainableGRatesConFact/. We expect to update the web site with the most current information later this month.

[2] Allowed expenditures for the first quarter of 1999 are based on the FY 1999 SGR.

[3] Allowed expenditures for the last three quarters of 1999 are based on the FY 2000 SGR.

Consistent with section 1848(d)(4)(E) of the Act, Table 32 includes our second revision of allowed expenditures for CY 2010, a recalculation of allowed expenditures for CY 2011, and our initial estimate of allowed expenditures for CY 2012. To determine the UAF for CY 2012, the statute requires that we use allowed and actual expenditures from April 1, 1996 through December 31, 2011 and the CY 2012 SGR. Consistent with section 1848(d)(4)(E) of the Act, we will be making revisions to the CY 2011 and CY 2012 SGRs and CY 2011 and CY 2012 allowed expenditures. Because we have incomplete actual expenditure data for CY 2011, we are using an estimate for this period. Any difference between current estimates and final figures will be taken into account in determining the UAF for future years.

We are using figures from Table 32 in the following statutory formula:

$$UAF_{12} = \frac{Target_{11} - Actual_{11}}{Actual_{11}} \times 0.75 + \frac{Target_{4/96-12/11} - Actual_{4/96-12/11}}{Actual_{11} \times SGR_{12}} \times 0.33$$

UAF_{12} = Update Adjustment Factor for CY 2012 = −4.0 percent

$Target_{11}$ = Allowed Expenditures for CY 2011 = $103.4 billion

$Actual_{11}$ = Estimated Actual Expenditures for CY 2011 = $101.1 billion

$Target_{4/96–12/11}$ = Allowed Expenditures for 4/1/1996–12/31/2011 = $1,118.7 billion

$Actual_{4/96–12/11}$ = Estimated Actual Expenditures from 4/1/1996–12/31/2011 = $1,133.3 billion

SGR_{12} = −16.9 percent (0.831)

$$\frac{\$103.4-\$101.1}{\$101.1}\times 0.75+\frac{\$1{,}118.7-\$1{,}133.3}{\$101.1\times 0.831}\times 0.33=-4.0\%$$

Section 1848(d)(4)(D) of the Act indicates that the UAF determined under section 1848(d)(4)(B) of the Act for a year may not be less than −0.07 or greater than 0.03. Since −0.04 (−4 percent) is between −0.07 and 0.03, the UAF for CY 2012 will be −0.04.

Section 1848(d)(4)(A)(ii) of the Act indicates that 1.0 should be added to the UAF determined under section 1848(d)(4)(B) of the Act. Thus, adding 1.0 to −0.04 makes the UAF equal to 0.96.

C. The Percentage Change in the Medicare Economic Index (MEI)

The MEI is authorized by section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973 may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that the higher level is justified by year-to-year economic changes. The current form of the MEI was detailed in the CY 2011 PFS final rule with comment period (75 FR 73262) which updated the cost structure of the index from a base year of 2000 to 2006.

The MEI measures the weighted-average annual price change for various inputs needed to produce physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide multifactor productivity. This index, which has CY 2006 base year weights, is comprised of two broad categories: (1) Physician's own time; and (2) physician's practice expense (PE).

The physician's compensation (own time) component represents the net income portion of business receipts and primarily reflects the input of the physician's own time into the production of physicians' services in physicians' offices. This category consists of two subcomponents: (1) Wages and salaries; and (2) fringe benefits.

The physician's practice expense (PE) category represents nonphysician inputs used in the production of services in physicians' offices. This category consists of wages and salaries and fringe benefits for nonphysician staff and other nonlabor inputs. The physician's PE component also includes the following categories of nonlabor inputs: Office expenses; medical materials and supplies; professional liability insurance; medical equipment; medical materials and supplies; and other professional expenses.

Table 33 presents a listing of the MEI cost categories with associated weights and percent changes for price proxies for the 2012 update. The CY 2012 final MEI update is 1.8 percent and reflects a 2.3 percent increase in physician's own time and a 1.4 percent increase in physician's PE. Within the physician's PE, the largest increase occurred in chemicals, which increased 10.2 percent, and rubber and plastic products, which increased 5.2 percent.

For CY 2012, the increase in the productivity adjusted MEI is 0.6 percent, which reflects an increase in the MEI of 1.8 percent and a productivity adjustment of 1.2 percent based on the 10-year moving average of economy-wide private nonfarm business multifactor productivity. The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private non-farm business MFP. Please see *http://www.bls.gov/mfp* which is the link to the BLS historical published data on the measure of MFP.

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TABLE 33: ANNUAL PERCENT CHANGE IN THE REVISED AND REBASED MEI CY 2012, ALL CATEGORIES

Cost Categories	2006 Weight [2]	CY 2012 Percent Changes
MEI Total, productivity adjusted	100.000%	0.6
Productivity: 10-year moving average of MFP[1]	N/A	1.2
MEI Total, without productivity adjustment	100.000%	1.8
Physician Compensation (Own Time) [3]	48.266%	2.3
Wages and Salaries	43.880%	2.2
Benefits	4.386%	3.2
Practice Expenses	51.734%	1.4
Nonphysician Compensation	19.153%	2.0
Nonphysician Wages	13.752%	1.7
P&T	6.006%	1.7
Management	1.446%	1.9
Clerical	4.466%	1.8
Services	1.834%	1.2
Nonphysician Benefits	5.401%	2.9
Other Practice Expenses	26.308%	1.0
Office Expenses	20.035%	1.5
Utilities	1.266%	2.5
Chemicals	0.723%	10.2
Paper	0.657%	4.9
Rubber & Plastics	0.598%	5.2
Telephone	1.501%	-0.7
Postage	0.898%	2.6
All Other Services	3.582%	1.6
All Other Products	0.500%	1.0
Fixed Capital	8.957%	0.4
Moveable Capital	1.353%	0.4
PLI [4]	4.295%	-1.1
Medical Equipment	1.978%	0.4
Medical supplies	1.760%	0.2
Other Professional Expenses	4.513%	1.0

[1] The forecasts are based upon the latest available Bureau of Labor Statistics data on the 10-year average of BLS private nonfarm business multifactor productivity published on May 19, 2011. (http://www.bls.gov/news.release/prod3.nr0.htm)

[2] The weights shown for the MEI components are the 2006 base-year weights, which may not sum to subtotals or totals because of rounding. The MEI is a fixed-weight, Laspeyres-type input price index whose category weights indicate the distribution of expenditures among the inputs to physicians' services for CY 2006. To determine the MEI level for a given year, the price proxy level for each component is multiplied by its 2006 weight. The sum of these products (weights multiplied by the price index levels) overall cost categories yields the composite MEI level for a given year. The annual percent change in the MEI levels is an estimate of price change over time for a fixed market basket of inputs to physicians' services.

[3] The measures of productivity, average hourly earnings, Employment Cost Indexes, as well as the various Producer and Consumer Price Indexes can be found on the Bureau of Labor Statistics Web site at http://stats.bls.gov.

[4] Derived from a CMS survey of several major commercial insurers.

N/A Productivity is factored into the MEI categories as an adjustment; therefore, no explicit weight exists for productivity in the MEI.

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D. Physician and Anesthesia Fee Schedule Conversion Factors for CY 2012

The CY 2012 PFS CF is $24.6712. The CY 2012 national average anesthesia CF is $15.5264.

1. Physician Fee Schedule Update and Conversion Factor

a. CY 2012 PFS Update

The formula for calculating the PFS update is set forth in section 1848(d)(4)(A) of the Act. In general, the PFS update is determined by multiplying the CF for the previous year by the percentage increase in the MEI times the UAF, which is calculated as specified under section 1848(d)(4)(B) of the Act.

b. CY 2012 PFS Conversion Factor

Generally, the PFS CF for a year is calculated in accordance with section 1848(d)(1)(A) of the Act by multiplying the previous year's CF by the PFS update.

We note section 101 of the Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) provided a 1-year increase in the CY 2007 CF and specified that the CF for CY 2008 must be computed as if the 1-year increase had never applied. Section 101 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) provided a 6-month increase in the CY 2008 CF, from January 1, 2008, through June 30, 2008, and specified that the CF for the remaining portion of CY 2008 and the CFs for CY 2009 and subsequent years must be computed as if the 6-month increase had never applied. Section 131 of the MIPPA extended the increase in the CY 2008 CF that applied during the first half of the year to the entire year, provided for a 1.1 percent increase to the CY 2009 CF, and specified that the CFs for CY 2010 and subsequent years must be computed as if the increases for CYs 2007, 2008, and 2009 had never applied. Section 1011(a) of the DODAA and section 5 of the TEA specified a zero percent update for CY 2010, effective January 1, 2010 through March 31, 2010. Section 4 of the Continuing Extension Act of 2010 (CEA) extended the zero percent update for CY 2010 through May 31, 2010. Subsequently, section 101(a)(2) of the PACMBPRA provided for a 2.2 percent update to the CF, effective from June 1, 2010 to November 30, 2010. Section 2 of the Physician Payment and Therapy Relief Act of 2010 (Pub. L. 111–286) extended the 2.2 percent through the end of CY 2010. Finally, section 101 of the MMEA provided a zero percent update for CY 2011, effective January 1, 2011 through December 31, 2011, and specified that the CFs for CY 2012 and subsequent years must be computed as if the increases in previous years had never applied. Therefore, under current law, the CF that would be in effect in CY 2011 had the prior increases specified above not applied is $25.4999.

In addition, when calculating the PFS CF for a year, section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ more than $20 million from what it would have been in the absence of these changes. If this threshold is exceeded, we must make adjustments to preserve budget neutrality. We estimate that CY 2012 RVU changes would result in a decrease in Medicare physician expenditures of more than $20 million. Accordingly, we are increasing the CF by 1.0018 to offset this estimated decrease in Medicare physician expenditures due to the CY 2012 RVU changes. We calculate the CY 2012 PFS CF to be $24.6712. This final rule with comment period announces a reduction to payment rates for physicians' services in CY 2012 under the SGR formula. These payment rates are currently scheduled to be reduced under the SGR system on January 1, 2012. The total reduction in MPFS rates between CY 2011 and CY 2012 under the SGR system will be 27.4 percent. By law, we are required to make these reductions in accordance with section 1848(d) and (f) of the Act, and these reductions can only be averted by an Act of Congress. While Congress has provided temporary relief from these reductions every year since 2003, a long-term solution is critical. We will continue to work with Congress to fix this untenable situation so doctors and beneficiaries no longer have to worry about the stability and adequacy of their payments from Medicare under the Physician Fee Schedule.

We illustrate the calculation of the CY 2012 PFS CF in Table 34.

TABLE 34: CALCULATION OF THE CY 2012 PFS CF

Conversion Factor in effect in CY 2011		$33.9764
CY 2011 Conversion Factor had statutory increases not applied		$25.4999
CY 2012 Medicare Economic Index	0.6 percent (1.006)	
CY 2012 Update Adjustment Factor	-4.0 percent (0.9600)	
CY 2012 RVU Budget Neutrality Adjustment	0.2 percent (1.0018)	
CY 2012 Conversion Factor		$24.6712
Percent Change from Conversion Factor in effect in CY 2011 to CY 2012 Conversion Factor		-27.4%

We note payment for services under the PFS will be calculated as follows:

Payment = [(RVU work × GPCI work) + (RVU PE × GPCI PE) + (RVU malpractice × GPCI malpractice)] × CF.

2. Anesthesia Conversion Factor

We calculate the anesthesia CF as indicated in Table 35. Anesthesia services do not have RVUs like other PFS services. Therefore, we account for any necessary RVU adjustments through an adjustment to the anesthesia CF to simulate changes to RVUs. More specifically, if there is an adjustment to the work, PE, or malpractice RVUs, these adjustments are applied to the respective shares of the anesthesia CF as these shares are proxies for the work, PE, and malpractice RVUs for anesthesia services. Information regarding the anesthesia work, PE, and malpractice shares can be found at the following: *https://www.cms.gov/center/anesth.asp.*

The anesthesia CF in effect in CY 2011 is $21.0515. As explained previously, in order to calculate the CY 2012 PFS CF, the statute requires us to calculate the CFs for all previous years

as if the various legislative changes to the CFs for those years had not occurred. Accordingly, under current law, the anesthesia CF in effect in CY 2011 had statutory increases not applied is $15.8085. The percent change from the anesthesia CF in effect in CY 2011 ($21.0515) to the CF for CY 2012 ($15.5264) is –26.2 percent. We illustrate the calculation of the CY 2012 anesthesia CF in Table 35.

TABLE 35: CALCULATION OF THE CY 2012 ANESTHESIA CF

2011 National Average Anesthesia Conversion Factor in effect in CY 2011		$21.0515
2011 National Anesthesia Conversion Factor had Statutory Increases Not Applied		$15.8085
CY 2012 Medicare Economic Index	0.6 (1.0060)	
CY 2012 Update Adjustment Factor	-4.0 (0.9600)	
CY 2012 Budget Neutrality Work and Malpractice Adjustment	0.2 (1.0018)	
CY 2012 Anesthesia Fee Schedule Practice Expense Increase	1.5 (1.0151496)	
CY 2012 Anesthesia Conversion Factor		$15.5264
Percent Change from 2011 to 2012		**-26.2%**

V. Other Physician Fee Schedule Issues

A. Section 105: Extension of Payment for Technical Component of Certain Physician Pathology Services

1. Background and Statutory Authority

Section 542(c) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), as amended by section 732 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), section 104 of division B of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), section 104 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), section 136 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) and section 3104 of the Affordable Care Act (Pub. L. 111–148), as amended by section 105 of the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309), continued payment to independent laboratories for the technical component (TC) of physician pathology services for fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital through CY 2011. The TC of physician pathology services refers to the preparation of the slide involving tissue or cells that a pathologist interprets. The professional component (PC) of physician pathology services refers to the pathologist's interpretation of the slide.

When the hospital pathologist furnishes the PC service for a hospital patient, the PC service is separately billable by the pathologist. When an independent laboratory's pathologist furnishes the PC service, the PC service is usually billed with the TC service as a combined service.

Historically, any independent laboratory could bill the Medicare contractor under the PFS for the TC of physician pathology services for hospital patients even though the payment for the costs of furnishing the pathology service (but not its interpretation) was already included in the bundled inpatient stay payment to the hospital. In the CY 2000 PFS final rule with comment period (64 FR 59408 and 59409), we stated that this policy has contributed to the Medicare program paying twice for the TC service: (1) To the hospital, through the inpatient prospective payment rate, when the patient is an inpatient; and (2) to the independent laboratory that bills the Medicare contractor, instead of the hospital, for the TC service. While the policy also permits the independent laboratory to bill for the TC of physician pathology services for hospital outpatients, in this case, there generally would not be duplicate payment because we would expect the hospital to not also bill for the pathology service, which would be paid separately to the hospital only if the hospital were to specifically bill for it. We further indicated that we would implement a policy to pay only the hospital for the TC of physician pathology services furnished to its inpatients.

Therefore, in the CY 2000 PFS final rule with comment period, we revised § 415.130(c) to state that for physician pathology services furnished on or after January 1, 2001 by an independent laboratory, payment is made only to the hospital for the TC of physician pathology services furnished to a hospital inpatient. Ordinarily, the provisions in the PFS final rule with comment period are implemented in the following year. However, the change to § 415.130 was delayed 1-year (until January 1, 2001), at the request of the industry, to allow independent laboratories and hospitals sufficient time to negotiate arrangements.

Full implementation of § 415.130 was further delayed by section 542 of BIPA and section 732 of the MMA, which directed us to continue payment to independent laboratories for the TC of physician pathology services for hospital patients for a 2-year period beginning on January 1, 2001 and for CYs 2005 and 2006, respectively. In the CY 2007 PFS final rule with comment period (71 FR 69788), we amended § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the TC of physician pathology services furnished to a hospital inpatient or outpatient. However, section 104 of the MIEA–TRHCA continued payment to independent laboratories for the TC of physician pathology services for hospital patients through CY 2007, and section 104 of the MMSEA further extended such payment through the first 6 months of CY 2008.

Section 136 of the MIPPA extended the payment through CY 2009. Section 3104 of the Affordable Care Act amended the prior legislation to extend the payment through CY 2010. Subsequent to publication of the CY 2011 PFS final rule with comment period, section 105 of the MMEA extended the payment through CY 2011.

2. Revisions to Payment for TC of Certain Physician Pathology Services

Consistent with this statutory change, we proposed to revise § 415.130(d) to specify that for services furnished after December 31, 2011, an independent laboratory may not bill the Medicare contractor for the TC of physician pathology services furnished to a hospital inpatient or outpatient. We would implement this provision effective for TC services furnished on or after January 1, 2012.

We received the following comments.

Comment: Several commenters indicated that it was unclear whether the TC payment is included in either the inpatient prospective payment rate or in the outpatient prospective payment system (OPPS) payment made to the hospital for the service. One commenter noted that there is no duplicate payment for outpatients because the hospital does not bill Medicare for the TC of outpatient pathology services in cases where the independent laboratory bills Medicare.

Response: Payment for the costs of furnishing the pathology service (but not its interpretation) is already included in the bundled inpatient stay payment to the hospital. We continue to believe that this payment provision represents a duplicate payment for the TC service: (1) To the hospital, through the inpatient prospective payment rate, when the patient is an inpatient; and (2) to the independent laboratory that bills the Medicare contractor, instead of the hospital, for the TC service. We agree that there generally is no duplicate payment for outpatient services because the hospital does not bill Medicare when the independent laboratory bills Medicare.

Comment: Commenters indicated that the proposal will shift costs to hospitals without any comparable change in reimbursement, resulting in administrative, financial, and operational hardships for both independent laboratories and hospitals. Under direct billing, laboratories submit a single bill to Medicare for both the TCs and the PCs. Without direct billing, laboratories will have to issue two bills, that is, one to Medicare for the PC and another to the hospitals for the TC, doubling their billing costs. Hospitals will incur additional costs of creating new billing systems. Such burdens will fall most heavily on small, rural, and critical access hospitals which often rely on independent labs for surgical pathology services. Some hospitals may choose not to provide surgical pathology services, thereby limiting access to care.

Response: We believe that the Medicare savings, resulting from the elimination of duplicate payments, offset the disadvantages to hospitals and laboratories of any additional administrative burden to implement the provision. Medicare payment under the IPPS encompasses almost all services provided to the hospital inpatient during their admission. We do not believe it would be a substantial burden to hospitals to bill for services provided by independent laboratories because this is how they bill for all other laboratory services provided to hospital inpatients. Further, hospitals and independent laboratories have had ample time to address modifications to billing systems.

Comment: A commenter noted that a demonstration project, mandated by the Affordable Care Act would allow laboratories to bill Medicare directly for a complex diagnostic test which is ordered by the patient's physician less than 14-days following the date of the patient's discharge from the hospital or critical access hospital. The demonstration will assess the impact of this billing process on access to care, quality of care, health outcomes, and expenditures. The commenter requested that we delay implementation of the provision until the demonstration project is complete.

Response: Section 3113 of the Affordable Care Act requires the Secretary to conduct a demonstration project under Part B of title XVIII of the Act under which separate payments are made for certain complex diagnostic laboratory tests. The demonstration project is independent of our proposal and involves a limited number of pathology services, none of which are s paid under the PFS. We continue to believe that Medicare currently makes a duplicate payment for such services and we will not delay implementation of this provision until the demonstration project is complete.

After consideration of all public comments, we are finalizing our proposal without modification. Absent additional legislation, for services furnished after December 31, 2011, an independent laboratory may not bill a Medicare contractor for the TC of physician pathology services for fee-for service Medicare beneficiaries who are inpatients or outpatients of a covered hospital. Accordingly, we are finalizing the proposed revisions to § 415.130(d)(1) and (2) to reflect this change.

B. Bundling of Payments for Services Provided to Outpatients Who Later Are Admitted as Inpatients: 3-Day Payment Window Policy and the Impact on Wholly Owned or Wholly Operated Physician Practices

1. Introduction

On June 25, 2010, the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (PACMBPRA) (Pub. L. 111–192) was enacted. Section 102 of this Act entitled, ''Clarification of 3-Day Payment Window,'' clarified when certain services furnished to Medicare beneficiaries in the 3-days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1-day) preceding an inpatient admission should be considered ''operating costs of inpatient hospital services'' and therefore included in the hospital's payment under the Hospital Inpatient Prospective Payment System (IPPS). This policy is generally known as the ''3-day payment window.'' Under the 3-day payment window, a hospital (or an entity that is wholly owned or wholly operated by the hospital) must include on the claim for a Medicare beneficiary's inpatient stay, the technical portion of any outpatient diagnostic services and nondiagnostic services related to the admission provided during the payment window. The new law makes the policy pertaining to admission-related nondiagnostic services more consistent with common hospital billing practices. Section 102 of the PACMBPRA is effective for services furnished on or after June 25, 2010.

2. Background

We discussed changes to the 3-day payment window policy in the interim final rule with comment period that was issued as part of last year's IPPS final rule (75 FR 50346). The PACMBPRA made no changes to the billing of ''diagnostic services'' furnished during the 3-day payment window, which are included in the ''operating costs of inpatient hospital services'' pursuant to section 1886(a)(4) of the Act. All diagnostic services furnished to a Medicare beneficiary by a hospital (or an entity wholly owned or wholly 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, continue to be included on the Part A bill for the beneficiary's inpatient stay at the hospital. In accordance with section 102(a)(1) of the PACMBPRA, for outpatient services

furnished on or after June 25, 2010, all nondiagnostic services, other than ambulance and maintenance renal dialysis services, provided by the hospital (or an entity wholly owned or wholly operated by the hospital) on the date of a beneficiary's inpatient admission and during the 3 calendar days (1 calendar day for a nonsubsection (d) hospital) immediately preceding the date of admission are deemed related to the admission and, therefore, must be billed with the inpatient stay, unless the hospital attests that certain nondiagnostic services are unrelated to the hospital claim (that is, the preadmission nondiagnostic services are clinically distinct or independent from the reason for the beneficiary's inpatient admission). In such cases, the unrelated outpatient hospital nondiagnostic services are covered by Medicare Part B, and the hospital may separately bill for those services.

Prior to the enactment of the 3-day payment window clarification under section 102 of the PACMBPRA, the term ''related to the admission'' was defined in section 40.3, Chapter 3, Inpatient Hospital Billing, of the Medicare Claims Processing Manual (Pub. 100–04) to mean an exact match between the principal ICD–9 CM diagnosis codes for the outpatient encounter and the inpatient admission. On November 5, 1990, section 4003(a) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) amended the statutory definition of ''operating cost of inpatient hospital services'' in section 1886(a)(4) of the Act to include the costs of certain services furnished prior to admission. Section 4003(a) also required that these preadmission services be included on the Medicare Part A bill for the subsequent inpatient stay. With this amendment, section 1886(a)(4) of the Act defines the operating costs of inpatient hospital services to include diagnostic services (including clinical diagnostic laboratory tests) or other services related to the admission (as defined by the Secretary) that are furnished by the hospital (or by an entity that is wholly owned or wholly operated by the hospital) to the patient during the 3-days prior to the date of the patient's admission to the hospital.

Section 1886(a)(4) of the Act was further amended by section 110 of the Social Security Amendments of 1994 (Pub. L. 103–432) enacted on October 31, 1994. This provision revised the payment window for hospitals that are excluded from the IPPS to include only those services furnished by the hospital or an entity wholly owned or wholly operated by the hospital during the 1-day (instead of the previous 3-days) prior to the patient's hospital inpatient admission. The hospital and hospital units excluded from the IPPS and affected by this policy are psychiatric hospitals and units, inpatient rehabilitation hospitals and units, long-term care hospitals, children's hospitals, and cancer hospitals. In the FY 1996 IPPS final rule (60 FR 45840), we noted that the term ''day,'' as referenced in the 3-day or 1-day payment window policy refers to the entire calendar day immediately preceding the date of admission and not the 24-hour time period that immediately precedes the hour of admission.

On February 11, 1998, we published a final rule (63 FR 6864), that responded to public comments received on a prior interim final rule on this policy. In that final rule, we confirmed that ambulance services and chronic maintenance of renal dialysis services are excluded from the 3-day payment window. This final rule with comment period also clarified that the payment window applies to outpatient services that are otherwise billable under Part B and does not apply to nonhospital services that are generally covered under Part A (such as home health, skilled nursing facility, and hospice). In addition the rule clarified the terms ''wholly owned or operated'' and ''admission-related'' for nondiagnostic services.

The 1998 final rule (63 FR 6866) defined an entity as wholly owned or wholly operated if a hospital has direct ownership or control over another entity's operations. Specifically, 42 CFR 412.2(c)(5)(i) states, ''An entity is wholly owned by the hospital if the hospital is the sole owner of the entity. An entity is wholly operated by a hospital if the hospital has exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity.'' The 1998 final rule also stated ''that we have defined services as being related to the admission only when there is an exact match between the ICD–9–CM diagnosis code assigned for both the preadmission services and the inpatient stay'' and that ''[a]'' hospital-owned or hospital-operated physician clinic or practice is subject to the payment window provision.'' Therefore, related preadmission nondiagnostic services provided by a wholly owned or wholly operated physician clinic or practice are also included in the 3-day (or 1-day) payment window policy, and services were considered related when there was an exact match between ICD–9 CM diagnosis codes for the outpatient encounter and the inpatient admission.

Prior to the June 25, 2010 enactment of section 102(a)(1) of PACMBPRA (Pub. L. 111–192), the payment window policy for preadmission nondiagnostic services was rarely applied in the wholly owned or operated physician's office or clinic because, as we previously noted, 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 be subject to the policy. Because the policy applied only in such narrow circumstances, until the recent statutory change, we have not provided further guidance to wholly owned or wholly operated physician offices on how nondiagnostic services are to be included on hospital bills when the 3-day payment window applied. However, the statutory change to the payment window policy made by Pub. L. 111–192 significantly broadened the definition of nondiagnostic services that are subject to the payment window to include any nondiagnostic service that is clinically related to the reason for a patient's inpatient admission, regardless of whether the inpatient and outpatient diagnoses are the same.

The FY 2012 IPPS proposed (76 FR 25960) and final rules (76 FR 51705) further discuss the application of the 3-day payment window for both preadmission diagnostic and related nondiagnostic services furnished to a patient at wholly owned or wholly operated physician practices after June 25, 2010. We do not know how many physician offices are wholly owned or wholly operated. Our expectation is that most hospital-owned entities providing outpatient services would be considered part of the hospital, likely as an outpatient department, and not as separate physician clinics or practices or other entities such as clinical laboratories. However, we believe there may be at least some hospital clinics that meet the definition of a wholly owned or wholly operated physician practice. When a physician furnishes a service in a hospital, including an outpatient department of a hospital, Medicare pays the physician under the physician fee schedule, generally at a facility-based payment rate that is lower than the ''nonfacility'' payment rate in order to avoid duplication of payment for supplies, equipment, and staff that are paid directly to the hospital by Medicare.

3. Applicability of the 3-Day Payment Window Policy for Services Furnished in Physician Practices

In circumstances where the 3-day payment window applies to nondiagnostic services related to an inpatient admission furnished in a wholly owned or wholly operated physician practice, we proposed that Medicare would make payment under the physician fee schedule for the physicians' services that are subject to the 3-day payment window at the facility rate. As explained more fully later in this section, the services that are subject to the 3-day payment window would be billed to Medicare in a similar manner to services that are furnished in a hospital, including an outpatient department of a hospital. We proposed that, effective on or after January 1, 2012, when a physician furnishes services to a beneficiary in a hospital's wholly owned or wholly operated physician practice and the beneficiary is admitted as an inpatient within 3 days (or, in the case of non-IPPS hospitals, 1 day), the payment window will apply to all diagnostic services furnished and to any nondiagnostic services that are clinically related to the reason for the patient's inpatient admission regardless of whether the reported inpatient and outpatient diagnosis codes are the same.

Comment: A few commenters expressed concern over the proposed phrase of ''physician clinics or practices,'' suggesting that CMS proposed to define the application of this provision too narrowly because the statutory provision on the 3-day payment window refers to ''entity'' and not specifically to physician clinics or practices. Another commenter suggested the phrase ''Free-standing facility or clinic'' to be more appropriate for the 3-day window payment policy, and refers CMS to the definition of ''Free-standing facility'' set forth in 42 CFR 413.65(a)(2).

Response: We appreciate commenters' attention to the discrepancy between the proposed term ''physician clinics or practices'' and the statutory reference to ''entity,'' and we agree that Public Law 111–192 applies the 3-day payment window policy to services related to the admission including all diagnostic services and clinically related services that are not diagnostic services, other than ambulance and maintenance renal dialysis services, for which payment may be made under Medicare Part B and that are provided by a hospital (or an entity wholly owned or operated by the hospital) to a patient. We agree with commenters that the statute does not limit this provision solely to physician offices or clinics. The term ''entity'' applies to Part B entities that provide diagnostic or related nondiagnostic services which would include a host of entities including clinical laboratory facilities and ambulatory surgical centers, and any other entity providing Part B outpatient services. If these entities are wholly owned or wholly operated by a hospital per the definitions set forth in the 1998 IPPS final rule (63 FR 6866), the 3-day payment window would apply to the preadmission diagnostic and nondiagnostic services provided by those entities when those preadmission services are clinically related to a patients inpatient admission within the payment window. We will amend our proposed regulation text defining facility practice expense RVUs to use the term ''entity'' in § 414.22(b)(5)(1)(A) instead of ''physician practice'' as proposed ''(A) the facility PE RVUs apply to services furnished to patients in the hospital, skilled nursing facility, mental health center, ambulatory surgical center, or in a wholly owned or wholly operated entity furnishing preadmission services pursuant to § 412.2(c)(5).''

The principal focus of our CY 2012 proposed rule and our discussion in the IPPS FY 2012 final rule with comment period was on physician offices and clinics. We are concerned that hospitals may not realize that some of the services provided by wholly owned or wholly operated entities that might furnish preadmission services, other than physician practices and clinics, such as ambulatory surgical centers, are subject to the payment window. The purpose of this discussion in the CY 2012 PFS proposed rule was to address how a wholly owned or wholly operated physician practice would bill for professional and technical services when provided within the 3-day payment window. We believe that physician practices are the majority of wholly hospital owned or wholly operated Part B entities providing nondiagnostic services that are related to an inpatient admission. We previously addressed applicability of the payment window policy to wholly owned or wholly operated entities in our 1998 final rule, and at that time emphasized that diagnostic services are always included in the 3-day payment window (75 FR 6866). In this final rule with comment period, we are addressing the policy's application to entities that are wholly owned or wholly operated physician practices and clinics, and we note that wholly owned or wholly operated entities providing diagnostic services always have been subject to the payment window. We encourage hospitals to bring any other wholly owned or wholly operated Part B entities into compliance with the 3-day payment window policy as discussed in this final rule. If needed, we will address specifics related to other Part B entities in future rulemaking.

Although rural health clinics (RHCs) and Federally qualified health centers (FQHCs) would be considered ''entities,'' we are not applying the 3-day payment window policy to these entities. Medicare pays RHCs and FQHCs for their services through an all-inclusive rate that incorporates payment for all covered items and services provided to a beneficiary on a single day by an RHC/FQHC physician, physician assistant, nurse practitioner, clinical nurse midwife, clinical psychologist, clinical social worker, or visiting nurse; and related services and supplies (Publication 100–04 (Medicare Claims Processing Manual), chapter 19, section 20.1). RHCs and FQHCs can only bill and be paid for services included in their all-inclusive rate. Although the majority of those services are professional services, it is impossible to distinguish within the all-inclusive rate the amount of the payment for any particular patient that represents the professional versus the technical portion. As previously discussed, the 3-day payment window policy requires a hospital to include in its bill for an inpatient admission the technical portion of any outpatient diagnostic services and admission-related nondiagnostic services provided during the preadmission payment window. Professional services are not considered to be operating costs of inpatient hospital services and, accordingly, are not subject to the 3-day payment window policy. Given that the 3-day payment window policy does not include professional services, and that RHCs and FQHCs are paid an all-inclusive rate within which the professional and technical portions are indeterminate, we do not consider RHC or FQHC services to be subject to the 3-day payment window policy. However, if in the future RHCs or FQHCs are no longer paid an all-inclusive rate, but rather, under a prospective or other payment system that allows distinction between the PC and TC for services, the 3-day payment policy would apply in these settings In addition the list of covered services paid through the RHC and FQHC benefits is relatively small. Practitioners who furnish additional services in RHCs or FQHCs bill Medicare Part B for any additional

services provided to a Medicare beneficiary during an RHC or FQHC visit. Any such additional services would not be considered RHC or FQHC services, but rather, would be considered the practitioner's services. If a patient is admitted as an inpatient, the additional services payable under Part B are subject to the 3-day payment window. With regard to the comment suggesting that we adopt the definition of ''free-standing facility'' in lieu of the term wholly owned or wholly operated entity, we believe the reference under section 1886(a)(4) of the Act to ''an entity wholly owned or operated by the hospital'' was intended to identify entities that have a significant degree of integration with the hospital but, for whatever reason, are not considered provider-based. As such, we do not believe it would be appropriate ''to use the term ''free-standing facility'' to describe wholly owned or wholly operated entities. As defined in § 412.2 (c)(5)(i), an entity is considered wholly owned or wholly operated by the hospital, and preadmission services furnished by the entity are subject to 3-day payment window policy, if the hospital is the sole owner of the entity or if the hospital has exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority ''over the entity.'' We continue to believe that this is the appropriate description of entity wholly owned or operated by the hospital.

Comment: Several commenters requested that CMS distinguish wholly owned and wholly operated physician practices from ''provider based'' physician practices and confirm that the proposed 3-day window payment policy makes no change in how provider-based physician practices currently bill Medicare for physician and non-physician practitioner services.

Response: As described previously, we believe the statutory reference in section 1886(a)(4) to an entity wholly owned or wholly operated by the hospital was not intended to identify provider-based entities. Rather, we believe the language was intended to identify entities that have a significant degree of integration with the hospital but, for whatever reason, are not considered to have provider-based status. As previously discussed, a hospital must include on the hospital claim for a Medicare beneficiary's inpatient stay, the technical portion of any outpatient diagnostic services and admission-related nondiagnostic services provided by the hospital, or by an entity that is wholly owned or wholly operated by the hospital, during the payment window. Entities with provider-based status are considered to be part of the hospital and the hospital should already be including costs of related outpatient services provided within the 3-day payment window on the claim for the inpatient admission. We agree with the commenters that the proposed 3-day window payment policy, adopted in this final rule with comment period, makes no change in how provider-based physician practices currently bill Medicare for the professional work of physician and non-physician practitioner services Those services are not subject to the 3-day payment window policy.

Comment: A number of commenters wanted CMS to further define admission-related nondiagnostic services. Some commenters encouraged CMS to return to the definition of admission-related that requires an exact match on the ICD–9–CM diagnosis codes for the inpatient and outpatient claims. They suggested that if an exact match is no longer an appropriate definition of nondiagnostic admission-related, CMS should develop some equally clear and easy standard. Some commenters went on to suggest that CMS identify all the nondiagnostic services that should be considered ''clinically related'' to an inpatient admission and subject to the 3-day payment window payment policy.

Response: We have stated that ''an outpatient service is related to the admission if it is clinically associated with the reason for a patient's inpatient admission'' (75 FR 50347). We believe that determining whether an outpatient service is ''clinically related'' requires knowledge of the specific clinical circumstances surrounding a patient's inpatient admission and can only be determined on a case by case basis. In the August 16, 2010 interim final rule with comment period (75 FR 50348), we indicated that we would develop a process for hospitals to attest on the outpatient hospital claim that nondiagnostic services are not clinically related to the admission when the hospital believes that certain provided outpatient services are unrelated. We discuss that mechanism for hospital billing of unrelated nondiagnostic services in the FY 2012 final rule (76 FR 51708). We also indicated that a hospital 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. Because the 3-day payment window applies equally to services provided by the hospital or the hospital's wholly owned or wholly operated entities, we would expect hospitals to make the same determination and documentation for services provided by wholly owned or wholly operated entities. Therefore, we expect hospitals and their wholly owned and wholly operated entities to ascertain whether nondiagnostic services provided in the 3-day payment window are clinically related to the subsequent inpatient admission given the context of the patient's unique clinical circumstances. If the nondiagnostic services are related, we expect the wholly owned or wholly operated entity to use the appropriate payment modifier, discussed in greater detail under section V.B.3.a of this final rule with comment period, to indicate that services are clinically related to the subsequent inpatient admission. If the nondiagnostic services are not clinically related, we would expect the hospital or wholly owned or wholly operated entity to document the reason those services are not clinically related in the beneficiary's medical record, and we would expect the wholly owned or wholly operated entity to receive the full nonfacility payment for provided services. We note that all diagnostic services provided in the 3-day payment window prior to an inpatient admission are subject to the 3-day payment window policy.

a. Payment Methodology

In the proposed rule, we indicated that we would establish a new Medicare HCPCS modifier that will signal claims processing systems to provide payment to wholly owned or wholly operated entities at the facility rate. We proposed to pay only the Professional Component (PC) for CPT/HCPCS codes with a Technical Component (TC)/PC split that are provided in the 3-day (or, in the case of non-IPPS hospitals, 1-day) payment window in a hospital's wholly owned or wholly operated physician practice. We proposed to pay at the facility rate for codes without a TC/PC split to avoid duplicate payment for the technical resources required to provide the preadmission services as those costs will be included on the hospital's inpatient claim for the related inpatient admission. The facility rate includes physician work, malpractice, and the facility practice expense, which is a payment to support services provided by the physician office when a physician treats patients at another facility. We proposed to modify our regulation at § 414.22(b)(5)(i), which defines the sites of service that result in a facility practice expense RVU for payment, to add an entity that is wholly

owned or wholly operated by a hospital, as defined in § 412.2(c)(5)(ii) when that entity furnishes preadmission services.

We indicated in the proposed rule that we would establish a new HCPCS modifier through sub-regulatory guidance. We said that we would require that this modifier be appended to the physician preadmission diagnostic and admission-related nondiagnostic services, reported with HCPCS codes, which are subject to the 3-day payment window policy. We stated that each wholly owned or wholly operated physician's practice would need to manage its billing processes to ensure that it billed for its physician services appropriately when a related inpatient admission has occurred.

We stated that the hospital will be responsible for notifying the practice of related inpatient admissions for a patient who received services in a wholly owned or wholly operated physician practice within the 3-day (or, when appropriate, 1-day) payment window prior to the inpatient stay. We proposed to make the new modifier effective for claims with dates of service on or after January 1, 2012, and we proposed that wholly owned or wholly operated physician practices would receive payment at the facility rate for related nondiagnostic services and receive payment for only the professional component for diagnostic services effective for services furnished on or after January 1, 2012.

Comment: Many commenters expressed concern that CMS has ''erred in their assumptions'' that the costs of preadmission services provided in entities wholly owned or wholly operated by a hospital are ''costs of the hospital.'' A few commenters suggested that it would be unlikely that outpatient visits furnished in a wholly owned or wholly operated entity would be documented in the medical record or captured in the hospital's accounting system before the inpatient admission and therefore, would not be properly included on the hospital's cost report. These commenters requested that CMS provide specific instructions on how hospitals should include the technical component costs of the physician office visit on hospital cost reports. Finally, a few commenters requested clarification on whether the facility cost involved with services furnished at a wholly owned or wholly operated entity are taken into account in determining prospective hospital inpatient payment under the IPPS. Another commenter asserted that even if the hospital includes charges for the wholly owned or wholly operated entity on the hospital's inpatient claim, the hospital's inpatient payment will not reflect this change until the costs are reflected in historical data used to calculate the prospective inpatient payment rates.

Response: We expect hospitals to include the technical component portion of all diagnostic and clinically related nondiagnostic services furnished by wholly owned or wholly operated entities in the 3-day payment window on their cost report. Hospitals should accumulate the costs incurred and the adjustments required for these services and report as costs with related organizations on the Medicare cost report. The costs for these services should be reported on the Medicare cost report as routine and/or ancillary accordingly, to achieve a proper matching of revenues and expenses. Each year, the IPPS uses the most recent full year of cost report data available to establish the relative cost-based weights. For example, for the FY 2012 IPPS update, we used data from cost reports that began during FY 2009, that is, on or after October 1, 2008 and before October 1, 2009, in computing the relative weights.

We expect that the cost of diagnostic and related nondiagnostic services that are provided in wholly owned or wholly operated entities during the 3-day payment window will be included in the data used to determine future IPPS relative payment weights. This cycle of having costs and charges reflected in the payment rates for future years is part of the longstanding methodology behind setting hospital prospective payment rates. Hospitals should already be including the costs of diagnostic services furnished by wholly owned or wholly operated entities on their cost report because the 3-day payment window policy for diagnostic services is longstanding. Furthermore, we note that the inclusion of charges for diagnostic and related nondiagnostic services that are provided in wholly hospital owned or wholly operated entities during the 3-day payment window on an inpatient claim could increase the probability that the claim for the inpatient admission would garner outlier payments.

Comment: Many commenters requested that CMS delay implementation a full year so that hospitals and wholly owned or wholly operated entities may appropriately develop internal claims processing procedures to ensure hospital/entity coordination when billing services subject to the payment window. Many commenters objected to CMS's proposal to allow each wholly owned or wholly operated physician practice to manage its billing practices and requested additional guidance from CMS to ensure that they bill appropriately and for requiring that the hospital be responsible for notifying the physician practice of an inpatient admission. Several commenters noted that physician practices may use independent software systems for patient registration, scheduling, billing, and accounting and went on to stress that the coordination efforts to ensure appropriate billing will be a substantial burden on both the hospital and the physician practice and that CMS is essentially asking practices to hold claims for all Medicare encounters at least 7 to 10 days after every office service is rendered.

Response: We appreciate commenters concerns for implementation and understand that each wholly owned or operated entity will face unique operational challenges as they incorporate the 3-day payment window policy into billing practices. While we understand that some entities may need to hold claims for a longer time period to comply with the policy, we note that the 3-day payment window policy is a hospital requirement. We believe that hospitals can assist their wholly owned or wholly operated entities in managing the unique aspects of billing for services subject to the payment window policy. In light of the consistent message from commenters that the billing and accounting systems are not yet coordinated, we are concerned that many hospitals and their wholly owned or wholly operated entities will not be able to establish the internal procedures and communication pathways needed to comply with the law by January 1, 2012. For this reason we will delay implementation until July 1, 2012.

Beginning on January 1, 2012, CMS payment modifier PD (Diagnostic or related nondiagnostic item or service provided in a wholly owned or wholly operated entity to a patient who is admitted as an inpatient within 3 days, or 1 day) will be available, and wholly owned or wholly operated entities should begin to append the modifier to claims subject to the 3-day payment window at that time. We expect that hospitals and their wholly owned or wholly operated entities will continue working toward establishing internal processes to ensure compliance with section 102 of PACMBPRA as quickly as possible to achieve coordinated billing for services subject to the 3-day payment window policy. We will require hospitals and their wholly owned or wholly operated entities to fully coordinate their billing and to properly bill for diagnostic and related nondiagnostic services subject to the

3-day payment window policy beginning July 1, 2012. We encourage hospitals to adjust their internal processes as quickly as possible to ensure a smooth implementation.

With regard to the comment that the hospital should not need to notify its wholly owned or wholly operated entities, we note that the 3-day payment policy implemented on October 1, 1991, is an existing statutory requirement located in the statutory definition of hospital operating costs, and that the purpose of this final rule is to clarify the implementation of the policy when a entity that is wholly owned or wholly operated by a hospital furnishes preadmission diagnostic and related nondiagnostic services to a patient who is later admitted as an inpatient within the payment window. In the FY 2012 IPPS final rule we responded to a comment on this topic, stating that because 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 (76 FR 51709).

Comment: One commenter asked if the ''minimally necessary'' privacy standard required by Health Insurance Portability and Accountability Act (HIPAA) would be met if hospital registration staff could access the patient database at a physician's office.

Response: We believe that neither hospital nor entity staff would violate a patient's privacy by notifying each other about admissions or furnished services for purposes of coordinating billing under the 3-day payment window policy. Wholly owned or wholly operated entities can exchange this information for billing purposes. The HIPAA regulations at 45 CFR §§ 164.502 and 164.506 allow a covered entity to use or disclose protected health information for ''treatment, payment, or health care operations.'' HIPAA covered entities should be able to carry out these requirements in accordance with those provisions.

Comment: A few commenters expressed concern that if a hospital fails to notify the wholly owned or operated practice of an inpatient admission, and if the practice submits the claim to Medicare without the appropriate modifier, the practice risks an overpayment or charges of filing a false claim.

Response: We expect hospitals and wholly owned or operated entities to ensure that claims submitted to Medicare for payment are in compliance with Medicare policy. We are delaying our proposed implementation from January 1, 2012 to July 1, 2012 to give hospitals and their wholly owned or wholly operated entities sufficient time to develop a compliant billing system and to develop a coordinated billing practice to ensure correct use of the new payment modifier. We would expect entities that find they have billed in error to submit a replacement claim, but we would expect this to be a rare occurrence.

Comment: A few commenters inquired about physicians billing for subordinate personnel under an ''incident to'' arrangement for purposes of the 3-day payment window policy in the nonfacility setting. Commenters also asked if drug and biological therapies were considered services subject to the payment window policy, and a few commenters specifically asked if CMS will deny Medicare payments for the TC for any diagnostic imaging or diagnostic testing provided within the 3-days of a hospital admission.

Response: The 3-day payment window makes no change to how an entity bills for physician services in the nonfacility setting. If, for example, an admitted hospital inpatient received services at a wholly owned or wholly operated entity prior to his admission, and some of those services were delivered by a nurse incident to the physician's service, the physician would still bill for those services under the 3-day payment window policy. The 3-day payment window applies to all diagnostic and related nondiagnostic services provided within the window, including drug therapies and imaging services, assuming those services are related to the inpatient admission.

We realize that the time frames associated with the global surgical package for many surgical services could overlap with the 3-day (or 1-day) payment window policy. Global surgical payment rules apply to major and minor surgeries, and endoscopies. Section 40.1 of the Claims Processing Manual (100–04 chapter 12 Physician/Nonphysician Practitioners) defines the global surgical package. Procedures can have a global surgical period of 0, 10, or 90-days. Generally, the global period for major surgeries is 1 day prior to the surgical procedure and 90 days immediately following the procedure. For minor surgeries, the global period is the day of the procedure and 10 days immediately following the procedure.

Medicare payment for the global surgical package is based on the typical case for a procedure, and includes preoperative visits, intra-operative services, and complications following surgery, postoperative visits, postsurgical pain management, supplies, and miscellaneous other services such as dressing changes and removal of sutures or staples. Medicare makes a single payment to the treating physician (or group practice) for the surgical procedure and any of the pre- and post-operative services typically associated with the surgical procedure provided within the global surgical period (10 or 90-days). The same section of the Claims Processing Manual (100–04 chapter 12 Physician/Nonphysician Practitioners) also discusses the services that are not included in payment for the global surgical period. In general, these services are unrelated to the surgery, are diagnostic or are part of the decision to pursue surgery, or are related to the surgery but are so significant they warrant an additional payment. Some examples of services not included in payment for the global surgical period include the initial evaluation of the problem by the surgeon to determine the need for major surgery; services of another physician; visits unrelated to the diagnosis for the surgical procedure unless the visits occur due to surgical complications; treatment that is not part of the normal recovery from surgery; diagnostic tests; distinct surgical procedures that are not re-operations; treatment for postoperative complications that require a return trip to the operating room; critical care unrelated to the surgery where a seriously injured or burned patient is critically ill and requires the constant attention of the physician; and immunosuppressive therapy for organ transplants.

The time frames for application of the 3-day payment window and the global surgical package could overlap. In some cases, the application of the 3-day payment window is straightforward. For example, a patient could have minor surgery in a wholly owned or wholly operated physician's office and, due to complications, need to be admitted within 3-days to an acute care hospital paid under the IPPS for follow-up surgery. Under the 3-day payment window policy, the practice expense portion of the initial surgery and any pre- and post-operative visits associated with the surgery (both those subject to the global surgery rules and separate diagnostic procedures) should be included on the hospital's Part A claim for the inpatient admission. The wholly owned or wholly operated physician practice would bill for the surgery performed for the inpatient as well as for the initial surgical procedure performed in the physician practice that

started the global period. The wholly owned or wholly operated physician practice would apply the HCPCS modifier to indicate that the 3-day payment window applies to each of those services. Medicare would pay the physician practice for the initial surgical procedure and the related procedure following inpatient admission at the facility rate. Finally, any preadmission diagnostic tests conducted by the wholly owned or wholly operated physician practice in the 3-day payment window would be included on the physician practice's claim with the HCPCS modifier, and Medicare would pay the wholly owned or wholly operated physician practice only the professional portion of the service.

However, the situation could arise where a global surgical period overlaps with the 3-day payment window, but the actual surgical procedure with the global surgical package occurred before the 3-day payment window. In this case, several post-operative services, such as follow-up visits, would occur during the global period, but the surgeon would not bill separately for those services. We proposed that services with a global surgical package would be subject to the 3-day payment window policy when wholly owned or wholly operated physician practices furnish preadmission diagnostic and nondiagnostic services that are clinically related to an inpatient admission when the date of the actual surgical procedure falls within the 3-day payment window policy. However, when the actual surgical procedure for a service that has a global surgical package is furnished on a date that falls outside the 3-day payment window, the 3-day window policy would not apply. We do not believe it would be appropriate to require the wholly owned or wholly operated physician practice to unbundle the post operative services associated with the global surgical procedure so that the practice expense portion of those services could be paid under the PFS at the facility rate and the costs included on the hospital's inpatient claim. However, any service that a wholly owned or wholly operated physician practice would bill separately from the global surgical package, such as a separate initial evaluation of a problem by the surgeon to determine the need for surgery or separate diagnostic tests, would continue to be subject to the 3-day payment window policy.

We did not receive any comments on our proposal to include diagnostic and related nondiagnostic services with a global surgical package in the 3-day payment window when the date of the surgical procedure falls within the 3 day payment window, and we are finalizing our policy without modification.

b. Identification of Wholly Owned or Wholly Operated Physician Practices

The 1998 final rule (63 FR 6864) defined wholly owned or wholly operated as a hospital's direct ownership or control over another entity's operations. In that rule, we added the regulation at 42 CFR 412.2(c)(5)(i) which states, ''An entity is wholly owned by the hospital if the hospital is the sole owner of the entity. An entity is wholly operated by a hospital if the hospital has exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity.''

Physician practices self-designate whether they are owned or operated by a hospital during the Medicare enrollment process. Currently, a physician practice enrolls in Medicare with CMS form ''855B.'' This enrollment form reports pertinent practice information such as ownership, organizational structure, and operational duties. Likewise, hospitals enroll in Medicare using CMS form ''855A'' also reporting pertinent hospital information such as ownership, organizational structure and operational duties. Medicare Administrative Contractors update files of physician practices that are owned and operated by hospitals, and the files of hospitals that own those physician practices, in their claims processing systems and use that data to confirm an ownership relationship for identified physician practices. We will investigate the feasibility of establishing national system edits within the Common Working File to fully identify whether a physician practice is wholly owned or wholly operated by a hospital and to associate such practice with its affiliated hospital.

Comment: Many commenters requested further clarification of the definition of ''wholly owned or wholly operated.'' A few commenters encouraged CMS to adopt the definition of ''wholly-owned'' as the term is described in 42 CFR 413.65(e)(1) which states ''The business enterprise is 100 percent owned by the main provider'' while other commenters requested examples of ownership interest and requested that CMS display a list of hospitals and their wholly owned or wholly operated entities. Other commenters encouraged CMS to modify the definition of ''wholly operated'' to provide more granularity than simply stating ''conducting and overseeing the entity's routine operations.''

Response: While we appreciate commenters' suggestions on revising the definition of wholly owned or wholly operated, section 102 of the PACMBPRA only clarified the scope of services furnished to Medicare beneficiaries within the 3-days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) preceding an inpatient admission that should be considered ''operating costs of inpatient hospital services'' and, therefore, included in the hospital's inpatient payment. In describing the scope of services subject to the 3-day window policy, section 102 did not change the existing statutory reference to ''an entity wholly owned or operated by the hospital.'' We have had in place longstanding definitions of these terms and, therefore, we did not propose a change to our longstanding definitions. We continue to believe that our longstanding definitions are consistent with the statute and appropriately descriptive for this purpose. Therefore, we will retain our current definitions.

The 3-day payment window policy has been applicable for all preadmission diagnostic and related nondiagnostic services provided by wholly owned or wholly operated entities for over a decade. In 1998, we clarified the definition of ''wholly owned'' and ''wholly operated,'' and we responded to comments on specific owner and operator relationships (63 FR 6866). In this rule, we discussed several different illustrative examples of ownership and operational interests and how the 3-day payment window will apply in each circumstance. These examples provide guidelines to help each entity determine whether they believe they are wholly owned or wholly operated by a hospital. For ease of reference, we are reprinting those responses here:

- Arrangement: A hospital owns a physician clinic or a physician practice that performs preadmission testing for the hospital. Policy: 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 in the inpatient bill and may not be billed separately. A physician's professional service is not subject to the window.
- Arrangement: Hospital A owns Hospital B, which in turn owns Hospital C. Does the payment window apply if preadmission services are performed at Hospital C and the patient is admitted to Hospital A? Policy: Yes. We would consider that Hospital A owns both

Hospital B and Hospital C, and the payment window would apply in this situation.

• Arrangement: Corporation Z owns Hospitals A and B. If Hospital A performs preadmission services and the patient is subsequently admitted as an inpatient to Hospital B, are the services subject to the payment window? Policy: No. The payment window does not apply to situations in which both the admitting hospital and the entity that furnishes the preadmission services are owned by a third entity. The payment window includes only those situations in which the entity furnishing the preadmission services is wholly owned or operated by the admitting hospital itself.

• Arrangement: A hospital refers its patient to an independent laboratory for preadmission testing services. The laboratory does not perform testing by arrangement with the admitting hospital. Are the laboratory services subject to the payment window provisions? Policy: No. The payment window does not apply to situations in which the admitting hospital is not the sole owner operator of the entity performing the preadmission testing.

• Arrangement: Hospital A is owned by Corporations Y and Z in a joint venture. Corporation Z is the sole owner of Hospital B. Does the payment window apply when one of these hospitals furnishes preadmission services and the patient is admitted to the other hospital? Policy: No. As noted previously, the payment window provision does not apply to situations in which both the admitting hospital and the entity that furnishes the preadmission services are owned or operated by a third entity.

• Arrangement: A clinic is solely owned by Corporation Z and is jointly operated by Corporation Z and Hospital A. Does the payment window apply if preadmission services are furnished by the clinic and the patient is subsequently admitted to Hospital A? Policy: No. The payment window does not apply because Hospital A is neither the sole owner nor operator of the clinic.

Comment: Some commenters caution CMS about using the 855 form as a definitive source of information on the owner and operator status of a physician practice or other entity stating, correctly, that the 855 forms do not indicate whether a practice is wholly owned or wholly operated. Commenters suggest that CMS will need a different mechanism to identify ownership interests.

Response: We agree that the 855 forms are not a complete record of wholly owned or wholly operated status, but we believe they may furnish contractors with some information to indicate entities with wholly owned or wholly operated status. We encourage entities to contact their Medicare claims processing contractor to update any 855 information that may be incomplete or out of date.

After consideration of the public comments we received, we are finalizing our proposal with clarification of the term ''entity'' and a modification of the implementation date from January 1, 2012 to July 1, 2012. The 3-day payment window policy applies to nondiagnostic services that are clinically related to an inpatient admission when preadmission services are furnished in a wholly owned or wholly operated entity and the patient is later admitted as an inpatient within the payment window. In such cases, Medicare will make payment for the preadmission services under the physician fee schedule at the facility rate. Specifically, a new Medicare HCPCS modifier PD will be available to wholly owned or wholly operated entities beginning January 1, 2012 and may be appended to Part B claims lines to identify preadmission services that are subject to the 3-day window policy. However, we will not formally implement the PD modifier for use by wholly hospital owned or wholly operated entities until July 1, 2012 in order to provide wholly owned or operated entities sufficient time to coordinate their billing practices for clinically related nondiagnostic preadmission services. The PD modifier will signal claims processing systems to provide payment only for the PC for CPT/HCPCS codes with a TC/PC split and to pay services without a PC/TC split at the facility rate when they are provided in the 3-day (or, in the case of non-IPPS hospitals, 1-day) payment window. The facility rate will be paid for codes without a TC/PC split to avoid duplicate payment for the technical resources required to provide the services. We agree with commenters that the statutory term ''entity'' is broader than physician practices or clinics. Accordingly, we are modifying our proposal to revise our regulatory definition of facility practice expense RVUs at section 42 CFR 414.22 by revising paragraph (b)(5)(i)(A) to include a wholly owned or wholly operated entity. In addition, the technical costs of diagnostic and related nondiagnostic services of the wholly owned or wholly operated entity subject to the 3-day payment window shall be included on the hospital's inpatient claim for the related inpatient admission and reflected appropriately on the hospital cost report. The definitions of ''wholly owned'' and ''wholly operated'' continue to be those set forth in the 1998 IPPS final rule (63 FR 6864), and this policy makes no change to the requirement that all diagnostic services furnished during the 3-day payment window must be included on the hospital claim for the inpatient admission.

C. Therapy Services—Outpatient Therapy Caps for CY 2012

Section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) applies an annual, per beneficiary combined cap on expenses incurred for outpatient physical therapy and speech-language pathology services under Medicare Part B. A separate but identical cap also applies for outpatient occupational therapy services under Medicare Part B. The caps apply to expenses incurred for therapy services furnished in outpatient settings, other than in an outpatient hospital setting which is described under section 1833(a)(8)(B) of the Act. The caps were in effect during 1999, from September 1, 2003 through December 7, 2003, and continuously beginning January 1, 2006. The caps are a permanent provision, that is, there is no end date specified in the statute for therapy caps.

Beginning January 1, 2006, the DRA provided for exceptions to the therapy caps until December 31, 2006. Provisions for the exceptions process for therapy caps was further extended through December 31, 2010 pursuant to four subsequent amendments (in MEIA–TRHCA, MMSEA, MIPPA, and Affordable Care Act). Section 1833(g)(5) of the Act (as amended by section 104 of the MMEA) extended the exceptions process for therapy caps through December 31, 2011.

The therapy cap amounts are required to be updated each year based on the MEI. The updated cap amount for CY 2012 is computed by multiplying the cap amount for CY 2011, which is $1,870, by the MEI for CY 2012, and rounding to the nearest $10. This amount is added to the CY 2011 cap to obtain the CY 2012 cap. Since the MEI for CY 2012 is 0.6 percent, the therapy cap amount for CY 2012 is $1,880.

Our authority to provide for exceptions to therapy caps (independent of the statutory exclusion for outpatient hospital therapy services) will expire on December 31, 2011, unless the Congress acts to extend it. If the current exceptions process expires, the caps will be applicable in accordance with

the statute, except for services furnished and billed by outpatient hospital departments.

IV. Other Provisions of the Final Rule

A. Part B Drug Payment: Average Sales Price (ASP) Issues

Section 1847A of the Act requires use of the average sales price (ASP) payment methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology applies to most drugs furnished incident to a physician's service, drugs furnished under the DME benefit, certain oral anti-cancer drugs, and oral immunosuppressive drugs.

1. Widely Available Market Price (WAMP)/Average Manufacturer Price (AMP)

Section 1847A(d)(1) of the Act states that ''The Inspector General of HHS shall conduct studies, which may include surveys, to determine the widely available market prices (WAMP) of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.'' Section 1847A (d)(2) of the Act states, ''Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the ASP under this section for drugs and biologicals with—

- The widely available market price (WAMP) for these drugs and biologicals, (if any); and
- The average manufacturer price (AMP) (as determined under section 1927(k) (1) of the Act) for such drugs and biologicals.''

Section 1847A(d)(3)(A) of the Act states that, ''The Secretary may disregard the ASP for a drug or biological that exceeds the WAMP or the AMP for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).'' Section 1847A(d)(3)(C) of the Act states that if the Inspector General (OIG) finds that the ASP for a drug or biological is found to have exceeded the WAMP or AMP by this threshold percentage, the OIG ''shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological, the lesser of—

- The widely available market price for the drug or biological (if any); or
- 103 percent of the average manufacturer price as determined under section 1927(k)(1) of the Act for the drug or biological.''

The applicable threshold percentage is specified in section 1847A(d)(3)(B)(i) of the Act as 5 percent for CY 2005. For CY 2006 and subsequent years, section 1847A(d)(3)(B)(ii) of the Act establishes that the applicable threshold percentage is ''the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the WAMP or the AMP, or both.'' In the CY 2006 (70 FR 70222), CY 2007 (71 FR69680), CY 2008 (72 FR 66258), CY 2009 (73 FR 69752), and CY 2010 (74 FR 61904) PFS final rules with comment period, we specified an applicable threshold percentage of 5 percent for both the WAMP and AMP. We based this decision on the fact that data was too limited to support an adjustment to the current applicable threshold percentage.

For CY 2011, we proposed to specify two separate adjustments to the applicable threshold percentages. When making comparisons to the WAMP, we proposed the applicable threshold percentage to remain at 5 percent. The applicable threshold percentage that we proposed for the AMP is addressed later in this section of the preamble. The latest WAMP comparison was published in 2008, and the OIG is continuing to perform studies comparing ASP to WAMP. Based on available OIG reports that have been published comparing WAMP to ASP, we did not have sufficient information at the time to determine that the 5 percent threshold percentage is inappropriate and should be changed. As a result, we believed that continuing the 5 percent applicable threshold percentage for the WAMP was appropriate for CY 2011. Therefore, we proposed to revise § 414.904(d)(3) to specify the 5 percent WAMP threshold for CY 2011. After soliciting and reviewing comments, we finalized our proposal to continue the 5 percent WAMP threshold for CY 2011 (75 FR 73469).

For CY 2012, we again proposed to specify a separate adjustment to the applicable threshold percentage for WAMP comparisons. When making comparisons to the WAMP, we proposed the applicable threshold percentage to remain at 5 percent. We still do not have sufficient information to determine that the 5 percent threshold percentage is inappropriate and, as a result, we believe that continuing the 5 percent applicable threshold percentage for the WAMP is appropriate for CY 2012. As we noted in the CY 2011 PFS final rule with comment period (75 FR 73470), we understand that there are complicated operational issues associated with the WAMP-based substitution policy. We continue to proceed cautiously in this area. We remain committed to providing stakeholders, including providers and manufacturers of drugs impacted by potential price substitutions with adequate notice of our intentions regarding such, including the opportunity to provide input with regard to the processes for substituting the WAMP for the ASP.

Comment: Several commenters supported maintaining the WAMP threshold at 5 percent, and not making price substitutions based on WAMP data until a framework has been developed, proposed, and finalized. Commenters agreed the price substitutions based on WAMP should be treated separately from substitutions based on AMP. Commenters also cited concerns about the lack of a specific definition for WAMP that would allow for the consistent collection of data and concerns about the time periods used by the OIG in their comparisons as reasons to further delay price substitutions based on WAMP. One commenter suggested incorporating a final check against WAMP into the AMP substitution policy that is discussed in the following sections.

Response: We agree with commenters concerns that the WAMP-based price substitutions currently are problematic. Unlike the OIG's AMP studies, the published WAMP studies do not show whether the prices for the examined groups of drugs consistently exceed the applicable percentage threshold across multiple quarters like the AMP studies. Because of the lack of data regarding WAMP to ASP comparisons and the dissimilar approaches in OIG studies, we will continue to treat WAMP separately from AMP in our ASP price substitution policies, and we will not implement a price substitution policy based on the comparison of WAMP to ASP at this time. For this reason, we decline to adopt the commenter's suggestion that we use WAMP as a final check on AMP-based price substitutions, which are discussed later in this rule. However, we will continue to work with the OIG and stakeholders to evaluate the relationship between WAMP and ASP, and based on comments, we will maintain the WAMP threshold at 5 percent. We will consider proposing a policy for the substitution of WAMP at a later date.

After reviewing the comments, we will continue to maintain separate price substitution policies for comparisons based on WAMP and AMP. We are finalizing our proposal to continue the 5 percent WAMP threshold for CY2012

and regulation text at 42 CFR 414.904(d)(3)(iv).

2. AMP Threshold and Price Substitutions

As mentioned previously in section V.A.1. of this final rule with comment period, when making comparisons of ASP to AMP, the applicable threshold percentage for CY 2005 was specified in statute as 5 percent. Section 1847A(d)(3) of the Act allows the Secretary to specify adjustments to this threshold percentage for years subsequent to 2005. For CY 2006 (70 FR 70222), CY 2007 (71 FR 69680), CY 2008 (72 FR 66258), CY 2009 (73 FR 69752), and CY 2010 (74 FR 61904), the Secretary made no adjustments to the threshold percentage; it remained at 5 percent.

For CY 2011, we proposed, with respect to AMP substitution, to apply the applicable percentage subject to certain adjustments such that substitution of AMP for ASP will only be made when the ASP exceeds the AMP by 5 percent in two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter. We further proposed to apply the applicable AMP threshold percentage only for those situations where AMP and ASP comparisons are based on the same set of National Drug Codes (NDCs) for a billing code (that is, ''complete'' AMP data).

Furthermore, we proposed a price substitution policy to substitute 103 percent of AMP for 106 percent of ASP for both multiple and single source drugs and biologicals as defined respectively at section 1847(A)(c)(6)(C) and (D) of the Act. Specifically, we proposed that this substitution—

- Would occur when the applicable threshold percentage has been met for two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter;
- Would permit for a final comparison between the OIG's volume-weighted 103 percent of AMP for a billing code (calculated from the prior quarter's data) and the billing code's volume weighted 106 percent ASP (as calculated by CMS for the current quarter) to avoid a situation in which the AMP-based price substitution would exceed that quarter's ASP; and
- That the duration of the price substitution would last for only one quarter.

We also sought comment on other issues related to the comparison between ASP and AMP, such as the following—

- Any effect of definitional differences between AMP and ASP, particularly in light of the definition of AMP as revised by section 2503 of the Affordable Care Act;
- The impact of any differences in AMP and ASP reporting by manufacturers on price substitution comparisons; and
- Whether and/or how general differences and similarities between AMP and manufacturer's ASP would affect comparisons between these two.

In the CY 2011 PFS final rule with comment, we did not finalize our proposed adjustments to the 5 percent AMP threshold or our price substitution policy because of legislative changes, regulatory changes, and litigation that affected this issue. Specifically—

- A preliminary injunction issued by the United States District Court for the District of Columbia in National Association of Chain Drug Stores et al v. Health and Human Services, Civil Action No. 1:07–cv–02017 (RCL) was still in effect;
- We were continuing to expect to develop regulations to implement section 2503 of the Affordable Care Act, which amended the definition of AMP, and section 202 of the Federal Aviation Administration Air Transportation Modernization and Safety Improvement Act (Pub. L. 111–226) as enacted on August 10, 2010, which further amended section 1927(k) of the Act; and
- We proposed to withdraw certain provisions of the AMP final rule published on July 17, 2007 (75 FR 54073).

As a result, we finalized the portion of our proposal that sets the AMP threshold at 5 percent for CY 2011 and revised the regulation text accordingly (75 FR 73471).

The preliminary injunction was vacated by the United States District Court for the District of Columbia on December 15, 2010. Currently, we continue to expect that regulations to implement section 2503 of the Affordable Care Act and section 202 of the Federal Aviation Administration Air Transportation Modernization and Safety Improvement Act will be developed. However, these statutory amendments became effective on October 1, 2010 without regard to whether or not final regulations to carry out such amendments have been promulgated by such date. Moreover, our Medicaid final rule published on November 15, 2010 finalized regulations requiring manufacturers to calculate AMP in accordance with section 1927(k)(1) of the Act (75 FR 69591). Since statutory and regulatory provisions exist and are currently utilized by manufacturers for the calculation and submission of AMP data, we revisited the AMP threshold and price substitution issues.

a. AMP Threshold

Section 1847A(d)(3) of the Act allows the Secretary to specify adjustments to the AMP threshold percentage for years subsequent to 2005, and to specify the timing for any price substitution. Therefore, for CY 2012, with respect to AMP substitution, we proposed (76 FR 42829) to apply the applicable percentage subject to certain adjustments. Specifically, a price substitution of AMP for ASP will be made only when the ASP exceeds the AMP by 5 percent in two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter.

In general, the ASP methodology reflects average market prices for Part B drugs for a quarter. The ASP is based on the average sales price to all purchasers for a calendar quarter. The AMP, in turn, primarily represents the average price paid by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturers, and also includes a subset of drugs sold to other purchasers. Accordingly, while the ASP payment amount for a billing code may exceed its AMP for that billing code for any given quarter, this may reflect only a temporary fluctuation in market prices that would be corrected in a subsequent quarter. We believe this is demonstrated by how few billing codes exceed the applicable threshold percentage over multiple quarters. For example, in the Inspector General's report ''Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2009,'' only 11 of 493 examined billing codes exceeded the applicable threshold percentage over multiple quarters (OEI–03–10–00380). We are concerned that substitutions based on a single quarter's ASP to AMP comparison will not appropriately or accurately account for temporary fluctuations. We believe that applying this threshold percentage adjusted to reflect data from multiple quarters will account for continuing differences between ASP and AMP, and allow us to more accurately identify those drugs that consistently trigger the substitution threshold and thus warrant price substitution.

We further proposed to apply the applicable AMP threshold percentage only for those situations where AMP and ASP comparisons are based on the same set of NDCs for a billing code (that

is, ''complete'' AMP data). Prior to 2008, the OIG calculated a volume-weighted AMP and made ASP and AMP comparisons only for billing codes with such ''complete'' AMP data. In such comparisons, a volume-weighted AMP for a billing code was calculated when NDC-level AMP data was available for the same NDCs used by us to calculate the volume-weighted ASP. Beginning in the first quarter of 2008, the OIG also began to make ASP and AMP comparisons based on ''partial'' AMP data (that is, AMP data for some, but not all, NDCs in a billing code). For these comparisons, the volume-weighted AMP for a billing code is calculated even when only such limited AMP data is available. That is, the volume-weighted AMP calculated by the Inspector General is based on fewer NDCs than the volume-weighted ASP calculated by CMS. Moreover, volume-weighted ASPs are not adjusted by the Inspector General to reflect the fewer number of NDCs in the volume-weighted AMP.

Because the OIG's partial AMP data comparison did not reflect all of the NDCs used in our volume-weighted ASP calculations, we discussed our concern about using the volume-weighted AMP in the CY 2011 PFS proposed rule. We believed that such AMP data may not adequately account for market-related drug price changes and may lead to the substitution of incomplete and inaccurate volume-weighted prices. Payment amount reductions that result from potentially inaccurate substitutions may impact physician and beneficiary access to drugs. Therefore, consistent with our authority as set forth in section 1847A(d)(1) and (3) of the Act, we proposed in the CY 2011 PFS proposed rule that the substitution of 103 percent of AMP for 106 percent of ASP should be limited to only those drugs with ASP and AMP comparisons based on the same set of NDCs.

In response to our CY 2011 proposed rule, the OIG changed its methodology for ''partial'' AMP data comparisons beginning with its report titled ''Comparison of First-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2010.'' Specifically, in addition to calculating a volume-weighted AMP based on ''partial'' data and identifying billing codes that exceeded the price substitution threshold, the OIG began to replace each missing NDC-level AMP with corresponding NDC-level ASP data. The OIG then calculated a volume-weighted AMP for the billing code. If the volume-weighted AMP continued to exceed the price substitution threshold, the report attributed this to an actual difference between ASPs and AMPs in the marketplace (OEI–03–10–00440).

We appreciate that the Inspector General has acknowledged the importance of protecting beneficiary and physician access in its methodology change. However, section 1847(A)(d)(2)(B) of the Act specifically indicates that the comparison be made to AMP as determined under section 1927(k)(1) of the Act. Moreover, we continue to be concerned that comparisons based on partial AMP data may not adequately account for market-related drug price changes and may lead to the substitution of incomplete and inaccurate volume-weighted prices. Therefore, for CY 2012, we proposed to apply the applicable AMP threshold percentage only for those situations where AMP and ASP comparisons are based on the same set of NDCs for a billing code (that is, ''complete'' AMP data). Furthermore, we proposed to revise § 414.904(d)(3) to reflect corresponding regulatory text changes.

Comment: One commenter supported the proposal to continue the use of a 5 percent applicable AMP threshold percentage. However, one commenter expressed specific concerns that a 5 percent threshold might not be accurate for CY 2012 given the changes to the statutory definition of AMP and the lack of detailed guidance available to the public about the reporting of AMP. Other commenters also expressed more general concerns about what they described as potential changes to the relationship of ASP and AMP because of the statutory changes to the definition of AMP.

Response: We will discuss general comments on the relationship of AMP and ASP in the following sections. With respect to the applicable AMP threshold percentage, we have no specific information that indicates that the threshold percentage should be modified at this time and we agree with the comment supporting the continued use of the 5 percent threshold. The 5 percent threshold has been in place since CY 2005.

Comment: Several commenters agreed with the concept of safeguards or limits on the application of AMP-based price substitutions. The commenters specifically agreed with basing price comparisons (and related calculations) on the same sets of NDCs because it is a more exact comparison than the use of unmatched sets of NDCs and is expected to more accurately reflect trends in the marketplace. One comment also suggested that AMP and ASP be calculated using the same sales volumes.

Response: We will discuss comments about additional safeguards we will use in the application of AMP based price substitutions, including duration of the substitution, and the exclusion of codes that exceed AMP for only one quarter in the following sections. We agree that the use of ''complete'' AMP data is likely to provide a more accurate comparison than the use of unmatched sets of NDCs, and we believe that the use of ''complete'' data will result in consistent volume weighting for ASP and AMP.

After reviewing the public comments, we are finalizing the 5 percent threshold for AMP comparisons for CY 2012 and the corresponding regulation text at 42 CFR 414.904(d)(3)(iii) as proposed, except that we are correcting one typographical error in which we referred to ASP instead of AMP. We are also finalizing the proposal that specifies that the AMP for a billing code is calculated using the same set of NDCs used to calculate the ASP for the billing code and corresponding regulation text at 42 CFR 414.904(d)(3)(iii)(B).

b. AMP Price Substitution

(1) Inspector General Studies

Section 1847A(d) of the Act requires the Inspector General to conduct studies of the widely available market price for drugs and biologicals to which section 1847A of the Act applies. However, it does not specify the frequency of when such studies should be conducted. The Inspector General has conducted studies comparing AMP to ASP for essentially each quarter since the ASP system has been implemented. Since 2005, the OIG has published 25 reports pertaining to the price substitution issue (see Table 36), of which 23 have identified billing codes with volume-weighted ASPs that have exceeded their volume-weighted AMPs by the applicable threshold percentage.

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TABLE 36: PUBLISHED OIG REPORTS ON PRICE SUBSTITUTIONS

Date	Report Title
8/2011	Comparison of First Quarter 2011 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2011 (OEI-03-11-00540)
7/2011	Comparison of Fourth Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2011 (OEI-03-11-00360)
5/2011	Comparison of Third-Quarter 2010 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2011 (OEI-03-11-00160)
4/2011	Comparison of Average Sales Prices and Average Manufacturer Prices: An overview of 2009 (OEI-03-10-00380)
2/2011	Comparison of Second-Quarter 2010 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2010 (OEI-03-11-00030)
11/2010	Comparison of First-Quarter 2010 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2010 (OEI-03-10-00440)
7/2010	Comparison of Fourth-Quarter 2009 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2010 (OEI-03-10-00350)
4/2010	Comparison of Third-Quarter 2009 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2010 (OEI-03-10-00150)
2/2010	Comparison of Average Sales Prices and Average Manufacturer Prices: An overview of 2008 (OEI-03-09-00350)
1/2010	Comparison of Second-Quarter 2009 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2009 (OEI-03-09-00640)
8/2009	Comparison of First-Quarter 2009 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2009 (OEI-03-09-00490)
8/2009	Comparison of Fourth-Quarter 2008 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2009 (OEI-03-09-00340)
4/2009	Comparison of ThirdQuarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for first Quarter 2009 (OEI-03-09-00150)
2/2009	Comparison of SecondQuarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2008 (OEI-03-09-00050)
12/2008	Comparison of FirstQuarter 2008 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2008 (OEI-03-08-00530)
12/2008	Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2007 (OEI-03-08-00450)

Date	Report Title
8/2008	Comparison of Fourth-Quarter 2007 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2008 (OEI-03-08-00340)
7/2008	A comparison of average sales price to widely available market prices for inhalation drugs (OEI-03-07-00190)
5/2008	Comparison of Third-Quarter 2007 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2008 (OEI-03-08-00130)
12/2007	Comparison of Second-Quarter 2007 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2007 (OEI-03-08-00010)
9/2007	Comparison of First-Quarter 2007 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2007 (OEI-03-07-00530)
7/2007	Comparison of Third-Quarter 2006 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2007 (OEI-03-07-00140)
7/2006	Comparison of Fourth-Quarter 2005 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2006 (OEI-03-06-00370)
6/2006	A Comparison of Average Sales Price to Widely Available Market Prices: Fourth Quarter 2005 (OEI-03-05-00430)
4/2006	Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Price to Average Manufacturer Prices (OEI-03-04-00430)

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In the quarterly report comparing AMP to ASP, titled ''Comparison of Third-Quarter 2010 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2011'' (OEI–03–11–00160), the Inspector General found that of 365 billing codes with ''complete'' AMP data in the third quarter of 2010, only 14 met the 5 percent threshold; that is, ASP exceeded AMP by at least 5 percent. Eight of these 14 billing codes also exceeded the AMP by at least 5 percent in one or more of the previous four quarters; only two drugs had ASPs that exceeded the 5 percent threshold in all four quarters under review. This Inspector General report further indicates that, ''If reimbursement amounts for all 14 codes with complete AMP data had been based on 103 percent of the AMPs during the first quarter of 2011, we estimate that Medicare expenditures would have been reduced $10.3 million in that quarter alone.'' The savings found by the Inspector General constitute potential savings for the Medicare program and beneficiaries. Since the publication of the proposed rule, the OIG has released two additional AMP comparison studies (OEI–03–11–00540, and OEI–03–11–00360)., Report OEI–03–11–00360, entitled ''Comparison of Fourth Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2011,'' has findings that indicate the potential for cost savings through the implementation of price substitution, and it states that ''of the 338 drug codes with complete AMP data, 15 exceeded the 5 percent threshold. If reimbursement amounts for all 15 codes had been based on 103 percent of the AMPS in the second quarter of 2011, Medicare would have saved an estimated $1.3 million. Under CMS proposed price substitution policy, reimbursement amounts for 5 of the 15 drugs would have been reduced, saving an estimated $554,000.'' The more recent report describes more modest cost savings than the report cited in the proposed rule.

(2) Proposal

As discussed previously, section 1847A(d)(3) of the Act provides authority for us to determine the applicable percentage subject to ''such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.'' We also have authority to specify the timing of any ASP substitution. Consistent with this authority, we proposed a policy to substitute 103 percent of AMP for 106 percent of ASP where the applicable percentage threshold has been satisfied for the two consecutive quarters immediately prior to the current pricing quarter, or for three of the previous four quarters immediately prior to the current pricing quarter. This policy would apply to single source drugs and biologicals, multiple source drugs, and biosimilar biological products as defined at section 1847A(c)(6)(C), (D), and (H) of the Act.

Comment: As mentioned previously, several commenters agreed with the concept of safeguards or limits on the application of AMP-based price substitutions. Of the commenters who specifically discussed the duration of ASP deviations above AMP, all agreed that deviations lasting only one quarter could be attributed to temporary market changes or fluctuations and should not trigger a piece substitution. There were no comments regarding which subsets of part B drugs or biologicals that the policy should apply to.

Response: We agree with the commenters and believe that focusing on those drugs that consistently exceed the applicable percentage threshold over multiple quarters is appropriate because we believe such an approach will minimize the potential for disruption to

access in cases of temporary market fluctuations.

After reviewing the public comments, we are finalizing our proposal that implements the substitution of 103 percent of AMP for 106 percent of ASP where the applicable percentage threshold has been satisfied for the two consecutive quarters immediately prior to the current pricing quarter, or for three of the previous four quarters immediately prior to the current pricing quarter and corresponding regulation text at 42 CFR 414.904(d)(3)(iii)(A). This policy will apply to single source drugs and biologicals, multiple source drugs, and biosimilar biological products as defined at section 1847A(c)(6)(C), (D), and (H) of the Act.

(3) Timeframe for and Duration of Price Substitutions

As stated in § 414.804(a)(5), a manufacturer's average sales price must be submitted to CMS within 30 days of the close of the quarter. We then calculate an ASP for each billing code in accordance with the process outlined at § 414.904. Then, as described in our CY 2005 PFS final rule (69 FR 66300), we implement these new prices through program instructions or otherwise at the first opportunity after we receive the data, which is the calendar quarter after receipt.

Section 1847A(d)(3)(C) of the Act indicates that a price substitution would be implemented ''effective as of the next quarter'' after the OIG has informed us that the ASP for a drug or biological exceeds its AMP by the applicable percentage threshold. The OIG does not receive new ASPs for a given quarter until after we have finalized our calculations for the quarter. Also, the results of the OIG's pricing comparisons are not available until after the ASPs for a given quarter have gone into effect. Therefore, we anticipate that there will be a three-quarter lag for substituted prices from the quarter in which manufacturer sales occurred, though this will depend in great part upon the timeframe in which we obtain comparison data from the OIG. Table 37 provides an example of this timeframe.

Comment: Two commenters expressed concern about the three quarter lag, how the duration disconnects price substitution policy from the marketplace, and the potential for divergence between ASP and AMP during the lag period. One commenter suggested that the proposal not be implemented unless a shorter turnaround could be put in place; one commenter stated that the lag should not exceed the ASP methodology's two quarter lag. Another commenter stated that the associated regulation text at 42 CFR 414.904(d)(iii)(A) may not accurately describe the timeframes for the comparisons because the comparison is not actually done using data from quarters that immediately precede the substitution.

Response: In developing our policy, we carefully considered the lag associated with the AMP based price substitution. ASPs reported to the OIG incorporate a two quarter lag between the reported sales and the time that an ASP is posted. Section 1847A(d)(3)(C) of the Act provides that the Secretary substitute prices as of the next quarter after the OIG informs the Secretary that the ASP exceed the AMP by the applicable threshold. This results in a minimum of a three quarter lag from the date that manufacturer sales occurred for the price substituted products and the price substitution. Given the current operational environment and the statutory requirement to implement price substitutions after the OIG provides information about drugs for which ASP exceed AMP by the applicable threshold (which is also reflected in regulation text at 42 CFR 414.904(d)(i)), it is not possible to reduce the lag at this time. We disagree with the assertion that the regulation text does not accurately describe the time frame for our price substitution policy. Our policy for comparisons between AMP and ASP is discussed later in this preamble and reflects the use of data from the most recent quarter where OIG data and ASPs are available.

TABLE 37: EXAMPLE PRICE SUBSTITUTION TIMEFRAME

	Q2-11	Q3-11	Q4-11	Q1-12
ASP Process	Manufacturer sells drug.	Manufacturer submits Q2-11 pricing data. CMS calculates ASP payment limits for Q4-11 and publishes Q4-11 payment limits.	Q4-11 payment limits apply.	Q1-12 payment limits apply, including any adjusted payment limit resulting from the price substitution.
			CMS calculates ASP payment limits for Q1-12. Compares calculated payment limits to OIG substitute prices. Publishes Q1-12 prices that may include OIG substitute prices.	
OIG Process		OIG receives Q4-11 payment limits from CMS and compares them to Q2-11 volume-weighted AMP data.	OIG notifies CMS of HCPCS for which Q4-11 ASP exceeds Q2-11 AMP by the applicable percentage threshold.	

Given this lag in time, the ASP for a billing code may have decreased since the OIG's comparison. Therefore, consistent with our authorities in section 1847A(d)(3) of the Act and our desire to provide accurate payments consistent with these provisions, we believe that the timing of any substitution policy should permit a final comparison between the OIG's volume-weighted 103 percent AMP for a billing code (calculated from the data from sales three quarters prior) and the billing code's volume-weighted 106 percent ASP (as calculated by CMS for the upcoming quarter). In Table 37 for example, this comparison would be done between the HCPCS payment limits calculated for Q1–12, and the OIG's volume-weighted AMPs from their examination of Q4–11 payment limits. This final comparison would assure the Secretary that the 106 percent ASP payment limit for the current pricing quarter continues to exceed 103 percent of the OIG's calculated AMP in order to avoid a situation in which the Secretary would inadvertently raise the Medicare payment limit through this price substitution policy. We specifically requested comments on this proposal.

Comment: We did not receive any specific comments about this issue. However several commenters touched on issues related to the final comparison. One commenter expressed concerns that there is no mechanism to rescind a substitution, while another comment remarked about the fact that AMPs could be restated for up to 12 quarters, and stated the assumption that a restated AMP would be used in the final comparison. Another commenter (discussed in section VI.A.1. of this final rule with comment period) suggested that WAMP be incorporated into the proposed final check.

Response: We appreciate the comments that have asked us to consider additional limits or safeguards related to the implementation of the AMP-based price substitution. As we developed the details of this proposal, we considered the lag period and the impact of brief periods where ASP exceeds AMP by more than the threshold percentage. At this time we still believe that when all of our limits (the comparison of ''complete'' AMP data against ASPs for the same NDCs, the 5 percent threshold, the requirement that ASP exceed the threshold for more than one quarter, and the final check against 106 percent of ASP that would otherwise be applied in a quarter) are considered together, they create satisfactory safeguards to prevent the inadvertent or unnecessary triggering of a price substitution, which, in turn, could affect provider payments and access to drugs. We also do not believe that additional limits or safeguards, particularly ones that have not already been proposed, should be applied at this time because they will not be subject to public comment.

We would like to clarify that our approach utilizes the OIG's calculation of AMP and does not incorporate the use of restated AMPs. We are not persuaded to incorporate restated AMPs into the calculation because, as discussed earlier in the rule and noted by commenters, AMP can fluctuate from quarter to quarter. The use of a restated AMP would require additional calculations and the incorporation of additional analysis similar to the safeguards finalized in this rule that confirm that the AMP to ASP comparison is not just a one quarter fluctuation that may not represent the actual state of the marketplace. The use of restated AMPs may also lead to comparisons that are beyond the 3 quarter lag and changes the comparison from one based on a single quarter to being based on potentially changing data; the ASP methodology generally relies on data from a single time period. We believe that additional pricing variations, which could result from the use of restated AMPs over multiple quarters could further increase providers' uncertainty about payment rates. The final comparison between the OIG's volume-weighted 103 percent AMP for a billing code (calculated from the data from sales three quarters prior) and the billing code's volume-weighted 106 percent ASP (as calculated by CMS for the upcoming quarter) is intended to minimize the effect of the three quarter lag and further minimize the effect of AMP fluctuation on our substitution policy, and we believe that this final check, as well as the additional safeguards described in this rule, are sufficient. An additional check based on restated AMP is not necessary at this time.

After reviewing the public comments, we are finalizing our proposal regarding the final comparison between AMP and ASP and the related regulation text at 42 CFR 414.904(d)(3)(ii)(B).

ASP payment limits are calculated on a quarterly basis as per section 1847A(c)(5)(A) of the Act, and we are particularly mindful that the ASP-based payment allowance for a billing code may change from quarter to quarter. As such, we proposed that any price substitution based on the comparison that triggered its application would last for one quarter.

Comment: Several commenters supported the one quarter duration for the price substitution.

Response: We agree with the comments. No commenters provided alternatives to the one quarter duration of the price substitution.

We are finalizing the one quarter duration for AMP-based price substitutions and the related regulation text at § 414.904(d)(3)(i). We note that in a subsequent quarter, the OIG may identify that a volume-weighted ASP continues to exceed the volume-weighted AMP for a billing code that previously triggered a price substitution. In this scenario, if the criteria for the price substitution policy are met, we would substitute 103 percent of the OIG's updated volume-weighted AMP for that billing code.

(4) Implementation of AMP-Based Price Substitution and the Relationship of ASP to AMP

In the preceding section, we have discussed various details, limitations, and safeguards regarding the AMP-based price substitutions. In general, comments regarding these items supported our proposals regarding those items, and agreed that we were being consistent with the cautious approach described in the proposal and previous rules. In this section, we will discuss whether the AMP based price substitutions should be implemented in CY 2012.

In general, we believe that our proposal to substitute 103 percent of AMP for 106 percent of ASP provides us with a viable mechanism for generating savings for the Medicare program and its beneficiaries because it will allow Medicare to pay based on lower market prices for those drugs and biologicals that consistently exceed the applicable threshold percentage. Moreover, it will enable us to address a programmatic vulnerability identified by the OIG.

In the CY 2010 proposed rule, we sought comment on other issues related to the comparison between ASP and AMP, and in the CY 2012 proposed rule we sought comments on the following issues again—

- The effect of definitional differences between AMP and ASP, particularly in light of the definition of AMP as revised by section 2503 of the Affordable Care Act;
- The impact of any differences in AMP and ASP reporting by manufacturers on price substitution comparisons; and
- Whether and/or how general differences and similarities between AMP and manufacturer's ASP would affect comparisons between these two.

Although most commenters agree with specific details of our proposals that we described and finalized, nearly all of the commenters were concerned about the impact of recent changes to the definition of AMP and how they would affect the relationship of AMP to ASP.

Comment: Comments disagreeing with the proposed CY 2012 implementation of the AMP-based price substitution policy generally related to the three previous bullet points and cited the following concerns:

- A lack of experience with the new definitions of AMP and an incomplete understanding of the relationship between ASP and the new definitions of AMP by the industry and CMS, particularly for AMP reporting of drugs with payment limits that are determined under the ASP methodology. Commenters indicated that the definition of AMP in the Affordable Care Act that describes drugs sold to retail community pharmacies is expected to increase AMP, but commenters expressed uncertainty about how the updated definition in the FAA Air Transportation Modernization and Safety Improvement Act would affect the AMP/ASP relationship.
- A lack of guidance in recent rulemaking and statutory provisions about assumptions that manufacturers should use in order to uniformly calculate AMP. In particular, commenters were concerned about how the phrase ''not generally dispensed through a retail community pharmacy,'' which was added in the updated definition of AMP in the FAA Air Transportation Modernization and Safety Improvement Act, might be defined in rulemaking;
- Uncertainty about how future rulemaking regarding the AMP would affect the ASP/AMP relationship;
- Inconsistency in how AMP and ASP incorporate prompt pay discounts; and
- Concern about any further reductions in payments to providers, particularly small practices and the potential effect on access to care.

Commenters also stated that implementation of a price substitution policy in 2012 was not consistent with the ''slow and cautious'' approach that we have described in previous rulemaking. They recommended delaying the implementation of a price substitution policy until additional guidance about AMP has been finalized and more experience has been gained.

Response: We agree that the definition of AMP has continued to evolve over time. The updated definitions of AMP in section 2503 of the Affordable Care act and section 202 of the Federal Aviation Administration Air Transportation Modernization and Safety Act (which includes injected, infused, implanted, instilled, and inhaled drugs) became effective on October 1, 2010 and remain in effect at this time. Although rulemaking that

pertains to specific issues and operational details regarding manufacturer reporting of AMP is pending, the current reporting process, including the updated definitions of AMP, is in place. Although we appreciate the comments that recommended that we delay the implementation of the AMP-based price substitution policy until a later time, we do not believe implementation of a price substitution policy should be further delayed for a number of reasons.

First, we disagree that implementation of the policy in CY 2012 is inconsistent with a slow and cautious approach regarding price substitution. While additional guidance and experience with the new definitions of AMP would be helpful, our 6-years' experience in monitoring AMP and ASP have shown that very few ASP payment limits exceed the existing AMP threshold (even absent the safeguards that we are finalizing in this rule). Moreover, most of the drugs that exceed the threshold in previous reports are infrequently used. We understand that the updated definition of AMP encompasses sales of injected, infused, instilled, inhaled, and implanted drugs that are not generally dispensed through a retail community pharmacy, including a wider range of customers and discounted sales to non-pharmacy entities, and commenters' concerns that implementation of the most recent definition could decrease AMP for certain drugs. However, we do not have any specific information from commenters that persuades us to believe that the AMP-based price substitution policy will be applied frequently or to high cost/high volume items, despite the changes to the definition of AMP. Therefore, we believe that proceeding with implementation in 2012 is consistent with a slow and cautious approach toward this policy.

Second, we have worked closely with the OIG and have reviewed 25 price substitution reports from the OIG over the past 6 years. The drugs and biologicals identified as candidates for price substitution were typically uncommonly used and many were inexpensive items. Based on this experience, we do not believe that this policy will substantially affect providers' financial situation, access to care for beneficiaries, the payment rate for highly utilized and expensive drugs and biologicals, or the manufacturers of these items. Further, we are finalizing in this rule additional safeguards to prevent the triggering of the price substitutions for drugs that do not consistently exceed the AMP threshold. We believe these safeguards are both consistent with a cautious approach and provide assurance that the price substitution policy will be applied only when appropriate.

Finally, while the Affordable Care Act did change the definition of AMP, and AMP data captures sales differently than ASP, the Congress did not modify its mandate that the OIG compare AMP to ASP for purposes of section 1847A(d)(3), nor did it change how prompt pay discounts are treated under ASP. Thus, in our view, the statute requires the Secretary to use AMP, as modified by the Affordable Care Act and updated by the FAA Air Transportation Modernization and Safety Improvement Act, as the basis for a comparison value and an alternative payment limit for ASP, and we will not make further revisions to the proposed implementation of this policy at this time. We appreciate the comments that we have received regarding this proposal and we look forward to continuing to work with the OIG and stakeholders on this matter.

In summary we are finalizing the implementation of an AMP based substitution policy to substitute 103 percent of AMP for 106 percent of ASP beginning in CY 2012 and proposed regulation text at 42 CFR 414.904(d)(3), as described in the ASP section of this rule. We note that although this policy will become effective on January 1, 2012, because of the three quarter lag, the earliest that price substitutions could occur is April 1, 2012.

Comment: Several commenters were also concerned that there is no mechanism for public notification and comments in advance of specific substitutions. Two commenters requested that CMS allow for dialogue about specific substitutions between the manufacturer and CMS.

Response: Although there is no statutory requirement that CMS notify the public about specific price substitutions or to accept comments regarding specific substitutions, we agree that public notification about specific price substitutions is important and will help us operate in a transparent manner. CMS will post a list of the HCPCS codes for which the policy is applied at the time that a quarter's ASPs are first posted to the CMS ASP Web site (*http://www.cms.gov/McrPartBDrugAvgSalesPrice/*). This will provide approximately two weeks' notice before the substituted payment amount goes into effect. Our experience with ASP has shown that this two week notification regarding ASPs has provided stakeholders with time to comment and inquire about potential problems regarding the new quarter's prices, and time for CMS to respond. We will accept inquiries about the list at the CMS ASP emailbox at *sec303aspdata@cms.hhs.gov.* However, we have not proposed, nor are we implementing, a mechanism for dialogue with stakeholders regarding specific substitutions, such as formal dispute resolution procedures, due to the relatively tight timeframe and commenters' concerns about further increasing the lag period.

3. ASP Reporting Update

a. ASP Reporting Template Update

For purposes of this part, unless otherwise specified, the term ''drugs'' will hereafter refer to both drugs and biologicals. Sections 1847A and 1927(b) of the Act specify quarterly ASP data reporting requirements for manufacturers. Specific ASP reporting requirements are set forth in section 1927(b)(3) of the Act. For the purposes of reporting under section 1847A of the Act, the term ''manufacturer'' is defined in section 1927(k)(5) of the Act and means any entity engaged in the following: Production; preparation, propagation, compounding, conversion or processing of prescription drug products; either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. The term manufacturer does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. However, manufacturers that also engage in certain wholesaler activities are required to report ASP data for those drugs that they manufacture. Note that the definition of manufacturers for the purposes of ASP data reporting includes repackagers.

Section 1927(b)(3)(A)(iii) of the Act specifies that manufacturers must report their average sales price and the number of units by NDC. As established by 42 CFR part 414 subpart J, manufacturers are required to report data at the NDC level, which includes the following elements: (1) The manufacturer ASP; (2) the Wholesale Acquisition Cost (WAC) in effect on the last day of the reporting period; (3) the number of units sold; and (4) the NDC. The reported ASP data are used to establish the Medicare payment amounts.

Section 1927(b)(3)(A)(iii)(II) of the Act specifies that the manufacturer must report the WAC if it is required for payment to be made under section 1847A of the Act. In the 2004 IFC that

implemented the ASP reporting requirements for Medicare Part B drugs and biologicals (66 FR 17935), we specified that manufacturers must report the ASP data to CMS using our Addendum A template. In 2005, we expanded the template to include WAC and additional product description details (70 FR 70221). We also initiated additional changes to the template in 2008 (73 FR 76032).

In order to facilitate more accurate and consistent ASP data reporting from manufacturers, we have proposed additional revisions to the Addendum A template. Specifically, we have proposed to revise existing reporting fields and add new fields to the Addendum A template as follows—

- To split the current NDC column into three separate reporting fields, corresponding to the three segments of an NDC;
- To add a new field to collect an Alternate ID for products without an NDC; and
- To expand the current FDA approval number column to account for multiple entries and supplemental numbers.

We have also added a macro to the Addendum A template that will allow manufacturers to validate the format of their data prior to submission. This will help verify that data are complete and submitted to CMS in the correct format, thereby minimizing time and resources spent on identifying mistakes or errors. We note that the use of this macro does not preclude or supersede manufacturers' responsibility to provide accurate and timely ASP data in accordance with the reporting obligation under section 1927(b)(3) of the Act. We also note that manufacturers who misrepresent or fail to report manufacturer ASP data will remain subject to civil monetary penalties, as applicable and described in sections 1847A and 1927(b) of the Act and codified in regulations at § 414.806.

Comment: Two commenters requested that the ''Alternate ID'' field be increased to a 23-character capacity from the proposed 13 character limit. Both commenters cited specific instances where their products are identified by an alpha-numeric identification that would exceed the limit of the proposed field.

Response: We agree with the importance of being able to accommodate Alternate IDs of various lengths. We have expanded the Alternate ID field to accommodate 23 characters. This will ensure the field is consistent with a variety of existing alternative product identifiers.

Comment: A commenter objected to the description in the revised Addendum A user guide regarding the inclusion of negative and zero values as valid ASP, Units, and WAC. The commenter stated that the required inclusion of all discounts in the ASP could create negative or zero ASP, Units or WAC values. They believed that negative numbers are invalid for these fields and urged CMS to revise the User Guide to indicate that negative values are not ''valid'' for ASP, ASP units, and WAC in Addendum A. They also requested that the Guide instead instruct manufacturers who have negative values to report ''0.000'' as manufacturers are instructed to do when they have no ASP, ASP units or WAC to report.

Response: We disagree with this comment. 1847A(c)(3) in the Act states, ''In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates * * *.'' This allows for lagged discounts, which may in turn create a negative ASP value. We therefore maintain the request for negative numbers within the User Guide and Addendum A template.

Comment: One commenter requested that the Agency provide the updated Addendum A template to manufacturers as soon as possible to facilitate internal system changes. The proposal for the reporting changes to be effective January 1, 2012 would appear to subject manufacturers to the new reporting format for the Q4 2011 reporting period due January 30, 2012. Manufacturers using their own systems, as well as those utilizing systems provided by a third party, will need adequate time to program and validate the system changes prior to the submission deadline.

Response: We agree with the need to give manufacturers as much time as possible to incorporate the revisions to the Addendum A template into their administrative systems. The finalized template will be posted online as soon as possible following the publication of the CY 2012 PFS final rule. However, we still require that this template be used to submit such data that is due at the end of January 2012. We also remind readers that submissions will continue to require certification that reported Average Sales Prices were calculated accurately and that all information and statements made in the submission are true, complete, and current.

In summary we are finalizing our proposal to amend the Addendum A template, including the use of a data validation macro and with the expansion of the ''Alternate ID'' field. The companion Users' Guide and other documents will be available on our ASP Web site: *https://www.cms.gov/McrPartBDrugAvgSalesPrice/* as soon as possible following the publication of this final rule.

b. Reporting of ASP Units and Sales Volume for Certain Products

As required by 42 CFR part 414 subpart J, manufacturers report ASP price and volume data at the NDC level. This is appropriate for most drug and biological products because an NDC is usually associated with a consistent amount of product that is being sold. Our experience with manufacturer reporting of ASPs has revealed that a limited number of drug products, as defined by an NDC, might contain a variable amount of active ingredient. This situation is common for plasma derived clotting factors; for example, we are aware of one product where a vial described as nominally containing 250 international units (IUs) of clotting factor activity might actually contain between 220 and 400 IUs. Although the exact factor activity is specified on the label, the amount of IUs contained in an NDC might vary between manufacturing lots. For these types of products, it is possible that vials with the same NDC but different amounts of clotting factor activity (as measured in IUs) might be sold during the same ASP reporting period. For drugs paid under Medicare Part B, such variability in the amount of drug product within an NDC appears to apply mostly to clotting factors that are prepared from plasma sources; it also applies to a few other products, including a plasma protein product used to treat antitrypsin deficiency.

As stated in the section 1847A(b)(2) of the Act, for years after 2004, the Secretary has the authority to ''establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement.'' There are limited situations when ASP price and volume reporting by product NDC may affect the accuracy of subsequent pricing calculations done by us (for example, when an NDC is associated with a variable amount of drug product as described in the paragraph previously). We believe that in such cases it is appropriate to amend the definition of the ASP unit associated with the NDC that is reported to us by manufacturers for the purposes of calculating ASP. Under the authority in the section

1847A(b)(2) of the Act, we proposed that we will maintain a list of HCPCS codes for which manufacturers report ASPs for NDCs on the basis of a specified unit. The specified unit will account for situations where labeling indicates that the amount of drug product represented by an NDC varies. Our initial list appears in Table 38 and is limited to items with variable amounts of drug product per NDC as described previously. However, we proposed to update this list as appropriate through program instruction or otherwise because we believe that the ability to make changes in a subregulatory manner will provide us with the flexibility to quickly and appropriately react to sales and marketing practices for specific drug products, including the introduction of new drugs or drug products. We plan to amend the list as necessary and to keep updates on the CMS ASP Web site at: *http://www.cms.gov/McrPartBDrugAvgSalesPrice/01_overview.asp.* Our proposal would be effective for ASP reports received on or after January 1, 2012 and would be reflected in our April 1, 2012 quarterly update.

In conjunction with the proposals in the preceding paragraph and the expectation that nearly all ASP price and sales volume reporting will continue to be at the NDC level (that is, the reported ASP sales and volume will be associated with a non-variable amount that is represented by the NDC), we proposed a clarification to existing regulation text at § 414.802. Current regulation text states that ''Unit means the product represented by the 11-digit National Drug Code.'' We proposed to update the definition to account for situations when an alternative unit of reporting must be used; the definition of the term unit will continue to be based on reporting of ASP data per NDC unless otherwise specified by CMS to account for situations where the amount of drug product represented by an NDC varies.

Comment: One commenter agreed with the proposal to revise reporting instructions for products which contain variable amounts of drug per NDC in order to align ASP reporting more closely with typical industry pricing conventions and to maintain the accuracy of ASP determinations, and recommended that CMS provide as much advance notice as possible about changes to the proposed list.

Response: Based on the comment, we will finalize this provision and the associated regulation text at 42 CFR 414.802 that defines an ASP ''unit.'' We plan to update the list of products that must be reported in units other than an NDC that is presented in Table 38, post it on the CMS ASP Web site (*http://www.cms.gov/McrPartBDrugAvgSalesPrice/*) soon after the rule is published, and incorporate updates for new products as discussed in the proposal.

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TABLE 38: HCPCS CODES FOR WHICH ASP REPORTING IS DONE IN UNITS OF MEASURE OTHER THAN AN NDC

2011 Code	2011 Long Descriptor	Reporting Unit
J0256	INJECTION, ALPHA 1 - PROTEINASE INHIBITOR - HUMAN, 10 MG	1MG
J1680	INJECTION, HUMAN FIBRINOGEN CONCENTRATE, 100 MG	1MG
J7184	INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMAN), WILATE, PER 100 IU VWF:RCO	1 IU VWF:RCO
J7185	INJECTION, FACTOR VIII (ANTIHEMOPHILIC FACTOR, RECOMBINANT) (XYNTHA), PER I.U.	1 IU
J7186	INJECTION, ANTIHEMOPHILIC FACTOR VIII/VON WILLEBRAND FACTOR COMPLEX (HUMAN), PER FACTOR VIII I.U.	1 IU
J7187	INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMATE-P), PER IU VWF:RCO	1 IU VWF:RCO
J7190	FACTOR VIII (ANTIHEMOPHILIC FACTOR, HUMAN) PER I.U.	1 IU
J7192	FACTOR VIII (ANTIHEMOPHILIC FACTOR, RECOMBINANT) PER I.U., NOT OTHERWISE SPECIFIED	1 IU
J7193	FACTOR IX (ANTIHEMOPHILIC FACTOR, PURIFIED, NON-RECOMBINANT) PER I.U.	1 IU
J7194	FACTOR IX, COMPLEX, PER I.U.	1 IU
J7195	FACTOR IX (ANTIHEMOPHILIC FACTOR, RECOMBINANT) PER I.U.	1 IU
J7197	ANTITHROMBIN III (HUMAN), PER I.U.	1 IU
J7198	ANTI-INHIBITOR, PER I.U. INJECTION, ANTITHROMBIN RECOMBINANT, 50 I.U.	1 IU

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The instructions for reporting products with variable amounts of drug product, along with general instructions on completing the revised ASP Data Form (Addendum A), will be delineated in a User Guide that will be available on the ASP Web site. In the User Guide, we will also be revising our instructions for the reporting of dermal grafting products as follows—

- If an NDC is not associated with a dermal grafting product, manufacturers should enter the UPC or other unique identifier (such as an internal product number) in the alternate ID column; and
- Manufacturers should report ASP prices and sales volumes for dermal grafting products in units of area by square centimeter.

The User Guide will be available on the CMS ASP Web site at: *http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01_overview.asp.* The Web site will also contain the revised ASP Data Form (Addendum A) and examples of how ASP data must be reported and formatted for submission.

We would also like to remind manufacturers that additional information about reporting ASP data to us is available (for examples, see the following: (69 FR 17936), (69 FR 66299), (70 FR 70215), (71 FR 69665), (72 FR 66256), (73 FR 69751), and (74 FR 61904)). Also, a link to the ASP Frequently Asked Questions (FAQs) is posted in the ''Related Links Inside CMS'' section of the ASP Overview Web page. We welcome comments on the ASP reporting proposals that are described in this section.

4. Out of Scope Comments

We received comments pertaining to: (1) Coding and pricing for new molecular diagnostic codes; (2) the continued use of G0440 and G0441 in 2012 as well as general comments on the coding and payment of skin substitute products; (3) updating supplying and dispensing fees for Part B drugs; (4) low reimbursement rates in a HCPCS-based claims systems for pharmacies and other community based practices; (5) the exclusion of prompt pay discounts from ASP calculations; and, (6) a request to pay all Part B drugs under the Part D benefit.

These comments are outside the scope of this rule, and therefore are not addressed in this final rule with comment period.

B. Discussion of Budget Neutrality for the Chiropractic Services Demonstration

Section 651 of MMA requires the Secretary to conduct a demonstration for up to 2 years to evaluate the feasibility and advisability of expanding coverage for chiropractic services under Medicare. Current Medicare coverage

for chiropractic services is limited to manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Act. The demonstration expanded Medicare coverage to include: ''(A) care for neuromusculoskeletal conditions typical among eligible beneficiaries; and (B) diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which such treatment is provided''. The demonstration was conducted in four geographically diverse sites, two rural and two urban regions, with each type including a Health Professional Shortage Area (HPSA). The two urban sites were 26 counties in Illinois and Scott County, Iowa, and 17 counties in Virginia. The two rural sites were the States of Maine and New Mexico. The demonstration, which ended on March 31, 2007, was required to be budget neutral as section 651(f)(1)(B) of MMA mandates the Secretary to ensure that ''the aggregate payments made by the Secretary under the Medicare program do not exceed the amount which the Secretary would have paid under the Medicare program if the demonstration projects under this section were not implemented.''

In the CY 2006, 2007, and 2008 PFS final rules with comment period (70 FR 70266, 71 FR 69707, 72 FR 66325, respectively), we included a discussion of the strategy that would be used to assess budget neutrality (BN) and the method for adjusting chiropractor fees in the event the demonstration resulted in costs higher than those that would occur in the absence of the demonstration. We stated that BN would be assessed by determining the change in costs based on a pre-post comparison of total Medicare costs for beneficiaries in the demonstration and their counterparts in the control groups and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We also stated that our analysis would not be limited to only review of chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs for other services.

In the CY 2010 PFS final rule with comment period (74 FR 61926), we discussed the evaluation of this demonstration conducted by Brandeis University and the two sets of analyses used to evaluate budget neutrality. In the ''All Neuromusculoskeletal Analysis,'' which compared the total Medicare costs of all beneficiaries who received services for a neuromusculoskeletal condition in the demonstration areas with those of beneficiaries with similar characteristics from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was $114 million higher costs for beneficiaries in areas that participated in the demonstration. In the ''Chiropractic User Analysis,'' which compared the Medicare costs of beneficiaries who used expanded chiropractic services to treat a neuromusculoskeletal condition in the demonstration areas, with those of beneficiaries with similar characteristics who used chiropractic services as was currently covered by Medicare to treat a neuromusculoskeletal condition from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was a $50 million increase in costs.

As explained in the CY 2010 PFS final rule, we based the BN estimate on the ''Chiropractic User Analysis'' because of its focus on users of chiropractic services rather than all Medicare beneficiaries with neuromusculoskeletal conditions, as the latter included those who did not use chiropractic services and who may not have become users of chiropractic services even with expanded coverage for them (74 FR 61926 through 61927). Users of chiropractic services are most likely to have been affected by the expanded coverage provided by this demonstration. Cost increases and offsets, such as reductions in hospitalizations or other types of ambulatory care, are more likely to be observed in this group.

As explained in the CY 2010 PFS final rule (74 FR 61927), because the costs of this demonstration were higher than expected and we did not anticipate a reduction to the PFS of greater than 2 percent per year, we finalized a policy to recoup $50 million in expenditures from this demonstration over a 5-year period, from CYs 2010 through 2014 (74 FR 61927). Specifically, we are recouping $10 million for each such year through adjustments to the chiropractic CPT codes. Payment under the PFS for these codes will be reduced by approximately 2 percent. We believe that spreading this adjustment over a longer period of time will minimize its potential negative impact on chiropractic practices.

We are continuing the implementation of the required budget neutrality adjustment by recouping $10 million in CY 2012. Our Office of the Actuary estimates chiropractic expenditures in CY 2012 will be approximately $470 million based on actual Medicare spending for chiropractic services for the most recent available year. To recoup $10 million in CY 2012, the payment amount under the PFS for the chiropractic CPT codes (CPT codes 98940, 98941, and 98942) will be reduced by approximately 2 percent. We are reflecting this reduction only in the payment files used by the Medicare contractors to process Medicare claims rather than through adjusting the RVUs. Avoiding an adjustment to the RVUs would preserve the integrity of the PFS, particularly since many private payers also base payment on the RVUs.

The following is the summary of the public comments we received and our responses.

Comment: One commenter, representing chiropractors, indicated that they continue to oppose our methodology for assuring budget neutrality under the demonstration. Instead of the application of an adjustment to the national chiropractor fee schedule, the commenter believes the Congressional intent was for CMS to make an adjustment to the totality of services payable under the Part B Trust Fund because of the language in section 651(f)(A) of the MMA, which directs the Secretary to ''provide for the transfer from the Federal Supplementary Insurance Trust Fund * * * of such funds as are necessary for the costs of carrying out the demonstration projects under this section.'' The commenter states that more information is necessary to fully understand the findings provided by the evaluator, Brandeis University.

Response: Section 651(f)(1)(B) of the MMA requires that the Secretary ''shall ensure that the aggregate payments made by the Secretary under the Medicare program do not exceed the amount which the Secretary would have paid under the Medicare program if the demonstration projects under this section were not implemented.'' The statute does not specify a particular methodology for ensuring budget neutrality, but leaves that decision to the Secretary. Our methodology meets the statutory requirement and appropriately impacts the chiropractic profession that is directly affected by the demonstration.

With respect to the commenter that requested more information, we note that the final evaluation report, which describes, among other things, our methodology for calculating budget neutrality for this demonstration, is located on our Web site at the following URL: *http://www.cms.gov/reports/downloads/Stason_ChiroDemoEvalFinalRpt_2010.pdf.* The evaluation examined the impact of expanded coverage for

chiropractic care on Medicare expenditures and found that chiropractic users in the demonstration areas had higher Medicare expenditures than chiropractic users in comparison areas that did not have the expanded coverage. Therefore, as proposed and reiterated in the 2006, 2007, 2008, 2009, 2010, and 2011 PFS rules, we are implementing this methodology and recouping from the chiropractor fee schedule codes. Our methodology meets the statutory requirement for budget neutrality and appropriately impacts the chiropractic profession that is directly affected by the demonstration.

Comment: The same commenter representing chiropractors noted that the increase in costs from the demonstration was completely due to the Illinois site, and not the other four sites. The commenter ''has concerns that the Chicago area did not meet the criteria for an appropriate demonstration site for this project.'' The commenter believes it is ''premature to use demonstration findings to estimate the cost of a national roll out of the expansion of chiropractic services without further analysis of the demonstration project data.''

Response: Section 651(c)(1) of the Act required the demonstration be conducted in 4 geographically diverse sites, specifically two rural and two urban regions, with each type including a HPSA. We discussed the design of this demonstration with the chiropractic industry and others prior to implementation. Based on these discussions, we included additional criteria for site selection in the design of this demonstration. The Chicago area met the site selection criteria for this demonstration. We refer readers to the January 28, 2005 notice (70 FR 4130) for a discussion of our site selection criteria and the sites selected for participation based on these criteria.

Regardless of the differences in the costs associated with the demonstration areas, the evaluation conducted by Brandeis University found that expanding coverage for chiropractic services under the demonstration resulted in increased Medicare expenditures, and the Secretary must recoup these costs in order to meet the budget neutrality requirement of the law.

In response to the comment suggesting that the data from this demonstration should not be used to estimate the cost of a national rollout of the expansion of chiropractic services, we note the data from the demonstration is the only information CMS had at the time of the Report to the Congress for estimating the costs of a national rollout.

After consideration of the public comments received, we are continuing the implementation of the required budget neutrality adjustment by recouping $10 million in CY 2012 by reducing the payment amount under the PFS for chiropractic codes (that is, CPT codes 98940, 98941, and 98942) by approximately 2 percent.

C. Productivity Adjustment for the Ambulatory Surgical Center Payment System, and the Ambulance, Clinical Laboratory, and DMEPOS Fee Schedules

Section 3401 of the Affordable Care Act requires that the update factor under certain payment systems be annually adjusted by changes in economy-wide productivity. The year that the productivity adjustment is effective varies by payment system. Specifically, section 3401 of the Affordable Care Act requires that in CY 2011 (and in subsequent years) update factors under the ambulatory surgical center (ASC) payment system, the ambulance fee schedule (AFS), the clinical laboratory fee schedule (CLFS) and the DMEPOS fee schedule be adjusted by changes in economy wide productivity. Section 3401(a) of the Affordable Care Act amends section 1886(b)(3)(B) of the Act to add clause (xi)(II) which sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be 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, year, cost reporting period, or other annual period). Historical published data on the measure of MFP is available on the Bureau of Labor Statistics' (BLS) Web site at *http://www.bls.gov/mfp.*

As stated in the CY 2012 PFS proposed rule (76 FR 42834 and 35), the projection of MFP is currently produced by IHS Global Insight, Inc. (IGI). The methodology for calculating MFP for the ASC payment system, and the AFS, CLFS, and DMEPOS fee schedules was finalized in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73399). As described in the CY 2011 PFS final rule with comment period (75 FR 73394), IGI replicates the MFP measure calculated by the BLS using a series of proxy variables derived from the IGI US macro-economic models. For CY 2012, we proposed to revise the IGI series used to proxy the labor index used in the MFP forecast calculation from man-hours in private nonfarm establishments (billions of hours—annual rate) to hours of all persons in private nonfarm establishments, (2005 = 100.00), adjusted for labor composition effects. We proposed this revision after further analysis showed that the proposed series is a more suitable proxy for the BLS private nonfarm business sector labor input series since it accounts for the changes in skill-mix of the workforce over time (referred to above as labor composition effects). The BLS labor input series includes labor composition effects. We did not propose any additional changes to the IGI MFP forecast methodology or its application to the CPI–U update factors for the ASC payment system, and the AFS, CLFS, and DMEPOS fee schedules.

We received one comment on our proposal to revise the labor proxy used to forecast MFP.

Comment: A commenter stated that CMS did not explain what the practical effect on reimbursements is likely to be after incorporating the new labor proxy. The commenter claimed that without this information, stakeholders are unable to provide comments on the effect of this change. The commenter urged CMS to provide a full explanation of how the proposed change is likely to impact the various fee schedules to which it will apply and also requested that CMS delay the implementation of this proposal in order to give the full and fair opportunity to comment.

Response: We disagree with the commenter's claim that we did not provide sufficient detail to comment on our proposal to revise the labor proxy used to calculate the MFP forecast. As stated in the CY 2012 proposed rule, our proposal to revise the labor proxy was based on our determination of the most technically appropriate labor proxy that most closely approximates the BLS private nonfarm business sector labor input series that is used to calculate BLS historical MFP. We note that when we evaluated the various labor proxies, we found that the correlation coefficient between the proposed revised IGI labor proxy and the BLS labor proxy was 0.992 compared to a correlation coefficient between the IGI labor proxy for CY 2011 and the BLS labor proxy of 0.987. Stated differently, the proposed IGI labor proxy is more consistent both in concept and in its movements with BLS' published labor proxy. Therefore, we believe that the proposal to revise the labor proxy is technically appropriate and helps achieve our objective to replicate the BLS historical MFP measure as closely as possible. We believe that enough detail was provided regarding the revised labor proxy for

stakeholders to comment since the proposed revision to the labor proxy was not based on the impact of this revision on the MFP forecast, but on the determination of a more technically suitable approximation of the BLS labor input series as explained in the proposed rule. However, in response to the comment, we note that the historical average growth in the revised IGI labor proxy tended to be just slightly higher than the historical average growth of the IGI labor proxy for CY 2011.

Therefore, we are finalizing our proposal to use hours of all persons in private nonfarm establishments, (2005 = 100.00), adjusted for labor composition effects as the proxy for labor index used in the MFP forecast calculation.

D. Clinical Laboratory Fee Schedule: Signature on Requisition

1. History and Overview

In the March 10, 2000 **Federal Register** (65 FR 13082), we published a proposed rule entitled ''Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services,'' to announce and solicit comments on the results of our negotiated rulemaking committee tasked to establish national coverage and administrative policies for clinical diagnostic laboratory services payable under Part B of Medicare.

In the November 23, 2001 **Federal Register** (66 FR 58788), we published a final rule, which established these national coverage and administrative policies. In that final rule, we explained our policy on ordering clinical diagnostic laboratory services and revised regulatory language in § 410.32. Our regulation at § 410.32(a) includes a requirement that states ''[a]ll diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary.'' In the November 23, 2001 final rule (66 FR 58809), we added paragraph (d)(2) to § 410.32 to require that the physician or qualified nonphysician practitioner (NPP) (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who orders the service must maintain documentation of medical necessity in the beneficiary's medical record. In both the March 10, 2000 proposed rule (65 FR 13089) and the November 23, 2001 final rule (66 FR 58802), we noted that ''[w]hile the signature of a physician on a requisition is one way of documenting that the treating physician ordered the test, it is not the only permissible way of documenting that the test has been ordered.'' In the preamble of these rules, we described the policy of not requiring physician signatures on requisitions for clinical diagnostic laboratory tests, but implicitly left in place the existing requirements for a written order to be signed by the ordering physician or NPP for clinical diagnostic laboratory tests, as well as other types of diagnostic tests. We further stated, in the March 10, 2000 proposed rule (65 FR 13089) and the November 23, 2001 final rule (66 FR 58802), that we would publish instructions to Medicare contractors clarifying that the signature of the ordering physician or NPP on a requisition for a clinical diagnostic laboratory test, is not required for Medicare purposes.

On March 5, 2002, we issued a program memorandum (Transmittal AB–02–030, Change Request 1998) implementing the administrative policies set forth in the November 23, 2001 final rule, including the following instruction:

> Medicare does not require the signature of the ordering physician on a laboratory service requisition. While the signature of a physician on a requisition is one way of documenting that the treating physician ordered the service, it is not the only permissible way of documenting that the service has been ordered. For example, the physician may document the ordering of specific services in the patient's medical record.

On January 24, 2003, we issued a program transmittal (Transmittal 1787, Change Request 2410) to manualize the March 5, 2002 program memorandum. The transmittal page, entitled ''Section 15021, Ordering Diagnostic Tests, manualizes Transmittal AB–02–030, dated March 5, 2002'', stated: ''In accordance with negotiated rulemaking for outpatient clinical diagnostic laboratory services, no signature is required for the ordering of such services or for physician pathology services.'' In the manual instructions in that transmittal (that is, Transmittal 1787), we stated in a note: ''No signature is required on orders for clinical diagnostic tests paid on the basis of the physician fee schedule or for physician pathology services.'' The manual instructions inadvertently omitted the reference to clinical diagnostic laboratory tests. Thus, the transmittal seemed to extend the policy set forth in the November 23, 2001 final rule (that no signature is required on requisitions for clinical diagnostic laboratory tests paid under the CLFS) to also apply to clinical diagnostic tests paid on the basis of the PFS and physician pathology services. In addition, the manual instructions used the term ''order'' instead of ''requisition,'' which we understand caused some confusion. In addition, when we transitioned from paper manuals to the current electronic Internet Only Manual (IOM) system, these manual instructions were inadvertently omitted from the new Benefit Policy Manual (BPM).

On August 28, 2008, we issued a program transmittal (Transmittal 94, Change Request 6100) to update the BPM to incorporate language that was previously contained in section 15021 of the Medicare Carriers Manual. The reissued language stated, ''No signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services.'' After the publication of the August 2008 Program Transmittal (Transmittal 94), we received numerous inquiries from laboratories, diagnostic testing facilities, and hospital representatives who had questions about whether the provision applied to all diagnostic services, including x-rays, magnetic resonance imaging (MRIs), and other nonclinical laboratory fee schedule diagnostic services.

To resolve any confusion surrounding the implementation of the CLFS policy in 2001 and subsequent transmittals, we restated and solicited public comments on our policy in the July 13, 2009 proposed rule (74 FR 33641 and 33642), entitled ''Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010'' (CY 2010 PFS proposed rule). At that time, our policy was that the signature of a physician or NPP was not required on a requisition for clinical diagnostic laboratory tests paid on the basis of the CLFS. However, we were clear that we would still require that it must be evident, in accordance with our regulations at § 410.31(d)(2) and (3), that the physician or NPP had ordered the services .

We clarified that this policy regarding requisitions for clinical diagnostic laboratory tests would not supersede other applicable Medicare requirements (such as those related to hospital conditions of participation (CoPs)), which require the medical record to include an order signed by the physician or NPP who is treating the beneficiary. In addition, we stated that we did not believe that our policy regarding signatures on requisitions for clinical diagnostic laboratory tests supersedes other requirements mandated by professional standards of practice or obligations regarding orders and medical records promulgated by

Medicare, the Joint Commission, or State law; nor did we believe the policy would require providers to change their business practices.

In the CY 2010 PFS proposed rule (74 FR 33641 and 33642), we also restated and solicited public comment on our longstanding policy, consistent with the principle in § 410.32(a), that a written order for diagnostic tests including those paid under the CLFS and those that are not paid under the CLFS (for example, that are paid under the PFS or under the OPPS), such as X-rays, MRIs, and the technical component (TC) of physician pathology services, must be signed by the ordering physician or NPP. We were clear that the policy that signatures are not required on requisitions for clinical diagnostic laboratory tests paid under the CLFS applied only to requisitions (as opposed to written orders).

Additionally, in the CY 2010 PFS proposed rule (74 FR 33642) we solicited public comments about the distinction between an order and a requisition. We noted that an ''order'' as defined in our IOM, 100–02, Chapter 15, Section 80.6.1, is a communication from the treating physician or NPP requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test ordered yields a certain value determined by the treating physician or NPP (for example, if test X is negative, then perform test Y). We further clarified in the CY 2010 PFS final rule with comment period (74 FR 61930) that an order may be delivered via any of the following forms of communication:

- A written document signed by the treating physician or NPP, which is hand-delivered, mailed, or faxed to the testing facility.
- A telephone call by the treating physician or NPP or his or her office to the testing facility.
- An electronic mail, or other electronic means, by the treating physician or NPP or his or her office to the testing facility.

If the order is communicated via telephone, both the treating physician or NPP, or his or her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records.

In contrast, in the CY 2010 PFS proposed rule (74 FR 33642), we defined a ''requisition'' as the actual paperwork, such as a form, which is furnished to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient. The requisition may contain patient information, ordering physician information, referring institution information, information on where to send reports, billing information, specimen information, shipping addresses for specimens or tissue samples, and checkboxes for test selection. We believed the requisition was ministerial in nature, assisting laboratories with the billing and handling of results, and serves as an administrative convenience to providers and patients. We believed that a written order, which may be part of the medical record, and the requisition, were two different documents, although a requisition that is signed may serve as an order.

During the public comment period for the CY 2010 PFS proposed rule, we received numerous comments on these issues. Subsequently, in the CY 2010 PFS final rule with comment period (74 FR 61931), we stated that we would continue to carefully consider the issue of physician signatures on requisitions and orders and that we planned to revisit these issues in the future.

In the CY 2011 PFS proposed rule (75 FR 40162 through 40163), we proposed to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid on the basis of the CLFS. We stated that we believed this policy would result in a less confusing process because a physician's signature would be required for all requisitions and orders, eliminating the uncertainty over whether the documentation is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician's or NPP's signature. We also stated that we believed the requirement would not increase the burden on physicians and it would be easier for the reference laboratory technicians to know whether a test was appropriately requested, which would minimize potential compliance problems for laboratories during the course of a subsequent Medicare audit because a signature would be consistently required. We solicited public comments on the CY 2011 PFS proposed rule.

After careful consideration of all the comments received, we finalized our proposed policy without modification to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS in the CY 2011 PFS final rule with comment period (75 FR 73483), which became effective on January 1, 2011. This policy did not affect physicians or NPPs who chose not to use requisitions to request clinical diagnostic laboratory tests paid under the CLFS. Such physicians or NPPs could continue to request such tests by other means, such as by using the annotated medical records, documented telephonic requests, or electronic requests.

2. Proposed Changes

In the June 30, 2011 **Federal Register** (76 FR 38344), we proposed to retract the policy we finalized in the CY 2011 PFS final rule with comment period (75 FR 73483) and reinstate the prior policy that the signature of the physician or NPP is not required on a requisition for Medicare purposes for a clinical diagnostic laboratory test paid under the CLFS. We proposed this policy based on continued and new concerns noted by stakeholders regarding the practical effect of the finalized policy on beneficiaries, physicians, and NPPs.

While we did not solicit further comments on the signature on requisition issue in the CY 2011 PFS final rule with comment period, we did receive additional feedback from industry stakeholders on the issue after its publication in the **Federal Register**. Industry stakeholders identified many scenarios where it would be difficult to obtain the physician's or NPP's signature on the requisition for clinical diagnostic laboratory tests paid under the CLFS. Industry stakeholders asserted that there are many different situations where the physician or NPP would direct staff to prepare requisitions for laboratory tests, but then would be unavailable to provide his or her signature on the requisition. As an example, and one that was raised by commenters on the CY 2011 PFS proposed rule, in the long-term care setting, the physician is typically not available in person on a daily basis. In these cases, the physician may keep abreast of the patient's condition by calling the nursing staff. If a patient's condition indicates that a clinical diagnostic laboratory test is required, the nursing staff typically transcribes the order from the physician over the telephone onto a requisition. The information has to be transmitted to the laboratory and, in this scenario, there is no physician's or NPP's signature on the requisition. Another example that occurs in many settings, including nursing homes, all types of hospitals (inpatient as well as outpatient), and physician offices, involves specimens that are packaged for transmission to the laboratory with a requisition by nursing staff. Because the specimen often is transferred directly from the patient to the nursing staff without, in most cases, a physician's or NPP's intervention, the

requisition that accompanies the specimen does not bear the signature of the physician or NPP.

Even in cases where the physician or NPP sees the patient in his or her offices for an appointment and recommends that clinical diagnostic laboratory testing be performed, we now better understand that, typically, the information is transcribed from the medical record onto a paper requisition by office staff after the physician or NPP and the patient have concluded their interaction. In practice, we can see how requiring the physician or NPP to sign the paper requisition could, in some cases, be very inconvenient and disruptive to the physician, NPP, the beneficiary, and other patients. The physician or NPP may need to take time either during appointments with subsequent patients or between patient appointments to make sure that the requisition is signed for a particular patient prior to his or her departure from the office. In addition, a beneficiary might have to wait for a physician or NPP to complete the requisition signature process before the beneficiary could depart from the office.

Another situation identified by industry stakeholders that we did not previously consider concerns physicians or NPPs who maintain several practice locations. A patient may see his or her physician or NPP only at one particular practice location. If that patient presents to the practice location with a medical issue that the physician or NPP believes warrants immediate laboratory testing, but the physician or NPP is physically at a different location that day, the physician or NPP may be able to direct his or her nursing staff to prepare a requisition for the laboratory test. But, if the physician or NPP must sign the requisition, there could be a delay of several days or longer before the physician or NPP is able to do so, which means the patient would have to wait to have the laboratory test performed.

The aforementioned scenarios have detrimental implications for expeditious patient care that were not evident to us until the new policy was effectuated and we started hearing from stakeholders in the industry that would be negatively impacted by the policy. In response to a comment suggesting that physicians be educated about this new requirement to alleviate problems of non-compliance, we stated, in the CY 2011 PFS final rule with comment period (75 FR 73482), that we would update our manuals and direct the Medicare contractors to educate physicians and NPPs on this policy. After publication of the CY 2011 PFS final rule with comment period, it became even clearer to us that some physicians, NPPs, and clinical diagnostic laboratories were not aware of, or did not understand, the policy. Therefore, in the first calendar quarter of 2011, we focused on developing educational and outreach materials to educate those affected by this policy. Further, we issued a statement that, once the educational campaign conducted in the first quarter of 2011 was fully underway, we would expect requisitions to be signed. While developing educational and outreach materials, we realized how difficult and burdensome the actual implementation of this policy was for physicians and NPPs and that, in some cases, the implementation of this policy could have a negative impact on patient care. At that point, we decided that the better course of action was to re-examine the policy.

We re-examined our policy and our reasons for adopting this policy in light of industry stakeholders' comments received after publication of the CY 2011 PFS final rule with comment period and comments received on the CY 2011 PFS proposed rule. We reviewed our beliefs and assumptions regarding the effect of our policy on access to care and with respect to administrative burden on physicians and NPPs, the effect on innovation, and the impact on laboratories. We originally believed that the policy would not have a negative impact on beneficiary access to care. However, we now believe that we underestimated the potential impact on beneficiary health and safety. As discussed previously, care may be delayed under this policy in situations where the physician or NPP orders the test but is not available onsite to sign the requisition. For example, we understand there are concerns that certain populations of patients, such as nursing home patients and patients confined to their homes, may have laboratory tests ordered urgently by a distant physician or NPP to obtain information that is imminently needed in order to assess a need for immediate referral to a hospital, emergency department or other facility. If the ordering physician or NPP is not onsite, it is unlikely that he or she would be able to receive, sign, and return a requisition in the timeframe needed to respond to the patient's urgent clinical status. We had not anticipated this impact on care when we finalized our policy.

We also believed that the administrative burden on physicians and NPPs would be minimal and would result in a less confusing process. Physicians and NPPs must document their orders, in some form, in one or more of the medical records of the patient. We still believe that signing a laboratory requisition at the time of the order, if the requisition is ready for signature, imposes little burden on the physician or NPP, while significantly increasing our ability to minimize improper payments due to fraud and abuse. However, we believe we may have underestimated the number of occasions in which the physician or NPP cannot perform both steps concurrently. We now understand that it is not always the case that a physician or NPP can perform both steps concurrently. For instance, a physician may sign an order at the time of delivering care, but the requisition may not be available for signature until sometime later. In that situation, the physician may need to interrupt a subsequent examination in order to sign a completed requisition so that the patient may leave with the requisition. Given recently released estimates of physician shortfalls in primary care (for example, as referenced in remarks by the Health Resources and Services Administration (HRSA) Administrator to the Bureau of Health Professions Advisory Committee on April 21, 2009), the cost of lost physician time must also be revalued upwards. Alternatively, the beneficiary may have to wait for the physician or NPP to conclude his or her subsequent appointment, which could be as long as 30 minutes or more. Neither of these situations—interrupting the physician or NPP in a subsequent appointment or making the beneficiary wait for an inconvenient period of time—is acceptable. Further, we believed that the policy resulted in a less confusing process because a physician or NPP signature would be required for all requisitions and orders, eliminating uncertainty over whether the documentation is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician or NPP signature. However, based on industry stakeholder comments subsequent to the publication of the CY 2011 PFS final rule with comment period, we now believe this process may not be less confusing. Further, industry stakeholders assured us that they had not been confused about the former physician/NPP signature policy and that they never intended for us to interpret their call for consistency in the signature process to mean that they should be burdened with an additional requirement when they were already signing the medical record.

In addition, we believed that many stakeholders either had converted or were in the process of converting to an electronic health records process that would negate the need for a requisition. Electronic health records and electronic transmission of health information are key pieces of this Administration's economic recovery plan and, moreover, are key elements of our plan to improve healthcare quality and efficiency. From the additional stakeholder concerns subsequent to our CY 2011 PFS final rule with comment period, we are sensitive to the increasing migration of information transfer away from paper forms, such as requisitions, to the direct electronic submission of requests for services. After we adopted the new policy, stakeholders expressed their concerns that the requirement for a signature would increase paperwork, in direct opposition to our promotion of time-saving electronic communications. We believe that the requirement for a signature on the requisition does not impact stakeholders who utilize an electronic process for ordering clinical diagnostic laboratory tests because the policy only applies to requisitions, which are paper forms. Our intent was not to suggest that a requisition was necessary in those cases. However, we recognize that members of the provider and supplier community still believe this regulation could inhibit their use of innovative technology and investment in healthcare IT resources. Therefore, we recognize that we underestimated the potential for paperwork burden.

Finally, we believed that the policy would make it easier for a reference laboratory to know whether a test is appropriately requested and to minimize potential compliance problems. Specifically, we believed that the policy would improve a laboratory's ability to authenticate requisitions. However, based on industry stakeholder concerns received after the CY 2011 PFS final rule with comment period and comments submitted on the CY 2011 PFS proposed rule (75 FR 40161 through 40163), we now believe this aspect of the policy is less financially beneficial than we had estimated, because the percentage of laboratory requests covered by the policy may be smaller than we predicted and may continue to shrink as new technology is adopted. We also believed the policy provided a mechanism for laboratories to fulfill their responsibility to ensure that they only provide and bill for services on the direct order of a physician or NPP because the signature on the requisition would provide documentation and evidence that the physician or NPP had ordered the service. However, industry stakeholders expanded on comments to the CY 2011 PFS proposed rule and informed us that there was a cost to adopting a rigid mechanism of establishing authenticity. Laboratories believe it is more efficient for them to use internal procedures and controls to ensure that they do not provide and bill for services without a physician authorization rather than through a Federal policy. Thus, we believe the expected benefits of the policy may be less than we originally estimated.

In summary, there were many situations that we did not recognize as problematic until we finalized the requisition signature policy and stakeholders began to implement it. Upon review of the concerns that industry stakeholders raised after we finalized our policy in the CY 2011 PFS final rule with comment period, and in reconsideration of comments to the CY 2011 PFS proposed rule, we proposed to retract the policy that was finalized in the CY 2011 PFS final rule with comment period, which required a physician's or NPP's signature on a requisition for clinical diagnostic laboratory tests paid under the CLFS (75 FR 73483). We proposed to reinstate our prior policy that the signature of the physician or NPP is not required on a requisition for a clinical diagnostic laboratory test paid under the CLFS for Medicare purposes.

We remain concerned about the costs and impact of fraud and abuse on the Medicare program. The requirement that the treating physician or NPP must document the ordering of the test remains, as does our longstanding policy that requires orders, including those for clinical diagnostic laboratory tests, to be signed by the ordering physician or NPP. We believe that all parties share in the responsibility of ensuring that Medicare services are provided only in accordance with all applicable statutes and regulations, such as the requirement for a physician or NPP order. In many instances, such as in the case of orders originating in hospitals, we believe that retaining all the other requirements previously discussed, especially requiring the physician or NPP who orders the service to maintain documentation of medical necessity in the beneficiary's medical record according to § 410.32(d)(2)(i), as well as the hospital CoPs on medical record services at § 482.24, are sufficient. However, we note that hospital CoPs do not apply to other settings, such as private offices.

We believe it is the responsibility of the clinical diagnostic laboratory, as it is for the provider of any service, to have sufficient processes and safeguards in place to ensure that all services are delivered only when ordered by a physician or NPP. This proposed rule does not preclude an individual laboratory from requiring a physician's or NPP's signature on the requisition. The laboratory may develop its own compliance procedures to ensure that it only furnishes services in response to a physician or NPP order. Such procedures could include internal audits, agreements with ordering physicians or NPPs to provide medical record evidence of the order in the event of an internal or external audit, steps to confirm the existence of an order under certain circumstances, or any other measures including the acceptance of risk by the clinical laboratory. We believe this financial and compliance responsibility was implicit in the 2001 final rule (66 FR 58788), was reiterated in the March 5, 2002 transmittal (Change Request 2410, Transmittal AB–02–030), and has remained a consistent element of the subsequent instructions.

Comment: All commenters supported CMS's proposal to retract the policy requiring a physician's or NPP's signature on a requisition for clinical diagnostic laboratory tests paid under the CLFS, which was finalized in the CY 2011 PFS final rule with comment period. All commenters also supported the proposal to reinstate the prior policy that the signature of the physician or NPP is not required on a requisition for a clinical diagnostic laboratory test paid under the CLFS for Medicare purposes.

Response: We thank the commenters for their support and, as discussed below, are finalizing our proposal without modification.

After consideration of the public comments received, we are finalizing our proposal to retract the policy that was finalized in the CY 2011 PFS final rule with comment period, which required a physician's or NPP's signature on a requisition for clinical diagnostic laboratory tests paid under the CLFS (75 FR 73483) and to reinstate our prior policy that the signature of the physician or NPP is not required on a requisition for a clinical diagnostic laboratory test paid under the CLFS for Medicare purposes.

E. Section 4103 of the Affordable Care Act: Medicare Coverage and Payment of the Annual Wellness Visit Providing a Personalized Prevention Plan Under Medicare Part B

1. Incorporation of a Health Risk Assessment as Part of the Annual Wellness Visit

a. Background and Statutory Authority—Medicare Part B Coverage of an Annual Wellness Visit Providing Personalized Prevention Plan Services

Preventive care and beneficiary wellness are important to the Medicare program and have become an increasing priority. In section 4103 of the Affordable Care Act, the Congress expanded Medicare Part B benefits to include an annual wellness visit providing personalized prevention plan services (hereinafter referred to as an annual wellness visit). The annual wellness visit is described more fully in section 1861(hhh) of the Act, and coverage was effective for services furnished on or after January 1, 2011. Regulations for Medicare coverage of the annual wellness visit are established at 42 CFR 410.15. The annual wellness visit may be performed by a physician, nonphysician practitioner (physician assistant, nurse practitioner, or clinical nurse specialist), or a medical professional (including a health educator, a registered dietitian, or a nutrition professional, or other licensed practitioner) or a team of such medical professionals, working under the direct supervision of a physician. In summary, for CY 2011, the first annual wellness visit includes—

- Establishment of an individual's medical and family history;
- Establishment of a list of current medical providers and suppliers involved in providing medical care to the individual;
- Measurement of an individual's height, weight, body mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the beneficiary's medical and family history;
- Detection of any cognitive impairment that the individual may have;
- Review of the individual's potential (risk factors) for depression;
- Review of the individual's functional ability and level of safety;
- Establishment of a written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the individual's health status, screening history, and age-appropriate preventive services covered by Medicare;
- Establishment of a list of risk factors for which primary, secondary or tertiary interventions are recommended or underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination (IPPE), and a list of treatment options and their associated risks and benefits;
- Furnishing of personalized health advice to the individual and referrals, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management; and
- Any other element determined appropriate through the national coverage determination process (NCD).

In summary, for CY 2011, subsequent annual wellness visits include—

- An update of the individual's medical and family history;
- An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual;
- Measurement of an individual's weight (or waist circumference), blood pressure and other routine measurements as deemed appropriate, based on the individual's medical and family history;
- Detection of any cognitive impairment that the individual may have;
- An update to the written screening schedule for the individual;
- An update to the list of risk factors and conditions for which primary, secondary, or tertiary interventions are recommended or are underway for the individual;
- Furnishing of personalized health advice to the individual and referrals, as appropriate, to health education or preventive counseling services;
- Any other element determined appropriate through the NCD process.

The annual wellness visit is specifically designed as a wellness visit that focuses on identification of certain risk factors, personalized health advice, and referral for additional preventive services and lifestyle interventions (which may or may not be covered by Medicare). The elements included in the annual wellness visit differ from comprehensive physical examination protocols with which some providers may be familiar since the annual wellness visit is a visit that is specifically designed to provide personalized prevention plan services as defined in the Act.

Section 1861(hhh)(1)(A) of the Act specifies that a personalized prevention plan for an individual includes a health risk assessment (HRA) that meets the guidelines established by the Secretary. In general, an HRA is an evaluation tool designed to provide a systematic approach to obtaining accurate information about the patient's health status, injury risks, modifiable risk factors, and urgent health needs. This evaluation tool is completed prior to, or as part of, an annual wellness visit. The information from the HRA is reflected in the personalized prevention plan that is created for the individual.

Although the annual wellness visit was effective on January 1, 2011, section 4103 of the Affordable Care Act provided the Secretary additional time to establish guidelines for HRAs after consulting with relevant groups and entities (see section 1861(hhh)(4)(A) of the Act). A technology assessment from the Agency for Healthcare Research and Quality (AHRQ) was commissioned to describe key features of HRAs, to examine which features were associated with successful HRAs, and to discuss the applicability of HRAs to the Medicare population. The finalized technology assessment was posted on July 6, 2011 and is publicly available on the CMS Web site at *http://www.cms.gov/determinationprocess/downloads/id79ta.pdf.*

We collaborated with the Centers for Disease Control and Prevention (CDC), due to their in-depth knowledge of HRAs, and because the CDC was directed by section 4004(f) of the Affordable Care Act to develop guidelines for a personalized prevention plan tool. In the November 16, 2010 **Federal Register** (75 FR 70009), CDC issued a notice to solicit feedback regarding HRA guidance development. Public comments were received from numerous relevant groups and entities including: The American Academy of Family Physicians, the American Dietetic Association, the American Geriatrics Society, the American College of Cardiology, Care Continuum Alliance, physician practices, public health agencies, healthcare research groups, and the general public.

The CDC convened a public meeting in Atlanta, Georgia in February 2011 to facilitate the development of guidance for HRAs. (See the December 30, 2010 **Federal Register** (75 FR 82400)—announcement for ''Development of Health Risk Assessment Guidance, Public Forum''). This meeting allowed broad public input from stakeholders and the general public into the

development of guidelines for evidence-based HRAs. The Interim Guidance for Health Risk Assessments developed by the CDC is available on the CMS Web site at *http://www.cms.gov/coveragegeninfo/downloads/healthriskassessmentsCDCfinal.pdf.* The CDC guidance resulted from a compilation and review of the current scientific evidence, the AHRQ technology assessment, and expert advice from those working in the field of HRA and wellness, and takes into account public feedback from the request for information and the public meeting. The CDC guidance includes questions and topics to be addressed as deemed appropriate for the beneficiary's age. Additional information regarding the CDC guidance development process is included as part of the guidance document. The CDC plans to publish ''A Framework for Patient-Centered Health Assessments, a Morbidity and Mortality Weekly Report (MMWR).'' The MMWR will include additional information applicable to the successful implementation of the HRA, such as the CDC interim guidance document, as well as information related to implementation, feedback, and follow-up that evidence suggests is critical for improving health outcomes using this process. We look forward to stakeholders engaging in the development of innovative tools or methods, which would provide health professionals the flexibility to adapt the HRA guidance to evaluate additional topics, as appropriate, to provide a foundation for development of a personalized prevention plan as part of the annual wellness visit. We also look forward to stakeholders engaging in the development of innovative electronic solutions for conducting a HRA and integration with electronic health records.

b. Implementation—Summary of Proposed Rule and Comments

Consistent with section 1861(hhh) of the Act and the initial CDC guidance document, we proposed to amend 42 CFR 410.15 by: (1) Adding the term ''health risk assessment'' and its definition; (2) revising the definitions of ''first annual wellness visit providing personalized prevention plan services'' and ''subsequent annual wellness visit providing personalized prevention plan services;'' and (3) incorporating the use and results of an HRA into the provision of personalized prevention plan services during the annual wellness visit.

The following is a summary of the provisions of the proposed rule and the comments received. We received 59 public comments from national and State professional associations, national medical advisory and patient advocacy groups, health insurance associations, health care systems, manufacturers, a government agency, and other national healthcare organizations. Thirty-two (32) comments supported incorporation of an HRA into the annual wellness visit and 5 were opposed. The remaining 22 comments provided feedback about the impact of the annual wellness visit as a whole requested modifications or additional elements to the annual wellness visit, and coverage for additional preventive services and vaccines.

Most supporters generally agreed with the proposed major HRA components. One commenter indicated that the inclusion of the HRA would help make care more preventive and proactive, and help avoid long-term maladies associated with aging and chronic diseases. Some commenters expressed concern that the proposal was too prescriptive and did not allow for sufficient flexibility. Other commenters were concerned that the HRA components were not sufficiently targeted to specific diseases. One commenter was of the opinion that there was a lack of evidence for the usefulness of an HRA, and believed the best evidence on the efficacy of comprehensive health risk assessment for the elderly comes from highly specialized geriatric assessment clinics capable of targeting individuals at high risk and providing longitudinal follow-up. This commenter believed that it would be impossible to replicate similar interventions without follow-up visits, and indicated that additional research is needed to determine how an HRA can be effectively translated into primary care practice.

Regarding flexibility of the HRA, some commenters supported a more flexible approach to HRA development and use, while others requested that a standardized tool be developed and certified by either CMS or an outside accrediting organization. A few commenters believed the HRA would be difficult for health professionals to implement since the CDC guidance had not been published and work had not been completed on establishing standards for interactive web-based programs to furnish HRAs, referencing other components of section 4103 of the Affordable Care Act.

In the proposed rule, we requested public comment on the overall impact and burden of the annual wellness visit on health professional practices, including the impact that incorporation and use of an HRA would have on health professionals and their practices. Two commenters believed that the incorporation of an HRA supports a systematic approach to patient wellness, providing a foundation for development of a personalized prevention plan and they supported the inclusion of a minimum set of topics as part of the HRA. Four commenters indicated that the use of an HRA would have a significant impact on health professional practices. One commenter stated that inclusion of an HRA would be somewhat or very difficult. Another was concerned that health professionals would be penalized if an individual refuses to complete an HRA or follow the personalized prevention plan recommendations. Another commenter was concerned with the lack of a publicly available HRA.

Of those commenters that provided feedback on the potential burden of the HRA as part of both first and subsequent AWVs on health professional practices, the comments ranged from requesting that HRAs be optional and used at the discretion of a health professional, to requesting that the CDC develop a standardized HRA tool for use with the Medicare aged population. One commenter opined that a quality HRA will provide health professionals information that shows patient progress over time without adding additional effort on the practitioner. This same commenter also believed that HRAs could have a positive impact on health professional practices by helping patients understand their health care needs. Three commenters indicated that development and implementation of an HRA that meets CDC guidelines could be a significant burden. One commenter recommended that the HRA implementation date be extended to July 1, 2012. Three comments expressed concern with what they believed to be a rigid approach that would require questions for all Medicare beneficiaries in conjunction with prevention plan services that they believed would not be applicable for every beneficiary on an annual basis.

(1) Definition of a ''Health Risk Assessment''

We proposed to revise § 410.15 by adding the term ''health risk assessment'' and defining such term as an evaluation tool that meets the following requirements:

- Collects self-reported information about the beneficiary.
- Can be administered independently by the beneficiary or administered by a health professional prior to or as part of the AWV encounter.
- Is appropriately tailored to and takes into account the communication

needs of underserved populations, persons with limited English proficiency, and persons with health literacy needs.

• Takes no more than 20 minutes to complete.

• Addresses, at a minimum, the following topics:

++ Demographic data, including but not limited to age, gender, race, and ethnicity.

++ Self assessment of health status, frailty, and physical functioning.

++ Psychosocial risks, including but not limited to depression/life satisfaction, stress, anger, loneliness/social isolation, pain, or fatigue.

++ Behavioral risks, including but not limited to tobacco use, physical activity, nutrition and oral health, alcohol consumption, sexual practices, motor vehicle safety (seat belt use), and home safety.

++ Activities of daily living (ADLs), including but not limited to dressing, feeding, toileting, grooming, physical ambulation (including balance/risk of falls), and bathing.

++ Instrumental activities of daily living (IADLs), including but not limited to shopping, food preparation, using the telephone, housekeeping, laundry, mode of transportation, responsibility for own medications, and ability to handle finances.

The standards outlined in the definition of the term health risk assessment represent a minimum set of topics that need to be addressed as part of an HRA, while allowing the health professional the flexibility to evaluate additional topics, as appropriate, to provide a foundation for development of a personalized prevention plan.

Comment: Commenters requested flexibility regarding the elements included in the HRA and/or the time allotted for administration. Four comments indicated that the amount of time allotted for HRA administration was not adequate, given the number of HRA components.

Response: We believe it is important to balance the comprehensiveness of the HRA with the potential burden on patients and health professional time constraints. The elements included in the HRA definition are those that experts in the field of HRAs advised are scientifically valid and for which there is evidence of effectiveness. In a study on HRA design, Mills and colleagues reported that there was a ''significant drop-off in completion after 20 minutes of engagement'' (Mills et al. J R Soc Med Sh Rep 2011;2:71. DOI 10.1258/shorts.2011.011015). We believe that the components of the HRA that we proposed could be completed by most patients within 20 minutes.

Comment: One commenter believes that information related to elements of the annual wellness visit could be collected efficiently through the HRA, such as family history, screening history, a list of providers and suppliers regularly involved in the individual's care, and current medications. Another commenter suggested that the HRA collect information about patient access to preventive services, including history of appropriate vaccinations.

Response: We recognize that medical and family history (including current medications) and preventive services utilization history are important components of the annual wellness visit and for inclusion in the patient's medical record. While we agree that these topics are important components in the provision of personalized prevention plan services, we believe it is important to balance the comprehensiveness of the HRA with the potential burden on patients and health professional time constraints. Medical and family history (as defined in § 410.15(a)) and development or update of the list of providers and suppliers that are involved in the patient's care are typically asked and reviewed by the health professional during the AWV encounter. Thus, we are not adopting the commenter's suggestions to add these topics as mandatory components of the HRA.

Comment: A few commenters requested that CMS include falls screening in the HRA. One commenter believes that fall risk assessments should be consistent with the clinical practice guidelines established by major geriatric societies, which include recommendations for screening with further assessment and referral as indicated. Another commenter requested that functional status data be collected through the HRA to enhance the fall risk assessment during the annual wellness visit.

Response: While we appreciate the suggestions offered by the commenters, the HRA is not meant to replace the patient and family history that is usually asked and reviewed by the health professional, but rather to be an adjunct to it, providing information on behaviors known only to the patient. It has been determined by medical providers and other experts in the field of HRA that risk for falls (for example, impaired balance) can best be assessed in a face-to-face encounter with a health professional. We note that a review of the beneficiary's level of safety is already required as part of the first annual wellness visit. Self assessment of health status, frailty, and physical functioning, along with physical activity and seat belt use (which is assessed as a safety measure), were included in the proposed definition of an HRA, which will be updated at each subsequent annual wellness visit. Discussion of these topics opens the possibility of additional provider inquiry in assessing other safety risks. Thus, we are not adopting the commenter's suggestion to add more detailed information about fall risk to the HRA.

Comment: One commenter supported the emphasis on the beneficiary's role in completing the HRA and suggested that we expand upon this effort to further engage patients in the AWV and the provision of personalized prevention plan services by adding patient goals for health and wellness as components of the HRA.

Response: Patient goals are identified through the process of shared decision-making where the health professional works with the patient to discover what is important to the patient and the patient's motivation to change behavior, as part of the provision of personalized prevention plan services during the annual wellness visit encounter. Thus, we are not adopting the commenter's suggestions to add patient goals as a component of the HRA.

Comment: Other commenters requested that the HRA incorporate the collection of more detailed nutrition data and data that may help health professionals assess risk for diabetes, heart disease, and cancer.

Response: Questions related to nutrition and hypertension were included in the proposed HRA definition. A more detailed nutrition assessment could be conducted by the provider if answers to the HRA questions indicate an issue with nutrition. Cancer risk can be identified through a complete patient history. As discussed in a previous response, the HRA is not meant to replace the patient and family history that is usually asked and reviewed by the health professional, but rather to be an adjunct to it, providing information on behaviors known only to the patient. Adding additional mandatory information as part of the HRA would increase the time it takes to complete the HRA, and we are mindful that adding too much information could be burdensome to patients. Thus, we are not mandating a more detailed nutritional assessment in the HRA.

Comment: A few commenters suggested that the HRA include tobacco use questions, collect information about tobacco use screening, and utilization of tobacco use cessation counseling. One

commenter requested that counseling for tobacco use cessation be included as part of subsequent annual wellness visits.

Response: We note that the definition of an HRA includes among other things, behavioral risks such as tobacco use. We agree that tobacco use cessation counseling is important for those individuals that use tobacco products. If positive tobacco use is identified during the annual wellness visit, additional questions can be asked by the health professional followed by the process of motivational interviewing (the health professional offers personalized information to the patient) and shared decision-making (the health professional works with the patient to discover what is important to the patient and the patient's motivation to change behavior) in the development of the personalized prevention plan during the annual wellness visit encounter.

In § 410.15(a), we defined first and subsequent annual wellness visits to include provisions for the furnishing of personalized health advice and referrals, as appropriate, to health education or preventive counseling services, including among other things, tobacco use cessation. We note that Medicare covers counseling to prevent tobacco use as an ''additional preventive service'' under Medicare Part B (additional information available in Pub. 100–03, Medicare National Coverage Determinations Manual, Chapter 1, Section 210.4.1). We believe that the health professionals who are furnishing the annual wellness visits, whether they are first or subsequent annual wellness visits, will establish or update an appropriate list of referrals for education services and preventive counseling services for each individual.

Comment: One commenter supported and appreciated the recognition of the importance of behavioral risks as part of the HRA. However, the commenter suggested that ''sexual practices'' be replaced with a term that would provide a more comprehensive view of the individual's mental and physical health, such as ''sexual health.''

Response: We agree with the comment and are changing the language in the final rule. Specifically, we are modifying paragraph (v)(D) of the definition of the term ''health risk assessment'' to read ''Behavioral risks, including but not limited to, tobacco use, physical activity, nutrition and oral health, alcohol consumption, sexual health, motor vehicle safety (seat belt use), and home safety.''

Comment: Many commenters were of the opinion that memory should be included in the HRA. One commenter agreed with the provisions of the proposed rule that did not include cognitive assessment as part of the HRA, however, the commenter believed that general questions about memory should be included in the HRA. Other commenters were concerned that an appropriate screening instrument for cognitive impairment was not included in either the HRA or annual wellness visit, and requested modifications to the definition of ''detection of any cognitive impairment'' to include use of an appropriate screening instrument.

Response: We agree with commenters that detection of cognitive impairment is important. We note that ''detection of any cognitive impairment'' is already part of the annual wellness visit, consistent with the statutory elements described in section 1861(hhh)(2) of the Act. As Boustani and colleagues (Ann Internal Medicine 2003;138:927–937) noted: ''Dementia causes a high burden of suffering for patients, their families, and society. For patients, it leads to increased dependency and complicates other comorbid conditions. For families, it leads to anxiety, depression, and increased time spent caring for a loved one. The annual societal cost of dementia is approximately $100 billion (health care and related costs as well as lost wages for patients and family caregivers).'' Because information related to cognitive impairment is already addressed as part of the annual wellness visit, we do not believe it is necessary to duplicate the collection of this information through the HRA.

We also note that an evidence-based, standardized screening tool for dementia is not currently available for assessment of cognitive impairments. The USPSTF noted: ''[M]ost screening tests have been evaluated in studies with small sample sizes, and the populations of patients on whom screening instruments have been tested have varied greatly, making it difficult to determine the overall performance of screening tests for dementia'' (*http://www.uspreventiveservicestaskforce.org/3rduspstf/dementia/dementrr.pdf*). Since there is no nationally recognized screening tool for the detection of cognitive impairments at the present time, we are not making any changes to the definition of ''detection of any cognitive impairment'' at this time. We believe that physicians can use their best clinical judgment in the detection and diagnosis of cognitive impairments, along with determining whether additional resources may need to be used in the course of screening and treatment of the patient.

We appreciate the interest in the identification and development of an appropriate cognitive screening instrument. We are collaborating with the National Institute on Aging, the Department of Veterans Affairs, CDC, AHRQ, and other relevant stakeholders to assess the current methods for detecting cognitive impairment to develop recommendations for health professionals with respect to appropriate responses to both positive and negative cognitive impairment assessment results. We will continue to monitor advancements in screening, collaborate with the USPSTF, and will consider revising this element if the evidence is sufficient and a standardized screening test becomes available. Thus, at this time, we are not adopting the suggestion to include additional mandatory components related to memory or cognitive assessment within the HRA.

Comment: Two comments supported inclusion of history of alcohol consumption in the HRA, but recommended that we add substance or drug use history to the HRA. One commenter indicated that illicit substance use and prescription drug misuse are significant concerns among older adults. Another commenter indicated that intravenous drug use is a risk factor for HIV transmission.

Response: We are not adopting the commenters' suggestions to include these topics as mandatory components in the HRA to reflect a history of drug use. Other components included in the HRA definition, such as those pertaining to alcohol consumption, provide an opportunity for health professionals to ask additional questions related to additional areas of potential substance use, including prescription drug misuse and illicit drug use.

(2) Changes to the Definitions of ''First Annual Wellness Visit'' and ''Subsequent Annual Wellness Visit''

In § 410.15, we adopted the components of the annual wellness visit, consistent with the statutory elements described in section 1861(hhh)(2) of the Act. The first and subsequent annual wellness visits, as defined in § 410.15(a), are meant to represent a beneficiary visit focused on prevention. Among other things, the annual wellness visit encourages beneficiaries to obtain the preventive services covered by Medicare that are appropriate for them. First and subsequent annual wellness visits also include elements that focus on the furnishing of personalized health advice and referral, as appropriate, to health education, preventive counseling services, programs aimed at improving

self-management, and community-based lifestyle interventions.

We proposed to revise the definitions for first and subsequent annual wellness visits to incorporate the use and results of an HRA in the provision of personalized prevention plan services during the annual wellness visit. The HRA is integral to the provision of personalized prevention plan services, consistent with section 1861(hhh) of the Act. We proposed to incorporate the HRA by revising the definitions for first and subsequent annual wellness visits as follows—

- Specify that the annual wellness visit take into account the results of an HRA;
- Add the review (and administration, if needed) of an HRA as an element of both first and subsequent annual wellness visits; and
- Specify that the establishment of a written screening schedule for the individual, such as a checklist, includes and takes into account the HRA.

The HRA facilitates a systematic method for identifying health behaviors and risk factors known to the patient (for example: tobacco use, physical activity, and nutritional habits) for which the medical provider can discuss and provide tailored feedback aimed at reducing risk factors as well as reducing the potential for developing the diseases to which they are related.

During the annual wellness visit encounter, the HRA information is utilized by the health professional in a thought process intended to develop a personalized prevention plan for the patient to improve health status and delay the onset of disease. For instance, if the information provided by the HRA indicated that the beneficiary had a current or past history of tobacco use, the health professional may deem it appropriate to perform those commonly used aspects of a clinical evaluation (for instance, listening to (auscultation) the heart and lungs) in order to provide the appropriate personalized health advice and referrals for additional preventive services such as tobacco use cessation counseling.

We believe that the incorporation of the HRA will increase the efficiency of the health professional's effort during the annual wellness visit. For instance, during the annual wellness visit encounter, the health professional furnishing the annual wellness visit would review the information reported in the HRA, which would serve as the basis for a personalized prevention plan provided during the annual wellness visit encounter. The beneficiary would leave the visit with personalized health advice, appropriate referrals, and a written individualized screening schedule, such as a check list. We would not expect that the health professional would provide only general recommendations during the annual wellness visit encounter and then mail a personalized prevention plan that incorporates an HRA to the beneficiary outside of the annual wellness visit encounter. While the annual wellness visit is a wellness visit that focuses on wellness and disease prevention, a follow-up visit to treat an identified illness may be needed to address an urgent health issue. For example, if a beneficiary is determined to have high blood pressure, a follow- up visit for further review of symptoms and evaluation and management, along with determining whether additional interventions are necessary, may be performed after the completion of the annual wellness visit as a separate service.

We also proposed changes to the definition of the term ''subsequent annual wellness visit providing personalized prevention plan services'' to clarify that the health professional should furnish personalized prevention plan services and updated information if there have been changes since the beneficiary's last annual wellness visit, whether that was a first annual wellness visit or a subsequent annual wellness visit. In the CY 2011 PFS final rule, we stated in the definition for subsequent annual wellness visits that certain elements should be updated based on information developed during the first annual wellness visit (for example, lists of risk factors and screening schedules). Since all annual wellness visits that follow the first annual wellness visit are considered subsequent annual wellness visits, the health professional should update elements that were developed during the previous annual wellness visit if there have been changes. We received one comment regarding the proposed changes to update elements of the annual wellness visit developed during the previous annual wellness visit. The commenter agreed with the proposed changes. The proposed changes to the definition for subsequent annual wellness visits, which we are finalizing in this final rule with comment period are as follows:

- Newly redesignated paragraph (iii) states ''an update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services''.
- Newly redesignated paragraph (vi)(B), states ''the list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services''.

Comment: A few comments requested that the annual wellness visit and HRA be treated as a combined approach to satisfy the elements that comprise personalized prevention plan services. One commenter was of the opinion that the HRA only addresses two of the annual wellness visit components: potential risk factors for depression, and functional ability and level of safety. This same commenter believes that the HRA should not be considered another component of the annual wellness visit, but rather the mechanism that helps drive the content of the office visit and the provision of personalized prevention plan services. Another commenter expressed concerns about whether an annual wellness visit would be covered by Medicare Part B if a beneficiary declined to fill out or complete an HRA.

Response: We agree with the commenters that an HRA is an important part of the annual wellness visit. We do not agree that the HRA must reflect all of the elements of the annual wellness visit, as this approach would be unduly duplicative and also burdensome to patients completing the HRA. As we discussed in the proposed rule, we believe that incorporation of the HRA supports a systematic approach to patient wellness and is integral to the furnishing of personalized prevention plan services during the annual wellness visit. The results of the HRA will facilitate and provide the foundation for the development of the personalized prevention plan. Thus, we are not making additional changes in response to these comments. While the statute requires that the HRA be included, and taken into account in the provision of personalized prevention plan services as part of the annual wellness visit, the statute and this rule do not speak to how a health professional should address items left blank. We expect that health professionals will act in good faith to assist beneficiaries to complete the items relevant to the development of a personalized prevention plan.

In the proposed rule, we included language that specified that first and subsequent annual wellness visits providing personalized prevention plan

services take into account the results of a HRA. In response to the comments received, we are modifying the introductory text of the definition of the term ''first annual wellness visit providing personalized prevention plan services'' to specify that the first AWV includes and takes into account the results of an HRA, consistent with section 1861(hhh)(1) of the Act. We continue to believe that review (and administration, if needed) of the HRA are also integral pieces of the provision of personalized prevention plan services. Therefore, we are finalizing the addition of new paragraph (i) ''review (and administration, if needed) of a health risk assessment'' to the definition of the term ''first annual wellness visit providing personalized prevention plan services.''

Comment: A few commenters expressed concern with what they believed to be a rigid approach that would require questions for all Medicare beneficiaries in conjunction with prevention plan services that they believed would not be applicable for every beneficiary on an annual basis.

Response: We agree with the commenters that a patient may not need to complete a full HRA if he or she obtains an annual wellness visit every year as permitted by the statute, but update the HRA. Therefore, we are modifying the introductory text and new paragraph (i) of the definition of the term ''subsequent annual wellness visit providing personalized prevention plan services'' to specify that the HRA be updated as part of subsequent visits. These changes will reduce the burden for both patients and health professionals while ensuring that the HRA is updated to reflect relevant changes.

Comment: Many commenters provided suggestions regarding administration of the HRA, specifically requesting that CMS allow a physician's office to mail the HRA to the beneficiary prior to the appointment or administer the HRA over the phone. Commenters asked for clarification about the staff that would be appropriate to administer the HRA.

One commenter suggested a hierarchy of preferred administration methods, starting with internet-based systems, kiosk-style systems, automated telephone response systems, and paper-based mail-in systems. However, the same commenter, along with several others, opined that the paper-based system may be the most appropriate for Medicare beneficiaries. Commenters believed that beneficiaries may not be comfortable with or use the internet for health information.

Response: As we stated in the proposed rule, we believe that the health professional should consider the beneficiary's needs when determining whether assistance would be needed for the beneficiary to complete the HRA, including whether administrative support by health professionals is necessary. We believe it is important that health professionals have the flexibility to address additional topics as appropriate, based on patient needs, consistent with our final rule. Thus, there is not only one type of HRA that will meet the CDC guidelines.

While we appreciate the commenters' concerns, we are not assigning particular tasks or restrictions for specific members of the team in this final rule. We believe it is better for the supervising physician to assign specific tasks to qualified team members (as long as they are licensed in the State and working within their State scope of practice). This approach gives the physician and the team the flexibility needed to address the beneficiary's particular needs on a particular day.

As we discussed in the proposed rule, the CDC plans to publish ''A Framework for Patient-Centered Health Assessments, a Morbidity and Mortality Weekly Report (MMWR).'' The MMWR will include additional information applicable for the successful implementation of the HRA, such as the CDC interim guidance document, as well as information related to implementation, feedback, and follow-up that evidence suggests is critical for improving health outcomes using this process.

Comment: Some comments recommended that CMS identify HRA tools that meet the criteria outlined in the proposed rule and also provide for an accreditation or certification process for HRA instruments.

Response: We believe it is important that health professionals have the flexibility to address additional topics as appropriate, based on patient needs, consistent with our final rule. Thus, there is not only one type of HRA that will meet the CDC guidelines.

As we discussed in the proposed rule, the CDC plans to publish ''A Framework for Patient-Centered Health Assessments, a Morbidity and Mortality Weekly Report (MMWR).'' The MMWR will include additional information applicable for the successful implementation of the HRA, such as the CDC interim guidance document, as well as information related to implementation, feedback, and follow-up that evidence suggests is critical for improving health outcomes using this process. While we are not including requirements for accreditation or certification of HRA instruments in this final rule, we may consider a certification process in the future.

We requested comments on the impact of the elements included in the definitions of first and subsequent annual wellness visits and requested comments on the modification of those annual wellness visit elements for which the Secretary has the authority to determine appropriateness.

Comment: One comment indicated that the annual wellness visit helped health professionals address preventive services in a more organized manner and believed the annual wellness visit was being furnished without difficulty. Another offered support for the establishment of a written screening schedule. One commenter believed that the annual wellness visit provided little benefit for the patient and created more burdens for the physician, while another believed that the annual wellness visit elements were rigid and onerous compared to other preventive services.

Some commenters requested that CMS include a comprehensive physical exam as part the annual wellness visit. Other commenters requested that additional biometric assessments and routine blood work also be included as part of the AWV. One indicated that furnishing and coding for a separate physical exam may be confusing for physicians and deter the provision of the annual wellness visit. One commenter said that the physical exam is necessary to develop an accurate and appropriate list of risk factors and conditions for which primary, secondary, and tertiary interventions are recommended or are underway. Other commenters requested that laboratory tests and blood work should also be included in the annual wellness visit since the commenter considers blood work and laboratory tests standards in physician practice.

Response: In § 410.15, we adopted the components of the annual wellness visit, consistent with the statutory elements described in section 1861(hhh)(2) of the Act. The first and subsequent annual wellness visits, as defined in § 410.15(a), are meant to represent a beneficiary visit focused on prevention. The annual wellness visit is not a ''routine physical check-up'' that some beneficiaries may receive periodically from their physician or practitioner. The annual wellness visit is specifically designed as a wellness visit that focuses on identification of certain risk factors, personalized health advice, and referral for additional preventive services and lifestyle

interventions (which may or may not be covered by Medicare). Therefore, we are not adopting the suggestion to mandate a comprehensive physical examination as part of the annual wellness visit.

Regarding requests that routine blood work be included in the annual wellness visit, we note that Medicare Part B already covers the following screenings that include blood work—

- Cardiovascular disease screenings once every 5 years (lipid panel, cholesterol, lipoprotein, and triglycerides); and
- Diabetes screening tests for beneficiaries that meet certain conditions (2 screening tests per year for beneficiaries diagnosed with pre-diabetes; 1 screening per year if previously tested, but not diagnosed with pre-diabetes, or if never tested).

Given that these are separate Part B benefits, we are not adding routine blood work as a component of the annual wellness visit.

Comment: We received several comments that supported the establishment of a written screening schedule that includes both services that are covered by Medicare as well as community-based services that may not be covered by Medicare. One commenter stated that coordination with wellness programs would greatly enhance the effectiveness of personalized prevention plan services as a tool to reduce individual health risks. Commenters explained that the discussion of appropriate preventive services should not be limited based on insurance coverage. Other commenters requested that health professionals consider providing voluntary HIV screening, and referrals for medical nutrition therapy, home health services, and outpatient rehabilitation services. Regarding mental health services, one commenter opined that there is a lack of mental health professionals involved in primary care and, thus, requested that CMS add a requirement to the annual wellness visit for referral to mental health professionals.

Response: We appreciate the comments received and agree that it is important for health professionals that furnish the annual wellness visit to include information regarding appropriate preventive services, based on the beneficiary's current risk factors. That being said, the annual wellness visit includes the following element: ''furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.''

We believe that the health professional who is furnishing an annual wellness visit will determine an appropriate list of referrals for education services and preventive counseling services for each individual as part of the provision of personalized prevention plan services. We believe that the definitions for first and subsequent annual wellness visits address commenters' concerns regarding referrals for community-based services, mental health issues, and medical nutrition therapy. Therefore, we are not making the requested changes.

(3) Additional Comments

Comment: One commenter was concerned that the term ''physician'' is defined, for purposes of the definition of ''health professional,'' to be either a doctor of medicine or a doctor of osteopathy as defined in section 1861(r)(1) of the Act. The commenter suggests that we use the full definition of ''physician'' as defined in section 1861(r) of the Act, instead. The commenter stated that doctors accredited through the Council on Chiropractic Education are prepared to practice as primary care chiropractic physicians.

Response: We did not propose to make any changes to the definition of ''physician'' as used in § 410.15 in the proposed rule and this comment is outside the scope of our current rulemaking. We are not making any changes in this final rule.

Comment: One commenter suggested that fall risk screening should be administered by physical therapists and other appropriately qualified professionals, along with requiring, for those individuals at risk for falls, that physical therapists create a plan of care.

Response: While we appreciate the commenter's concerns, we are not assigning particular tasks for specific members of the team, such as those tasks suggested by the commenter, in this final rule. We believe it is better for the supervising physician to assign specific tasks to qualified team members (as long as they are licensed in the State and working within their State scope of practice). This approach gives the physicians and the team the flexibility needed to address the beneficiary's particular needs on a particular day. It also empowers the physician to determine whether specific medical professionals (such as physical or occupational therapists) who will be working on his or her wellness team are needed on a particular day. The physician is able to determine the coordination of various team members during the annual wellness visit.

Comment: Another commenter requested that the Secretary use authority under § 4105 of the Affordable Care Act to remove the IPPE referral requirement for abdominal aortic aneurysm screening, and make the one-time screening available via referral during the annual wellness visit.

Response: This comment is outside the scope of our proposed rulemaking as we made no proposals with respect to section 4105 of the Affordable Care Act. Our current coverage for abdominal aortic aneurysm screening is established in § 410.19. Thus, we are not making any changes based on this comment at the present time.

Comment: One commenter expressed concern that the proposed rule did not include voluntary advanced care planning as part of the annual wellness visit and was disappointed that the proposed rule was silent on this issue.

Response: In the proposed rule, we did not propose to add voluntary advanced care planning to the definitions for first or subsequent annual wellness visits. We are not making changes as suggested by this commenter at this time.

Comment: We received a few comments regarding the relationship between the IPPE and the annual wellness visit. Some commenters recommended that we eliminate the IPPE since they believe that it is similar to the provisions of the annual wellness visit.

Response: We appreciate the attention drawn to the similarity between the IPPE and the annual wellness visit. While we did model some elements of the annual wellness visit after elements in the IPPE, we note that these statutory provisions are separate and distinct benefits and that Medicare beneficiaries are eligible to receive both of these benefits in sequence if regulatory requirements are met.

Comment: A few commenters were disappointed that CMS did not add screening for depression and screening for risk of falls to the elements included in subsequent annual wellness visits. Commenters disagreed with CMS' assertion that lack of information regarding optimal frequency for depression screening was a sufficient reason for not including depression screening in subsequent annual wellness visits, and that the risk of change over a 12-month period is significant.

Response: We agree that depression screening is important. Effective October 14, 2011, Medicare covers screening for depression in adults as an ''additional preventive service.'' The decision memorandum is available on the CMS Coverage Web site at *https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=251&ver=6&NcaName=Screening+for+Depression+in+Adults&bc=AiAAAAAAIAAA&.* We believe that providing this screening as a separate Part B benefit will help to address the commenter's concerns.

We also acknowledge that assessment of functional ability and level of safety are important, and we agree that for certain individuals, functional status and safety assessments (for example, fall prevention) may be important to consider on a more routine basis. The annual wellness visit does allow for an individualized approach with a personalized prevention plan. For certain individuals where these areas are determined to be priorities, specific evaluations may be voluntary parts of subsequent visits. We also note that the HRA (which is updated during subsequent annual wellness visits) includes components related to functional ability and level of safety such as self assessment of health status, frailty, physical functioning, and behavioral risks, such as seat belt use and home safety. Therefore, we are not making the suggested changes.

Comment: We received several comments requesting that we expand or modify Medicare coverage of preventive services.

Response: While we appreciate the commenters' support for expanded coverage of preventive services under the Part B program, we did not solicit comments concerning ''additional preventive services'' in our proposed rule and these comments are outside the scope of this rulemaking. To the extent that the public is seeking expanded coverage for additional preventive services under § 410.64, we are required by statute to use the national coverage determination process. Information on how to request an NCD is available in our Guidance Document: ''Factors CMS Considers in Opening a National Coverage Determination,'' at *http://www.cms.gov/mcd/ncpc_view_document.asp?id=6.* We will also continue to monitor access to preventive services and may also consider using the authority granted by section 4105 of the Affordable Care Act in the future.

Comment: One commenter recommended that CMS provide more education and outreach regarding the annual wellness visit. Others requested that CMS provide guidance to beneficiaries and health professionals regarding the elements included in the annual wellness visit.

Response: We agree that it is important to provide information about Medicare's coverage of the annual wellness visit. We have conducted significant educational campaigns in 2011 to encourage the use of the annual wellness visit. We will issue other educational information to Medicare providers and beneficiaries, including an MLNMatters article regarding implementation of the changes to the annual wellness visit as described in this final rule.

(4) Summary

In summary, as a result of the comments received, we are finalizing the provisions of the proposed rule, with the following modifications, in this final rule:

- We are modifying sub-paragraph (v)(C) of the definition of the term ''health risk assessment'' to read, ''Psychosocial risks, including but not limited to, depression/life satisfaction, stress, anger, loneliness/social isolation, pain, and fatigue'' to correct a typographical error in the proposed rule.

- We are modifying paragraph (v)(D) of the definition of the term ''health risk assessment'' to read, ''Behavioral risks, including but not limited to, tobacco use, physical activity, nutrition and oral health, alcohol consumption, sexual health, motor vehicle safety (seat belt use), and home safety.''

- We are modifying the introductory text of the definition of the term ''subsequent annual wellness visit providing personalized prevention plan services'' to read as follows: ''subsequent annual wellness visit providing personalized prevention plan services means the following services furnished to an eligible beneficiary by a health professional that include, and take into account the results of an updated health risk assessment, as those terms are defined:''

- We are modifying newly designated paragraph (i) of the definition of ''subsequent annual wellness visit providing personalized prevention plan services'' to read as follows: ''(i) Review (and administration, if needed) of an updated health risk assessment (as defined in this section).''

2. The Addition of a Health Risk Assessment as a Required Element for the Annual Wellness Visit Beginning in 2012

a. Payment for AWV Services With the Inclusion of an HRA Element

In the CY 2011 PFS final rule with comment period (75 FR 73411), we stated ''that when the HRA is incorporated in the AWV, we will reevaluate the values for HCPCS codes G0438 and G0439''. As discussed in the CY 2011 PFS final rule with comment period, the services described by CPT codes 99204 and 99214 already include ''preventive assessment'' forms. For CY 2012, we believe that the current payment crosswalk for HCPCS codes G0438 and G0439 continue to be most accurately equivalent to a level 4 E/M new or established patient visit; and therefore, we proposed to continue to crosswalk HCPCS codes G0438 and G0439 to CPT codes 99204 and 99214, respectively.

Comment: Commenters were generally supportive of the addition of the HRA element when furnishing AWV services effective January 1, 2012. However, many commenters disagreed that the CDC guidance that the HRA is best completed on-line and prior to an AWV visit was appropriate for the Medicare population. One commenter noted that ''access to a meaningful HRA requires accommodation for individuals with physical, sensory, or cognitive limitations'' and Medicare beneficiaries often have multiple co-morbidities that will limit their ability to complete an HRA without assistance from a health professional.

Most commenters agreed that CPT codes 99204 and 99214 include ''preventive assessment,'' but continued to believe the payment is insufficient for the complexity of the HRA elements created by CDC and that the administration of the HRA will place a burden on practitioners and, even more so on their office staff, for which they would not be compensated under the equivalent of a level 4 E/M office visit payment. We wish to clarify that not only does the physician work in 99204 and 99214 include ''preventive assessment'' but that we finalized in our 2011 PFS final rule with comment period (75 FR 73409) the addition of preventive assessment forms as a direct PE input to HCPCS codes G0438 and G0439 as we had for HCPCS code G0402 (Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment) in addition to the PE inputs for CPT Codes 99204 and 99214.

Many commenters did not identify a specific adjustment to account for the additional complexity introduced by the HRA, but indicated that they should be compensated for the additional time that their staff will have to dedicate to helping Medicare beneficiaries complete the HRA over the phone or in person at their AWV. A few commenters provided a specific recommendation for reflecting staff resources needed to support the HRA and suggested that CMS add the RVUs for CPT code 99420 (Administration and interpretation of a Health Risk Assessment Instrument), which is currently not covered, to the current practice expense RVUs for the AWV. Some commenters requested that CMS add additional physician work RVUs to the AWV without specifying how much to add. One commenter suggested adding CPT code 99406 (smoking and tobacco use cessation visit, intermediate, greater than 3 minutes up to 10 minutes) to the level 4 payment to reflect the additional physician work associated with adding the HRA element to the AWV visit.

Response: We appreciate commenters' support of the addition of the HRA element. We agree with commenters that Medicare beneficiaries likely will need assistance from physician office staff in completing the HRA envisioned in the CDC Interim Guidance on Health Risk Assessments available at *http://www.cms.gov/coveragegeninfo/downloads/healthriskassessmentsCDCfinal.pdf.* Therefore, we will increase the PE RVUs from the current level 4 E/M service to include greater clinical labor time. We believe that some beneficiaries may be able to complete the HRA on their own, that others may need assistance completing the HRA, and that many will need some assistance completing more challenging questions. Because the CDC estimates that an HRA should take no more than 20 minutes to complete, we increased the clinical labor time for the initial AWV by half, 10 minutes, to reflect additional staff work across the range of beneficiary capability. For the subsequent AWV, typically we would expect Medicare beneficiaries to update the HRA. Therefore, we increased the clinical labor time for the subsequent AWV by 5 minutes. In response to the commenter request that we add the RVUs for CPT code 99420 (Administration and interpretation of a Health Risk Assessment Instrument) to the AWV RVUs, we note that our addition of 10 minutes to the initial AWV is similar to the 15 minutes of clinical labor time the AMA RUC has valued for 99420. Currently this code is not covered, and CMS has not reviewed the RUC's recommended RVUs. The AMA RUC's valuation of 99420 also includes a paper booklet. We have not included that additional practice expense input into the RVUs for the AWV because it duplicates the ''preventive assessment forms'' already included in the direct PE inputs for HCPCS codes G0438 and G0439.

We disagree with the commenters that believe review of the HRA during the AWV requires additional physician work. The level 4 E/M code RVUs that are used to establish payment for the initial and subsequent AWV already include physician review of preventive assessment forms. While we agree that greater staff time will be required to help Medicare beneficiaries to complete the HRA, we do not believe that review of the HRA during the visit constitutes more physician work than is already contemplated by a level 4 E/M visit.

In consideration of public comments, we are finalizing our CY 2012 proposal for the first and subsequent AWV services with modification. Beginning January 1, 2012, we will crosswalk G0438 and G0439 to CPT codes 99204 and 99214, with the addition of direct PE inputs for preventive assessment forms as finalized in CY 2011 final rule with comment period (75 FR 73409) and, for CY 2012, an increase the direct PE inputs for clinical labor time to recognize an additional 10 and 5 minutes, respectively. We agree with commenters that furnishing a meaningful HRA to Medicare beneficiaries will require accommodation and that those beneficiaries may need assistance from physician office staff when completing the HRA. The following Table 39, shows the final total RVUs adjusted for the inclusion of additional clinical labor time to support beneficiary completion of the required HRA element during the first and subsequent AWV services furnished on or after January 1, 2012.

TABLE 39: FINAL RVUS FOR AWV SERVICES

HCPCS Code	Short Descriptor	CY 2011 Total RVUs	Final CY 2012 RVUs including +10/5 Minutes of Clinical Labor Time
G0438	Annual wellness visit including PPPS, initial visit	4.74	4.99
G0439	Annual wellness visit, including PPPS, subsequent visit	3.16	3.26

F. Quality Reporting Initiatives

1. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

a. Program Background and Statutory Authority

The Physician Quality Reporting System is a quality reporting program that provides incentive payments and payment adjustments to identified eligible professionals who satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period. The Physician Quality Reporting System was initially implemented in 2007 as a result of section 101 of Division B of the Tax Relief and Health Care Act of 2006. The Physician Quality Reporting System was extended and further enhanced as a result of the Medicare, Medicaid, and SCHIP Extension Act of 2008 (MMSEA), the Medicare Improvements for Patients and Providers Act of 2009 (MIPPA), which was enacted on July 15, 2008, and the Affordable Care Act, which was enacted on March 23, 2010.

Changes to the Physician Quality Reporting System as a result of these laws, as well as information about the Physician Quality Reporting System in 2007, 2008, 2009, 2010, and 2011 are discussed in detail in the CY 2008 PFS proposed and final rules (72 FR 38196 through 38204 and 72 FR 66336 through 66353, respectively), CY 2009 PFS proposed and final rules (73 FR 38558 through 38575 and 73 FR 69817 through 69847, respectively), CY 2010 PFS proposed and final rules (74 FR 33559 through 33600 and 74 FR 61788 through 61861, respectively), and CY 2011 PFS proposed and final rules (75 FR 73487 through 73552). Further detailed information, about the Physician Quality Reporting System, related laws, and help desk resources, is available on the CMS Web site at *http://www.cms.gov/PQRS.*

We received numerous comments that were not related to our specific proposals for the 2012 Physician Quality Reporting System. While we appreciate the commenters' feedback, these comments are outside the scope of the issues addressed in this final rule with comment period.

b. Methods of Participation

There are two ways an eligible professional may participate in the Physician Quality Reporting System: (1) as an individual eligible professional or (2) as part of a group practice under the Physician Quality Reporting System group practice reporting option (GPRO). The details of each method of participation are described in this section.

(1) Individual Eligible Professionals

As defined at 42 CFR 414.90(b) the term ''eligible professional'' means any of the following: (1) a physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act; (3) a physical or occupational therapist or a qualified speech-language pathologist; or (4) a qualified audiologist. For more information on which professionals are eligible to participate in the Physician Quality Reporting System, we refer readers to the ''List of Eligible Professionals'' download located in the ''How to Get Started section of the Physician Quality Reporting CMS Web site at: *http://www.cms.gov/PQRS/03_How_To_Get_Started.asp#TopOfPage.*

(2) Group Practices

(A) Background and Authority

As required by section 1848(m)(3)(C)(i) of the Act, we established and have had in place since January 1, 2010, a process under which eligible professionals in a group practice are treated as satisfactorily submitting data on quality measures under the Physician Quality Reporting System if, in lieu of reporting measures under the Physician Quality Reporting System, the group practice reports measures determined appropriate by the Secretary, for example measures that target high-cost chronic conditions and preventive care, in a form and manner, and at a time specified by the Secretary. Section 1848(m)(3)(C)(ii) of the Act requires that this process provide for the use of a statistical sampling model to submit data on measures, for example the model used under the Medicare Physician Group Practice (PGP) demonstration project under section 1866A of the Act. We established a GPRO for the Physician Quality Reporting System under 42 CFR 414.90(g).

(B) Definition of Group Practice

Under 42 CFR 414.90(b), a ''group practice'' means ''a single Tax Identification Number (TIN) with two or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN''. We proposed (76 FR 42840) to change the definition of ''group practice'' under 42 CFR 414.90(b). Specifically, we proposed that under the Physician Quality Reporting System, a ''group practice'' would consist of a physician group practice, as defined by a TIN, with 25 or more individual eligible professionals (or, as identified by NPIs) who have reassigned their billing rights to the TIN.

For the 2010 Physician Quality Reporting System, our definition of ''group practice'' was limited to practices with 200 or more eligible professionals because our intent was to model the Physician Quality Reporting System GPRO after a quality reporting program that group practices may already be familiar with—the PGP demonstration. Since participation in the PGP demonstration was limited to large group practices, we wanted to initially limit participation in the Physician Quality Reporting System GPRO to similar large group practices. In 2011, we expanded this definition to include practices with 2–199 eligible professionals because we developed a second reporting option (GPRO II) specifically for smaller group practices that was based largely on the Physician Quality Reporting System reporting options for individual eligible professionals. We have since observed that many of these smaller group practices that self-nominated to participate in GPRO II for 2011 subsequently elected to opt out of participation in the GPRO II for 2011 so that members of the group practices can participate in the Physician Quality Reporting System individually instead. Out of 107 total groups that self-nominated for GPRO II, only 25 group practices comprised of 2–10 eligible professionals and 15 group practices comprised of 11–25 eligible professionals are still participating in GPRO II for 2011 at this time.

Since the GPRO II seems to be a less attractive reporting option than GPRO I, we proposed (76 FR 42840) to consolidate GPRO I and II into a single GPRO. Since our experience with using the GPRO submission web interface under the Physician Quality Reporting System has been limited to larger practices or practices participating in demonstration projects, we hesitated to expand what we referred to as GPRO I to all group practices until we gain some experience with smaller practices on a larger scale. For example, we believe that participation under the Physician Quality Reporting System GPRO is a more effective method of participation for larger as opposed to smaller group practices. As described in section VI.F.1.e.6 of this final rule with comment period, a group practice must take extra steps to participate in the Physician Quality Reporting System GPRO, for example reporting on more measures overall than is required for individual eligible professionals. In contrast, members of a group practice who choose to participate in the

Physician Quality Reporting System as individual eligible professionals could satisfactorily report by reporting as few as 3 measures. We believe the additional reporting burden associated with participating under the Physician Quality Reporting System GPRO may make the GPRO less attractive for smaller practices. We also believe that smaller group practices are more closely akin to individual eligible professionals with respect to participation under the Physician Quality Reporting System. For these reasons, we proposed to change the definition of ''group practice'' at 42 CFR 414.90(b) to groups with 25 or more eligible professionals.

We recognize that a group's size can fluctuate throughout the year as professionals move from practice to practice. We allow for fluctuation of the group practice's size throughout the reporting period. However, we proposed (76 FR 42840) that the group practice's size after the group practice's participation is approved by CMS must continue to meet the definition of a group practice as proposed in 42 CFR 414.90(b) for the entire reporting period.

We also proposed (76 FR 42840) that under 42 CFR 414.90(g)(1), a group practice of any size (including solo practitioners) or comprised of multiple TINs participating in a Medicare approved demonstration project of other programs would also be deemed to be participating in the Physician Quality Reporting System GPRO. For example, the PGP demonstration, as well as the Medicare Shared Savings Program (governing accountable care organizations (ACOs)), and Pioneer ACO have incorporated or proposed to incorporate aspects of the Physician Quality Reporting System reporting requirements and incentives under those respective programs.

Our intention to recognize (deem) group practices participating in such other programs or demonstration projects as having participated in the Physician Quality Reporting System was to ensure that such groups would not be barred from participating in the group practice reporting option under the eRx Incentive program, since we previously required and have proposed to continue to require that group practices interested in participating in the eRx Incentive Program GPRO also participate in the Physician Quality Reporting System GPRO. We are not changing the eligibility for group practices, including those participating in the programs mentioned previously, to participate in the eRx Incentive program. As discussed in the changes to the eRx Incentive Program in section VI.F.1.e.2. later in this final rule with comment period, however, a group practice must self-nominate to participate under the eRx Incentive Program's group practice reporting option. We invited comments on the proposed change to the definition of ''group practice'' under 42 CFR 414.90(b) under the Physician Quality Reporting System and also, whether we should retain the existing definition under the regulation despite our proposal to retain only the GPRO I for 2012. Following is a summary of the comments received that were related to this proposal.

Comment: Some commenters supported our proposed definition of group practice. One commenter supported our proposed definition of group practice due to low participation by smaller group practices in the 2011 GPRO II. Other commenters supported our proposed inclusion of smaller group practices comprised of 25–199 eligible professionals into the 2011 GPRO I model.

Response: We agree. For the reasons stated previously, we are finalizing our proposal to change the definition of ''group practice'' at 42 CFR 414.90(b) to groups with 25 or more eligible professionals.

Comment: One commenter opposed our proposal to eliminate GPRO II and only allow group practices to participate under GPRO I. The commenter noted that the low participation rate was likely due to the limited number of measures groups available for reporting.

Response: We appreciate the commenter's feedback. However, due to low participation in GPRO II in 2011 and the fact that the number of measures groups available for reporting in 2012 remains limited, we are eliminating the GPRO II reporting option for 2012. We are continuing to explore other options that would enable smaller group practices to participate in GPRO for future years of the program.

Comment: Several commenters were opposed to our proposal to define group practices as groups consisting of 25 or more eligible professionals. These commenters urged us to continue to include groups consisting of 2–24 eligible professionals to participate in the Physician Quality Reporting System GPRO.

Response: As stated previously, in 2011, we expanded the 2010 definition of group practice to include groups comprised of 2–199 eligible professionals because we developed GPRO II, but we proposed to eliminate the GPRO II reporting option due to low participation levels in GPRO II. To reflect our desire to continue to have group practices smaller than 200 eligible professionals participate in the 2012 Physician Quality Reporting System GPRO, we proposed to change the definition of group practice to groups comprised of 25 or more eligible professionals. We are interested in allowing group practices comprised of less than 25 eligible professionals to participate in the Physician Quality Reporting System via the GPRO in the future. However, at this time, it is not operationally feasible for us to allow groups smaller than 25 eligible professionals to participate in GPRO, as the sampling methodology and method for reporting under the GPRO was designed to accommodate larger groups. We are thinking of ways to modify this GPRO to accommodate smaller groups in the future. Furthermore, it is not likely that group practices comprised of 2–24 eligible professionals will be able to meet the patient sample threshold for satisfactory reporting under the GPRO. We are working to develop the GPRO so that it may be a viable reporting option for group practices smaller than 25 eligible professionals in future program years.

Comment: One commenter stated that, although the commenter believed that it was reasonable to require that a group practice continue to meet the definition of a group practice while participating in the Physician Quality Reporting System GPRO, the commenter suggested that we provide notice to groups that fall below the group practice definition during the reporting period.

Response: The group size is determined at the time of self-nomination and during the first quarter vetting period. However, if we find that a group practice should fall below our finalized minimum group size of 25 at any point during the reporting period, if feasible, we will work with the group practice to inform the group practice of its remaining reporting options, since, as the group size would be smaller than our minimum group practice size threshold, the group would cease to be able to participate under the Physician Quality Reporting System GPRO.

Based on the comments received and for the reasons stated above, we are finalizing our proposal to change the definition of ''group practice'' at 42 CFR 414.90(b) to recognize groups with 25 or more eligible professionals. In addition, as we did not receive comments to make a technical change to 42 CFR 414.90(g)(1) to eliminate the reference to group practices in demonstrations that are deemed to have participated in the Physician Quality Reporting System, we are finalizing that change to the regulation. We believe that this language is unnecessary given the regulation at 42 CFR 414.92(b). In addition, we believe

that retaining the reference at 42 CFR 414.90(g)(1) may cause confusion with regard to participation under the Physician Quality Reporting System or inappropriately suggest that duplicate Physician Quality Reporting System incentive payments are available to group practices under both the Physician Quality Reporting System and the other types of programs mentioned previously. We are also finalizing our proposal to make a technical change to 42 CFR 414.92(b), which defines group practices participating under the eRx GPRO discussed in section VI.F.2.b. of this final rule, to more broadly address group practices in other types of programs that incorporate Physician Quality Reporting System reporting requirements and incentives, so that the regulation does not solely reference demonstrations.

(C) Process for Physician Group Practices To Participate as Group Practices

In order to participate in the Physician Quality Reporting System GPRO for 2012 and subsequent years, we proposed to require group practices to complete a self-nomination process and to meet certain technical and other requirements described in the proposed rule (76 FR 42841 and 42842). As in prior years, we proposed to require these self-nomination and additional process requirements so that we may identify which group practices are interested in participating in the Physician Quality Reporting System as a GPRO as well as to ensure that group practices participating in the GPRO understand the process for satisfactorily reporting Physician Quality Reporting System quality measures under the GPRO method of reporting.

We proposed that the self-nomination statement would be submitted by the group practice wishing to participate in the GPRO for the first time via a web-based tool. However, we also stated that if it is not operationally feasible for us to collect self-nomination statements via a web-based tool for 2012, we would require group practices interested in participating in the Physician Quality Reporting System GPRO to submit a self-nomination statement via a letter accompanied by an electronic file submitted in a format specified by us (such as a Microsoft Excel file). At this time, it is not technically feasible to collect self-nomination statements via a web-based tool. Therefore, until the web-based tool is fully capable of accepting self-nomination statements, we are finalizing our proposal that group practices submit the self-nomination statement via a letter accompanied by an electronic file submitted in a format specified by us (such as a Microsoft Excel file) that includes the group practice's TIN(s) and name of the group practice, the name and email address of a single point of contact for handling administrative issues as well as the name and email address of a single point of contact for technical support purposes. However, once the web-based tool is capable of accepting self-nomination statements, which we anticipate will occur by the 2013 Physician Quality Reporting System, the web-based tool is the method for a group practice to submit a self-nomination statement for the respective program year.

A group practice that submits an incomplete self-nomination statement (such as, a valid email address is not provided), would not be considered for inclusion in the 2012 Physician Quality Reporting System GPRO, though as we noted in the proposed rule, we would notify a group practice should we receive an incomplete self-nomination statement.

We proposed that the Physician Quality Reporting System GPRO self-nomination statement must also indicate the group practice's compliance with the following requirements:

- Agree to attend and participate in all mandatory GPRO training sessions.
- Is an established Medicare provider that has billed Medicare Part B on or after January 1 and prior to October 29 of the year prior to the reporting period for the respective year. For example, for purposes of participating in the 2012 Physician Quality Reporting System GPRO, the group practice must have billed Medicare Part B on or after January 1, 2011 and prior to October 29, 2011.
- Agree to have the results on the performance of their Physician Quality Reporting System measures publicly posted on the Physician Compare Web site.
- Obtain and/or have access to the identity management system specified by CMS (such as, but not limited to, the Individuals Authorized Access to CMS Computer Systems, or IACS) to submit Medicare clinical quality data to a CMS clinical data warehouse.
- Provide CMS access (upon request for health oversight purposes like validation) to review the Medicare beneficiary data on which Physician Quality Reporting System GPRO submissions are founded or provide to CMS a copy of the actual data (upon request for health oversight purposes like validation).

To ensure that accurate data is being reported, we reserve the right to validate the data submitted by GPROs.

For 2012 and future years, we proposed that a group practice that wishes to participate in both the Physician Quality Reporting System and eRx GPRO (see the eRx Incentive Program's section VI.F.2.(b).(2).(B) of this final rule with comment period) must indicate its desire to participate in both programs in its self-nomination statement.

In addition, in the proposed rule (76 FR 42841 and 42842), we stated that we were interested in testing the extraction of EHR data submitted by group practices through the GPRO web interface in 2012. Group practices wishing to participate in this test must state their interest to participate in the group practice's self-nomination letter.

We further proposed (76 FR 42842) that group practices that wish to self-nominate must do so by January 31 of the calendar year in which the group practice wishes to participate in the Physician Quality Reporting System GPRO. For example, in order to participate in the GPRO for the 2012 Physician Quality Reporting System, the group practice will need to self-nominate by January 31, 2012. Upon receipt of the self-nomination statements, we would assess whether the participation requirements for the respective reporting period were met by each group practice using Medicare claims data from the year prior to the respective reporting period. We would not preclude a group practice from participating in the GPRO if we discover, from analysis of the Medicare claims data, that there are some eligible professionals (identified by NPIs) that are not established Medicare providers (that is, have not billed Medicare Part B on or after January 1 and prior to or on October 29 of the year prior to the respective reporting period) as long as the group has at least the minimum proposed number (that is, 25) of established Medicare providers required to participate in the Physician Quality Reporting System as a group practice. Eligible professionals, as classified by their NPIs, who do not submit Medicare Part B claims for PFS covered professional services during the reporting period, however, will not be included in our payment calculations.

Furthermore, we proposed (76 FR 42842) that group practices who have previously participated in the Physician Quality Reporting System GPRO would automatically be qualified to participate in the GPRO in 2012 and future program years. For example, group practices that were selected to participate in the 2011

Physician Quality Reporting System GPRO I or GPRO II (provided the group practice is still comprised of at least 25 eligible professionals) would automatically be qualified to participate in the 2012 Physician Quality Reporting System GPRO and will not need to complete the 2012 Physician Quality Reporting System GPRO qualification process. These practices will, however, need to notify CMS in writing of their desire to continue participation in the Physician Quality Reporting System GPRO for the respective program year.

We indicated that we recognized that, for various reasons, there potentially could be a discrepancy between the number of eligible professionals (that is, NPIs) submitted by the practice during the self-nomination process and the number of eligible professionals billing Medicare under the practice's TIN as people move in and out of practices. Therefore, if we find more NPIs in the Medicare claims than the number of NPIs submitted by the practice during the self-nomination process and this will result in the practice being subject to different criteria for satisfactory reporting, we will notify the practice of this finding as part of the self-nomination process. At this point, the practice will have the option of either agreeing to be subject to the different criteria for satisfactory reporting or opting out of participation in the Physician Quality Reporting System GPRO to enable the members of their practice to participate in the Physician Quality Reporting System as individual eligible professionals.

We invited public comment regarding our proposed process for group practices to participate in the Physician Quality Reporting System GPRO. We received the following comment regarding this proposal.

Comment: One commenter stated that, instead of requiring group practices who have previously participated in the Physician Quality Reporting System GPRO in prior years to self-nominate each year, we should consider group practices who have formerly participated in the Physician Quality Reporting System GPRO as participating until the group practice opts out of GPRO participation.

Response: We appreciate the commenter's feedback. However, we note that the self-nomination process that we have proposed and are finalizing applies only to group practices that wish to participate in the Physician Quality Reporting System GPRO for the first time. Group practices that have previously participated in the GPRO do not need to submit a self-nomination statement to indicate their desire to participate in the GPRO in future program years. However, we note that group practices that have previously participated in the GPRO may have to participate in other GPRO activities, such as attending informational sessions that demonstrate how to report under the GPRO for the respective program year.

Based on the comments received and for the reasons stated previously, we are finalizing the self-nomination and participation processes for group practices under the Physician Quality Reporting System GPRO. As we noted previously, it was not technically feasible to develop a web-based tool by the time of this final rule, and therefore, for 2012, self-nomination statements must be submitted via a letter accompanied by and electronic file described previously.

c. Reporting Period

Since the implementation of the Physician Quality Reporting System in 2007, depending on an eligible professional's chosen reporting mechanism, we have offered up to two different reporting periods for satisfactorily reporting Physician Quality Reporting System quality measures: a 12-month reporting period (from January 1 through December 31of the respective program year) and a 6-month reporting period (from July 1 through December 31of the respective program year). Section 1848(m)(5)(F) of the Act requires CMS to provide alternative reporting periods and criteria for measures groups and registry reporting. To comply with this provision, for 2012 and subsequent years, we proposed (76 FR 42842) to retain the 6-month reporting period option for the reporting of Physician Quality Reporting System measures groups via registry. We invited but received no comments on our proposal to retain the 6-month reporting period for measures groups via registry. For the reasons described previously, we are finalizing our proposal to retain the 6-month reporting period for 2012 and beyond. We are therefore modifying 42 CFR 414.90(f)(1)(ii)(B) to reflect this finalized proposal.

Additionally, we proposed (76 FR 42842) to modify 42 CFR § 414.90(g)(1) to specify a 12-month reporting period (that is, January 1through December 31of the respective program year) for the Physician Quality Reporting System GPRO. We received no comments regarding our proposal to modify 42 CFR § 414.90(g)(1) to specify a 12-month reporting period (that is, January 1 through December 31of the respective program year) for the Physician Quality Reporting System GPRO for 2012 and beyond, and are therefore, finalizing this proposal. As such, we are making technical changes to modify the clause numbers under 42 CFR 414.90(g) to reflect our finalized proposal to indicate a 12-month reporting period for the GPRO under 42 CFR 414.90.

Furthermore, for 2012 and subsequent years, we proposed (76 FR 42842) to modify 42 CFR 414.90(f)(1) to specify a 12-month reporting period (that is, January 1 through December 31of the respective program year), consistent with section 1848(m)(6)(C)(i)(II) of the Act, for the satisfactory reporting of Physician Quality Reporting System quality measures for claims, registry, and EHR-based reporting. In proposing these modifications to 42 CFR 414.90, we proposed to eliminate the 6-month reporting period for claims and registry previously available under the Physician Quality Reporting System (with the exception of reporting measures groups via registry). Although we did not propose a 6-month reporting period for claims and registry reporting, we note that the 12-month reporting period aligns with other CMS quality reporting programs. In addition, the elimination of the 6-month reporting period for claims and registry reporting (for reporting individual measures via registry) will align the reporting periods of these mechanisms with the EHR reporting mechanism and the GPRO. We further believe that the elimination of the 6-month reporting period for claims and registry reporting (for reporting individual measures via registry) will help to streamline and simplify the reporting requirements for the Physician Quality Reporting System without substantial burden to eligible professionals who may still satisfactorily report using the 12-month reporting period.

We invited public comment on our proposal to eliminate the 6-month reporting period for claims and registry reporting (for reporting individual measures via registry). The following is a summary of the comments regarding this proposal.

Comment: Some commenters supported our proposal to eliminate the 6-month reporting period as we proposed. The commenters concurred with our desire to align our reporting periods with that of other CMS quality reporting programs.

Response: We appreciate the commenters' support. We are finalizing our proposal to eliminate the 6-month reporting period claims and registry reporting (individual measures via registries).

Comment: Several commenters were opposed to our proposal to eliminate the 6 month reporting period for reporting under the Physician Quality Reporting System. One commenter suggested that having an additional 6-month reporting period in which to report would allow eligible professionals to still correct errors that are detected after the distribution of interim feedback reports. Another commenter stated that the 6-month reporting period may be used by eligible professionals as an additional opportunity to meet the requirements for satisfactory reporting under the Physician Quality Reporting System.

Response: As we noted previously, we are finalizing our proposal to retain the 6-month reporting option for reporting on measures groups via registry. Therefore, the 6-month reporting period is still available to those eligible professionals wishing to use this reporting period. As we stated in the proposed rule (76 FR 42842), we proposed to eliminate the 6-month reporting option (for certain mechanisms and types of measures) in order to streamline the program. We understand that this eliminates additional options under which eligible professionals may participate in the Physician Quality Reporting System. However, we believe that data based on a 12-month reporting period provides more meaningful insight to patient experience and care than data collected during a shorter, 6-month reporting period. The Tax Relief and Health Care Act of 2006 (TRHCA), enacted on December 20, 2006, required the Secretary to implement the first reporting period on July 1, 2007. Therefore, a 6-month reporting period from July 1, 2007 through December 31, 2007 was the first reporting period in which eligible professionals could report on quality measures under the Physician Quality Reporting System (then called the Physician Quality Reporting Initiative or PQRI). We retained the 6-month reporting option to encourage participation in the program. 2012 will mark the 6th year of the Physician Quality Reporting System. As such, we believe that eligible professionals have had ample time to familiarize themselves with the program and its requirements. Therefore, we believe our desire to streamline the program, align our reporting periods with other various CMS programs, and collect more meaningful data outweighs stakeholders' desire to retain the 6-month reporting period we are eliminating.

Based on the comments received and for the reasons stated above, for 2012 and beyond, we are finalizing our proposal to modify 42 CFR 414.90(f)(1) to specify a 12-month reporting period (that is, January 1 through December 31of the respective program year) for the satisfactory reporting of Physician Quality Reporting System quality measures for claims, registry, and EHR-based reporting. In addition to the 12-month reporting period available for all reporting methods, we are also finalizing a 6-month reporting period (that is, July 1 through December 31 of the respective program year) for reporting measures groups via registry.

d. Reporting Mechanisms—Individual Eligible Professionals

For the purpose of reporting quality measures under the Physician Quality Reporting System, we proposed (76 FR 42842) to retain the claims-based, registry-based, and EHR-based reporting mechanism for 2012 and beyond. Accordingly, we proposed to modify 42 CFR 414.9(f) to reflect this proposal. We proposed to retain these reporting mechanisms in order to provide eligible professionals with multiple mechanisms from which to satisfactorily report Physician Quality Reporting System quality measures. We hope that offering multiple reporting mechanisms will aid in encouraging participation in the Physician Quality Reporting System.

We invited public comment concerning the general, proposed reporting mechanisms for the Physician Quality Reporting System for 2012 and beyond. The following is a summary of the comments received that were related to our proposal to retain the claims, registry, and EHR-based reporting mechanisms for 2012 and beyond.

Comment: One commenter suggested that the program move towards one method of reporting, rather than provide different methods of reporting under the Physician Quality Reporting System.

Response: We appreciate the commenter's feedback. However, as we stated in the proposed rule (76 FR 42842), we believe it is important to provide eligible professionals with multiple reporting mechanisms to encourage and facilitate satisfactory participation in the Physician Quality Reporting System. We also note that eligible professionals continue to actively utilize all 3 reporting mechanisms. For example, the 2009 Reporting Experience indicates that in 2009, approximately 190,000 eligible professionals and 33,000 eligible professionals participated in the Physician Quality Reporting System via the claims-based and registry-based reporting mechanism, respectively. The EHR-based reporting mechanism was not included as a Physician Quality Reporting System reporting mechanism until 2010.

Comment: Several commenters supported our proposal to retain the claims, registry, and EHR-based reporting mechanisms for 2012 and beyond in order to provide multiple reporting mechanisms for which eligible professionals may use to report on Physician Quality Reporting quality measures.

Response: We agree and appreciate the commenters' feedback. We are finalizing the claims, registry, and EHR-based reporting mechanisms for 2012 and beyond.

Comment: Some commenters encouraged us to provide resources to assist eligible professionals in choosing a reporting mechanism.

Response: For 2012 and beyond, as in previous years, we will provide various resources to assist eligible professionals in choosing a reporting mechanism as well as general guidance on how to participate in the Physician Quality Reporting System through, for example, resources posed on the Physician Quality Reporting System Web site (*http://www.cms.gov/PQRS/*), national provider calls, special open door forums, and the QualityNet Help Desk.

Based on the comments received and for the reasons explained previously, we are finalizing the claims, registry, and EHR-based reporting mechanisms under the Physician Quality Reporting System for 2012 and beyond.

As in previous years, the individual quality measures or measures groups an eligible professional selects will dictate the applicable reporting mechanism(s). In addition, while eligible professionals can attempt to qualify for a Physician Quality Reporting System incentive under multiple reporting mechanisms, the eligible professional must satisfy the criteria for satisfactory reporting for the respective program year, with respect to a single reporting mechanism to qualify for an incentive. We will not combine data submitted via multiple reporting mechanisms to determine incentive eligibility.

(1) Claims-Based Reporting

As we noted previously, we proposed (76 FR 42843) to retain the claims-based reporting mechanism for the Physician Quality Reporting System for 2012 and beyond. For eligible professionals who choose to participate in the Physician Quality Reporting System by submitting data on individual quality measures or measures groups through the claims-based reporting mechanism, we proposed (76 FR 42843) that the eligible professional be required to submit the appropriate Physician Quality Reporting

System quality data codes (QDCs) on the professionals' Medicare Part B claims.

QDCs for the eligible professional's selected individual Physician Quality Reporting System quality measures or measures group may be submitted to CMS at any time during the reporting period for the respective program year. However, as required by section 1848(m)(1)(A) of the Act, all claims for services furnished during the reporting period, would need to be processed by no later than two months after the end of the reporting period, to be included in the program year's Physician Quality Reporting System analysis. For example, all claims for services furnished for the 2012 Physician Quality Reporting System would need to be processed by no later than two months after the end of the reporting period for the 2012 Physician Quality Reporting System, that is, processed by February 22, 2013 for the reporting period that ends December 31, 2012.

We invited public comment on our proposed requirements for eligible professionals who choose the claims-based reporting mechanism for 2012 and beyond. The following is a summary of the comments we received regarding this proposal.

Comment: Some commenters supported our proposal to retain the claims-based reporting mechanism, since many small practices may not be linked to registry or EHR systems.

Response: We agree and appreciate the commenter's feedback.

Based on the comments received and for the reasons stated in our responses and above, we are finalizing our proposal to retain the claims-based reporting mechanism under the Physician Quality Reporting System for 2012 and beyond.

(2) Registry-Based Reporting

(A) Requirements for the Registry-based Reporting Mechanism—Individual Eligible Professionals

As stated previously, we proposed (76 FR 42843) to retain the registry-based reporting mechanism via a qualified registry (as defined in section VI.F.1.2.B.) for the Physician Quality Reporting System for 2012 and beyond. With regard to specific requirements for registry-based reporting for individual eligible professionals under the Physician Quality Reporting System, we proposed that, in order to report quality data on the Physician Quality Reporting System individual quality measures or measures groups for the respective program year through a qualified registry, an eligible professional or group practice would be required to enter into and maintain an appropriate legal arrangement with a qualified Physician Quality Reporting System registry. Such arrangements would provide for the registry's receipt of patient-specific data from the eligible professional and the registry's disclosure of quality measures results and numerator and denominator data on Physician Quality Reporting System quality measures or measures groups on behalf of the eligible professional to CMS. Thus, the registry would act as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA) Business Associate and agent of the eligible professional. Such agents are referred to as ''data submission vendors.'' The ''data submission vendors'' would have the requisite legal authority to provide clinical quality measures results and numerator and denominator data on individual quality measures or measures groups on behalf of the eligible professional for the Physician Quality Reporting System.

We proposed that the registry, acting as a data submission vendor, would submit CMS-defined, registry-derived measures information to our designated database for the Physician Quality Reporting System, using a CMS-specified record layout, which will be provided to the registry by CMS. Similarly, we proposed that eligible professionals choosing to participate in the Physician Quality Reporting System through the registry-based reporting mechanism for the respective program year must select a qualified Physician Quality Reporting System registry and submit information on Physician Quality Reporting System individual quality measures or measures groups to the selected registry in the form and manner and by the deadline specified by the registry.

We proposed to post a list of qualified registries for the Physician Quality Reporting System for the respective program year on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.gov/pqrs*, which would include the registry name, contact information, the measures and/or measures group (if qualified) for which the registry is qualified and intends to report for the respective program year, and information regarding the cost of the registry to eligible professionals. However, we do not anticipate making this list available prior to the start of the respective program year. That is, we do not anticipate making the list of qualified registries for the 2012 Physician Quality Reporting System available prior to the start of the 2012 program year. We anticipate posting the names of the Physician Quality Reporting System qualified registries for the respective reporting period in the following 3 phases based on: (1) the registry's success in submitting Physician Quality Reporting System quality measures results and numerator and denominator data on the quality measures in a prior Physician Quality Reporting System program year (2008, 2009, 2010, 2011, etc.); (2) the registry's submission of a letter indicating their continued interest in being a Physician Quality Reporting System registry by October 31 of the year prior to the program year (that is, by October 31, 2011 for the 2012 program year); and (3) the registry's compliance with the Physician Quality Reporting System registry requirements for the respective program year as indicated by CMS' registry vetting process. The listing of a qualified registry will depend on which of the 3 proposed phases is most applicable to the registry. The manner in which we post the list of qualified registries is based on prior experience with participation in the Physician Quality Reporting System as a registry vendor.

We invited public comment on our proposed process and requirements for using the registry-based reporting mechanism for individual eligible professionals. The following is a summary of the comments we received regarding this proposal.

Comment: Several commenters supported our proposal to retain the registry reporting mechanism. One commenter stated that eligible professionals have met the criteria for satisfactory reporting at greater rates than when using the claims-based reporting mechanism. Some commenters stated that we should encourage use of registry-based reporting.

Response: We appreciate the commenter's feedback and are finalizing our proposal to retain the registry-based reporting mechanism.

Comment: One commenter noted that use of the registry-based reporting mechanism results in additional costs to the eligible professional wishing to participate in the Physician Quality Reporting System via the registry-based reporting mechanism.

Response: We understand that the use of registries may result in additional costs to the eligible professional, as many registries charge for their services. However, we note that the registry-based reporting mechanism optional and is only one of three mechanisms that may be used to report Physician Quality Reporting System measures. There is no up-front, monetary cost associated with participating in the

Physician Quality Reporting System via the claims-based reporting mechanism.

Comment: One commenter suggested that we develop a free, national registry that would meet the requirements for being a ''qualified'' registry so that a free registry option would be available for eligible professionals.

Response: We respectfully disagree. As we noted previously, many but not all registries charge for their services. As such, it is possible for eligible professionals to elect a free registry on which to report Physician Quality Reporting System quality measures. As there are free registry options, we do not see the need for a national registry.

Based on the comments received and for the reasons stated previously, we are finalizing the requirements described above for individual eligible professionals choosing the registry-based reporting option for the 2012 Physician Quality Reporting System and beyond.

(B) 2012 Qualification Requirements for Registries

Although we proposed to establish the registry-based reporting mechanism as a way to report Physician Quality Reporting System quality measures for 2012 and beyond, we proposed (76 FR 42843 through 42845) the following qualification requirements only apply for the 2012 program year. For the Physician Quality Reporting System in 2012, as in prior program years, we proposed to require a self-nomination process for registries wishing to submit Physician Quality Reporting System quality measures or measures groups on behalf of eligible professionals for services furnished during the applicable reporting periods in 2012. This qualification process allows us to ensure that registries are fully informed of the Physician Quality Reporting System reporting process and to ensure the registry is qualified, thereby improving the likelihood of accurate reporting.

We note that third party intermediaries may participate in various capacities under the Physician Quality Reporting System. In addition, in an effort to encourage the electronic submission of quality measures data from eligible professionals' EHRs, we proposed EHR-based reporting, as discussed later in this section. As a result, we believe it is important to distinguish entities that collect their data from an EHR from those entities that collect their data from other sources. As such, as discussed here and later in this section, we proposed, the following two categories of third party intermediaries that would be able to submit Physician Quality Reporting System measures data on behalf of eligible professional: (1) a registry, as defined at 42 CFR 414.90(b), which would be any data submission vendor submitting data from a source other than an EHR on behalf of eligible professionals that meets the proposed registry qualification requirements later in this section; and (2) EHR data submission vendors, which would be a data submission vendor that obtains its data from an eligible professional's EHR and that meets the 2012 EHR qualification requirements. However, for operational reasons, we may reserve the right to limit such entities to a single role such that the entity would need to decide whether it wants to serve as a registry or EHR data submission vendor but not both. We note that a registry could serve as an ''EHR data submission vendor'' to the extent that it obtains data from an eligible professional's EHR, but would need to meet the proposed 2012 EHR qualification requirements. To be considered a qualified registry for purposes of serving as a registry under the program and submitting individual quality measures on behalf of eligible professionals who choose the registry reporting mechanism for 2012, we proposed that both registries new to the Physician Quality Reporting System and those previously qualified must:

- Be in existence as of January 1, 2012.
- Have at least 25 participants by January 1, 2012.
- Provide at least 1 feedback report, based on the data submitted to them for the 2012 Physician Quality Reporting System incentive reporting period, but if technically feasible, provide at least 2 feedback reports throughout the year to participating eligible professionals. Although it is not a requirement that registries provide interim feedback reports, we believe it is in the stakeholder's interest to require early registry collection of data for purposes of providing a feedback report to eligible professionals before the end of the 2012 Physician Quality Reporting System incentive reporting period to determine what steps, if any, an eligible professional should take or may rectify to meet the criteria for satisfactory reporting.
- For purposes of distributing feedback reports to eligible professionals, collect an eligible professional's email addresses and have documentation from the eligible professional authorizing the release of his or her email address.
- Not be owned and managed by an individual locally-owned single-specialty group (in other words, single-specialty practices with only 1 practice location or solo practitioner practices are prohibited from self-nominating to become a qualified Physician Quality Reporting System registry).
- Participate in ongoing 2012 Physician Quality Reporting System mandatory support conference calls hosted by CMS (approximately 1 call per month), including an in-person registry kick-off meeting to be held at CMS headquarters in Baltimore, MD. Registries that miss more than one meeting will be precluded from submitting Physician Quality Reporting System data for the reporting year (2012).
- Be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 3 measures, which is the minimum amount of measures on which an eligible professional is required to report, in the 2012 Physician Quality Reporting System (according to the posted 2012 Physician Quality Reporting System Measure Specifications);
- Be able to calculate and submit measure-level reporting rates or, upon request, the data elements needed to calculate the reporting rates by TIN/NPI.
- Be able to calculate and submit, by TIN/NPI, a performance rate (that is, the percentage of a defined population who receive a particular process of care or achieve a particular outcome based on a calculation of the measure's numerator and denominator specifications) for each measure on which the TIN/NPI reports or, upon request the Medicare beneficiary data elements needed to calculate the performance rates.
- Be able to separate out and report on Medicare Part B FFS patients.
- Provide the name of the registry.
- Provide the reporting period start date the registry will cover.
- Provide the reporting period end date the registry will cover.
- Provide the measure numbers for the Physician Quality Reporting System quality measures on which the registry is reporting.
- Provide the measure title for the Physician Quality Reporting System quality measures on which the registry is reporting.
- Report the number of eligible instances (reporting denominator).
- Report the number of instances a quality service is performed (performance numerator).
- Report the number of performance exclusions, meaning the quality action was not performed for a valid reason as defined by the measure specification.
- Report the number of reported instances, performance not met (eligible professional receives credit for

reporting, not for performance), meaning the quality action was not performed for no valid reason as defined by the measure specification.

- Be able to transmit this data in a CMS-approved XML format.
- Comply with a CMS-specified secure method for data submission, such as submitting the registry's data in an XML file through an identity management system specified by CMS or another CMS-approved method, such as use of appropriate Nationwide Health Information Network specifications, if technically feasible.
- Submit an acceptable ''validation strategy'' to CMS by March 31, 2012. A validation strategy ascertains whether eligible professionals have submitted accurately and on at least the minimum number (80 percent) of their eligible patients, visits, procedures, or episodes for a given measure, which, as described in section VI.F.1.e.2., is the minimum percentage of patients on which an eligible professional must report on any given measure. Acceptable validation strategies often include such provisions as the registry being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method.
- Perform the validation outlined in the strategy and send the results to CMS by June 30, 2013 for the 2012 reporting year's data.
- Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the registry's receipt of patient-specific data from the eligible professionals, as well as the registry's disclosure of quality measure results and numerator and denominator data and/or patient-specific data on Medicare beneficiaries on behalf of eligible professionals who wish to participate in the Physician Quality Reporting System.
- Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the registry has authorized the registry to submit quality measure results and numerator and denominator data and/or patient-specific data on Medicare beneficiaries to CMS for the purpose of Physician Quality Reporting System participation. This documentation must be obtained at the time the eligible professional signs up with the registry to submit Physician Quality Reporting System quality measures data to the registry and must meet any applicable laws, regulations, and contractual business associate agreements.
- Provide CMS access (upon request for health oversight purposes like validation) to review the Medicare beneficiary data on which 2012 Physician Quality Reporting System registry-based submissions are founded or provide to CMS a copy of the actual data (upon request).
- Provide CMS a signed, written attestation statement via mail or email which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete.
- Use Physician Quality Reporting System measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated. CMS will provide registries a standard set of logic to calculate each measure and/or measures group they intend to report in 2012.
- Provide a calculated result using the CMS supplied measure calculation logic and XML file for each measure that the registry intends to calculate. The registries will be required to show that they can calculate the proper measure results (that is, reporting and performance rates) using the CMS-supplied logic and send the calculated data back to CMS in the specified format.

In addition to meeting all the requirements specified previously for the reporting of individual quality measures via registry, for registries that intend to report on 2012 Physician Quality Reporting System measures groups, we proposed that both registries new to the Physician Quality Reporting System and those previously qualified must:

- Indicate the reporting period chosen for each eligible professional who chooses to submit data on measures groups.
- Base reported information on measures groups only on patients to whom services were furnished during the 2012 reporting period.
- Agree that the registry's data may be inspected or a copy requested by CMS and provided to CMS under our oversight authority.
- Be able to report consistent with the reporting criteria requirements, as specified in section IV.F.1.e.2.

We noted in the proposed rule that we intended to post the final 2012 Physician Quality Reporting System registry requirements on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.gov/pqrs* by November 15, 2011 or shortly thereafter. We anticipate that new registries that wish to self-nominate for 2012 would be required to do so by January 31, 2012.

Furthermore, we proposed (76 FR 42845) that registries that were ''qualified'' for 2011 and wish to continue to participate in 2012 will not need to be ''re-qualified'' for 2012, but instead are only required to demonstrate that they can meet the new 2012 data submission requirements. For technical reasons, however, we did not expect to be able to complete this vetting process for the new 2012 data submission requirements until mid-2012. Therefore, for 2012, we indicated we may not be able to post the names of registries that are qualified for the 2012 Physician Quality Reporting System until we have determined the previously qualified registries that wish to be qualified for the 2012 Physician Quality Reporting System are in compliance with the new registry requirements.

We proposed that registries ''qualified'' for 2011, who are successful in submitting 2011 Physician Quality Reporting System data, and wish to continue to participate in 2012 would indicate their desire to continue participation for 2012 by submitting a self-nomination statement via a web-based tool to CMS indicating their continued interest in being a Physician Quality Reporting System registry for 2012 and their compliance with the 2012 Physician Quality Reporting System registry requirements by no later than October 31, 2011. Additionally, registries that were qualified but unsuccessful in submitting 2011 Physician Quality Reporting System data (that is, fail to submit 2011 Physician Quality Reporting System data per the 2011 Physician Quality Reporting System registry requirements) must go through a full self-nomination vetting process for 2012.

We further proposed that by March 31, 2012, registries that are unsuccessful at submitting registry data in the correct data format for 2011 must be able to meet the 2012 Physician Quality Reporting System registry requirements and go through the full vetting process again. This would include CMS receiving the registry's self-nomination by March 31, 2012. We proposed that the aforementioned registry requirements would also apply for the purpose of a registry qualifying to submit the electronic prescribing measure for the 2012 eRx Incentive Program. We anticipate finalizing the list of 2012 Physician Quality Reporting System registries by Summer 2012.

For eligible professionals considering this reporting mechanism, we point out that even though a registry is listed as

''qualified,'' we cannot guarantee or assume responsibility for the registry's successful submission of the required Physician Quality Reporting System quality measures results or measures group results or required data elements submitted on behalf of a given eligible professional.

We invited public comments on the proposed requirements to be considered a qualified registry for purposes of the 2012 Physician Quality Reporting System. We also sought comment on disallowing previously-qualified registries from submitting data on Physician Quality Reporting System quality measures in future years if it is found that the data the registries provide are found to be significantly inaccurate (76 FR 42845). The following is a summary of the comments received regarding those proposals.

Comment: One commenter supported our proposal to have registries and EHRs (including both direct EHR-based reporting and EHR data submission vendors) provide at least two feedback reports throughout the year to participating eligible professionals, if technically feasible.

Response: We appreciate the commenter's support and are finalizing this requirement.

Comment: One commenter sought clarification on the terms ''needed data elements.''

Response: The type of data we are referring to is the same type of data we required in prior years; however, the specific data elements will be addressed in subsequent guidance. We anticipate that the data elements will be similar to the elements contained within the 2011 Physician Quality Reporting System Registry XML Specifications which are posted on the PQRS section of the CMS Web site at *http://www.cms.gov/PQRS/20_AlternativeReportingMechanisms.asp#TopOfPage.* This information is made available within 4–6 weeks of the publication of this final rule to allow interested vendors the opportunity to evaluate their systems for the needed functionality and implement any new capabilities as needed.

Comment: One commenter was opposed to our requirement that registries qualified for 2012 only report on Medicare Part B FFS patients.

Response: We appreciate the commenter's feedback. However, as the Physician Quality Reporting System is a Medicare program, we would like to concentrate the data we collect on data that assesses the quality of care our beneficiaries receive. Furthermore, since we can only receive data on Medicare beneficiaries via claims, which is another reporting mechanism we are finalizing for 2012 and beyond, and we are interested in collecting the same type of data throughout each reporting mechanism, we are finalizing the requirement that registries only report on Medicare Part B FFS patients.

Comment: One commenter was opposed to our proposed vetting timelines to qualify registries for the 2012 Physician Quality Reporting System. The commenter urged us to accelerate the qualification process for registries.

Response: We appreciate the commenter's feedback. However, we must allow sufficient time after the publication of the qualification requirements in this final rule with comment period for vendors to decide if they wish to participate in the Physician Quality Reporting System and become qualified. After self-nomination, we attempt to allow ample time for vendors to submit test files and resubmit them if their first submission is unacceptable. We would like to give every interested vendor as much time to qualify as is possible without delaying the dissemination of this information (who is a qualified vendor) to eligible professionals who may wish to use one of these systems or vendors to participate in the Physician Quality Reporting System.

Comment: Some commenters urged us to post the list of qualified registries for the Physician Quality Reporting System prior to the start of the respective program year. Some commenters also asked that we post cost information. Commenters believed that providing the list of registries earlier, as well as posting cost information, would help eligible professionals make a more informed decision with respect to purchasing registries.

Response: We understand that it would benefit eligible professionals to have the list of qualified 2012 Physician Quality Reporting System registries available earlier. However, due to the time it takes to vet registries for qualification for the Physician Quality Reporting System, we anticipate that we will not be able to post the list of qualified registries prior to the start of the respective program year. However, we will make every effort to post the list of qualified registries for each respective year as soon as possible. With respect to posting registry cost information, upon further consideration, we are not posting cost information with our list of qualified registries.

Comment: Although several commenters supported our proposal to add a the new EHR data submission vendor classification, several commenters opposed our proposal to limit entities that may qualify as both a registry and EHR data submission vendor to a single role such that the entity would need to decide whether it wants to serve as a registry or EHR data submission vendor but not both. These commenters stated that these entities should be allowed to qualify as both qualified registries and qualified EHR data submission vendors.

Response: We appreciate the commenters' feedback and understand that some entities who believe they fulfill the qualification requirements for both registries and EHR data submission vendors desire to be qualified for reporting under the Physician Quality Reporting System as both. However, we believe this requirement is necessary to separate vendors qualifying as registries and EHR data submission vendors, and therefore, we are finalizing this requirement.

Comment: One commenter supported the idea of disqualifying registries that submit inaccurate data in future program years. Although one commenter was not opposed to disqualifying registries that submit inaccurate information in future program years, the commenter noted that we should allow for reporting errors that are outside a registry's control.

Response: We are aware of many of the issues registries encounter during the collection of data they receive from the eligible professionals for whom they provide services. However, we do, as part of its vetting process, require registries to attest to the accuracy of their data and have a validation process in place to ensure the data is complete and accurate. As we move towards implementing the Value-Based Modifier, the collection of accurate data will become increasingly important. We anticipate adopting in future rulemaking the option of disqualifying a registry from future Physician Quality Reporting System reporting if their data is inaccurate for future years of the program. Details about this option, including the basis for disqualifying a registry for submission of inaccurate data, will be addressed in future rulemaking.

Based on the comments received and for the reasons explained previously, we are finalizing the proposed requirements that registries must complete in order to be ''qualified'' for 2012. Although we proposed the use of a web-based tool, but it has not yet been developed to handle self-nomination requests; therefore, we are finalizing submission of this self-nomination statement via a letter to CMS.

As we indicated, we anticipate finalizing the list of 2012 Physician

Quality Reporting System registries by Summer 2012. We understand that it would benefit eligible professionals to have the list of qualified 2012 Physician Quality Reporting System registries available earlier. However, due to the time it takes to vet these registries, we may not be able to finalize and post the list of 2012 Physician Quality Reporting System registries until Summer 2012.

(3) EHR-Based Reporting

For 2012 and beyond, we proposed (76 FR 42846) that eligible professionals who choose to participate in the Physician Quality Reporting System via the EHR-based reporting mechanism have the option of submitting quality measure data obtained from their Physician Quality Reporting System qualified EHR to CMS either: (1) Directly from his or her qualified EHR, in the CMS-specified manner, or (2) indirectly from a qualified EHR data submission vendor (on the eligible professional's behalf), in the CMS-specified manner. We invited but received no public comments on our proposal to allow for EHR-based reporting for 2012 and beyond via a qualified direct EHR-based reporting or qualified EHR data submission vendor. Therefore, we are finalizing our proposal to allow eligible professionals to submit quality measure data obtained from their Physician Quality Reporting System qualified EHR to CMS either: (1) Directly from his or her qualified EHR, in the CMS-specified manner or (2) indirectly from a qualified EHR data submission vendor (on the eligible professional's behalf), in the CMS-specified manner.

(A) Direct EHR-Based Reporting

(i) Requirements for the Direct EHR-Based-Reporting Mechanism—Individual Eligible Professionals

For 2012 and beyond, we proposed to retain the EHR-based reporting mechanism via a qualified EHR (as defined in section VI.F.1.d.(3).(b)) for the purpose of satisfactorily reporting Physician Quality Reporting System quality measures. We proposed the following requirements for individual eligible professionals associated with EHR-based reporting: (1) Selection of a Physician Quality Reporting System qualified EHR product and (2) submission of Medicare clinical quality data extracted from the EHR directly to CMS, in the CMS-specified manner.

We proposed (76 FR 42846) that, in addition to meeting the appropriate criteria for satisfactory reporting of individual measures for the 2012 Physician Quality Reporting System EHR reporting option, eligible professionals who choose the EHR-based reporting mechanism for the 2012 Physician Quality Reporting System would be required to have a Physician Quality Reporting System qualified EHR product. We understand that eligible professionals may have purchased Certified EHR Technology for purposes of reporting under the Medicare and Medicaid EHR Incentive Programs. Such Certified EHR Technology may or may not be qualified for purposes of the 2012 Physician Quality Reporting System. Eligible professionals would need to ensure that their Certified EHR Technology is also qualified for purposes of the 2012 Physician Quality Reporting System to participate in the Physician Quality Reporting System via the EHR-based reporting mechanism for 2012.

For 2012, we proposed to modify the current list of EHR vendors qualified under the Physician Quality Reporting System to indicate which of the qualified vendors' products have also received a certification for the purposes of the EHR Incentive Programs.

We invited public comment on the 2012 proposed qualifications for direct EHR-based reporting. The following is a summary of the comments we received regarding these proposals.

Comment: Some commenters were opposed to our requirement that Certified EHR Technology must also be qualified for purposes of reporting 2012 Physician Quality Measures. Therefore, one commenter opposed all requirements for EHR qualification that did not align with the requirements for Certified EHR Technology. One commenter stated that eligible professionals should not have the added burden of having to determine which Certified EHR Technology systems are also qualified for purposes of reporting 2012 Physician Quality Reporting System measures.

Response: We appreciate the commenters' feedback. However, at this time, it is not technically feasible to automatically qualify Certified EHR Technology to report 2012 Physician Quality Reporting System measures. As we stated in the proposed rule (76 FR 42846), the certification process for EHR technology does not test the EHR product's ability to output a file that meets the Physician Quality Reporting System measures file specifications. We are currently exploring ways to further align these two programs' reporting requirements for future years so that Certified EHR Technology may be used to satisfy both the Medicare EHR Incentive Program and the Physician Quality Reporting System without any additional testing.

For the reasons stated previously, we are finalizing these requirements for individual eligible professionals choosing the direct EHR-based reporting-based reporting mechanism. We anticipate that testing for qualified direct EHR-based reporting products will occur in late 2012, immediately followed by the submission of the eligible professional's actual 2012 Physician Quality Reporting System data in early 2013. This entire final test/production data submission timeframe for 2012 is expected to be December 2012 through February 2013. We are currently vetting newly self-nominated EHR vendor products for possible qualification for the 2012 Physician Quality Reporting System program year. Similar to prior years, we expect to list the 2012 Physician Quality Reporting System qualified EHR products by January 2012.

(ii) 2012 Qualification Requirements for Direct EHR-Based Reporting Products

For EHR-based reporting products to be qualified to be used to directly report 2012 Physician Quality Reporting System quality measures data on behalf of eligible professionals, we proposed (76 FR 42846) that a test of quality data submission from eligible professionals who wish to report 2012 quality measure data directly from their qualified EHR product would be required.

For EHR-based reporting vendors wishing to qualify EHR products for participation in the 2012 Physician Quality Reporting System-Medicare Incentive Pilot for the Medicare EHR Incentive Program (discussed in section VI.H. of this final rule with comment period), we proposed (76 FR 42846) a separate, accelerated vetting process for EHR vendors and their products. This vetting process would be the same process as the vetting process for EHR vendor products for the 2012 Physician Quality Reporting System that is currently underway. We will begin the vetting process for these additional EHR vendors and their products in the beginning of 2012 and anticipate that the vetting process be completed by Summer/Fall 2012.

We further proposed that any EHR vendor interested in having one or more of their products being ''qualified'' to submit quality data extracted from an EHR to CMS on eligible professionals' behalf for the 2012 Physician Quality Reporting System would be required to self-nominate. We anticipate that the self-nomination deadline will occur no later than December 31, 2011. We

expect to post instructions for self-nomination by the 4th quarter of CY 2011 on the Physician Quality Reporting System section of CMS Web site.

We invited public comment on the proposed 2012 qualification requirements for EHR products capable of directly reporting. The following is a summary of the comments we received regarding this proposal.

Comment: One commenter was opposed to our proposed vetting timelines to qualify EHRs for the 2012 Physician Quality Reporting System. The commenter urged us to accelerate the process to qualify EHR systems.

Response: We appreciate the commenter's feedback. However, we must allow sufficient time after the publication of the qualification requirements in this final rule with comment period for vendors to decide if they wish to participate in the Physician Quality Reporting System and become qualified. After self-nomination, we attempt to allow ample time for vendors to submit test files and resubmit them if their first submission is unacceptable. We would like to give every interested vendor as much time to qualify as is possible without delaying the dissemination of this information (who is a qualified vendor) to eligible professionals who may wish to use one of these systems or vendors to participate in the Physician Quality Reporting System.

Comment: Some commenters urged us to align our EHR qualification requirements with the requirements needed to become Certified EHR Technology under the EHR Incentive Program.

Response: We agree with the recommendation to align the EHR Incentive Program with the Physician Quality Reporting System, particularly with respect to reporting clinical quality measure results under the Physician Quality Reporting System-Medicare EHR Incentive Pilot discussed in the following section VI.H. of this final rule with comment period. We are also exploring ways to align the format for receiving the measures data used by both programs.

Comment: One commenter was opposed to all qualification requirements for EHRs (including both direct EHR-based reporting and EHR data submission vendors) that exceed the requirements to become Certified EHR Technology (which is the EHR technology used in the EHR Incentive Program).

Response: We are unsure of the specific objection the commenter is expressing with respect to EHR requirements. CMS only requires EHR vendors who desire to have their products directly submit quality measure data to CMS for the Physician Quality Reporting System to undergo a vetting and testing process in order to determine if the product(s) can properly directly submit data to CMS. This testing process will help to provide more certainty for an eligible professional who is relying on their software to participate in the Physician Quality Reporting System. Without this testing, we believe there would be a risk of a given product not being able to export the quality data in the format that CMS can receive and process it.

Based on the comments received and for the reasons stated above, we are finalizing the qualification requirements as proposed for direct EHR products.

(B) EHR Data Submission Vendors

(i) Requirements for the EHR Data Submission Vendor-Based Reporting Mechanism—Individual Eligible Professionals

For 2012 and beyond, we proposed (76 FR 42846) a second EHR-based reporting mechanism via a qualified EHR data submission vendor (as defined in 42 CFR 414.90(b)) for the purpose of satisfactorily reporting Physician Quality Reporting System quality measures. We proposed the following requirements for individual eligible professionals associated with indirect EHR-based reporting-based reporting: (1) Selection of a Physician Quality Reporting System qualified EHR data submission vendor and (2) submission of Medicare clinical quality data extracted from the EHR to a qualified ''EHR data submission vendor'' (which may include some current registries, EHR vendors, and other entities that are able to receive and transmit clinical quality data extracted from an EHR) to CMS, in the CMS-specified manner. For eligible professionals who choose to electronically submit Medicare clinical quality data extracted from their EHR to a qualified EHR data submission vendor, the EHR data submission vendor would then submit the Physician Quality Reporting System measures data to CMS in a CMS-specified manner on the eligible professional's behalf for the respective program year.

For 2012, we proposed that in order for an eligible professional to submit Medicare clinical quality data extracted from his or her EHR to CMS via an EHR data submission vender, the eligible professional must enter into and maintain an appropriate legal arrangement with a qualified 2012 EHR data submission vendor that is capable of receiving and transmitting Medicare clinical quality data extracted from an EHR. Such arrangements would provide for the EHR data submission vendor's receipt of beneficiary-specific data from the eligible professional and the EHR data submission vendor's disclosure of the beneficiary-specific data on behalf of the eligible professional to CMS. Thus, the EHR data submission vendor would act as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA) Business Associate and agent of the eligible professional. Such agents are referred to as ''EHR data submission vendors.'' The ''EHR data submission vendors'' would have the requisite legal authority to provide beneficiary-specific data on the 2012 Physician Quality Reporting System EHR measures on behalf of the eligible professional to CMS for the Physician Quality Reporting System.

We also proposed that eligible professionals choosing to participate in the 2012 Physician Quality Reporting System through the EHR-based reporting mechanism via an EHR data submission vendor for 2012 must select a qualified Physician Quality Reporting System EHR data submission vendor and submit information on Physician Quality Reporting System EHR measures to the selected EHR data submission vendor in the form and manner, and by the deadline specified by the EHR data submission vendor.

We invited but received no public comments on the proposed requirements for individual eligible professionals using EHR data submission vendors to submit Physician Quality Reporting System quality measures data. Therefore, we are finalizing the 2012 qualification requirements as proposed for individual eligible professionals using EHR data submission vendors to submit Physician Quality Reporting System quality measures data.

We will also be vetting those self-nominated EHR data submission vendors for possible qualification to submit 2012 Physician Quality Reporting System measures on eligible professionals' behalf under the EHR-based reporting mechanism. We expect to list the entities that are EHR data submission vendors qualified to submit 2012 Physician Quality Reporting System EHR measures on eligible professionals' behalf by mid-2012.

Please note that we cannot assume responsibility for the successful submission of data from eligible professionals' EHRs. In addition, eligible professionals who decide to submit the Physician Quality Reporting System measures directly from his or

her EHR should begin attempting submission soon after the opening of the clinical data warehouse in order to assure the eligible professional has a reasonable period of time to work with his or her EHR and/or its vendors to correct any problems that may complicate or preclude successful quality measures data submission through that EHR.

(ii) 2012 Qualification Requirements for EHR Data Submission Vendors

Similar to our 2012 qualification requirements for vendors that provide EHR products that are qualified as being capable of directly reporting, we proposed that qualified EHR data submission vendors that wish to submit 2012 quality measures data obtained from an eligible professional's qualified EHR product to CMS on the eligible professional's behalf would have to meet certain 2012 qualification requirements, explained in detail the proposed rule (76 FR 42847).

We invited public comment on the proposed qualification requirements on the 2012 for EHR data submission vendors who wish to submit Physician Quality Reporting System quality measures data. Please note that some of the issues raised by commenters regarding the 2012 qualification requirements for registries, which were addressed previously, were similar or the same as those raised about the qualification requirements for EHR data submission vendors. Therefore, we addressed many of those issues previously. The following is a summary of the comments we received regarding these ERH data submission vendor proposals.

Comment: One commenter was opposed to our proposed timelines to qualify EHRs for the 2012 Physician Quality Reporting System. The commenter urged that we accelerate the process to qualify EHRs for the 2012 Physician Quality Reporting System to provide earlier notice to eligible professionals as to which EHR vendors have been qualified.

Response: We appreciate the commenter's feedback. However, we must allow sufficient time after the publication of the qualification requirements in this final rule with comment period for vendors to decide if they wish to participate in the Physician Quality Reporting System and become qualified. After self-nomination, we attempt to allow ample time for vendors to submit test files and resubmit them if their first submission is unacceptable. We would like to give every interested vendor as much time to qualify as is possible without delaying the dissemination of this information (who is a qualified vendor) to eligible professionals who may wish to use one of these systems or vendors to participate in the Physician Quality Reporting System.

Comment: Some commenters urged us to align our EHR qualification requirements (for both direct EHR-based reportingand EHR data submission vendors) with the requirements needed to become Certified EHR Technology under the EHR Incentive Program.

Response: We agree with the recommendation to align the EHR Incentive Program with the Physician Quality Reporting System, particularly with respect to reporting clinical quality measure results under the Physician Quality Reporting System-Medicare EHR Incentive Pilot discussed in section VI.F.4. of this final rule with comment period. We are also exploring ways to align the format for receiving the measures data used by both programs.

Based on the comments received and for the reasons stated above, we are finalizing the 2012 qualification requirements as proposed for EHR data submission vendors who wish to submit Physician Quality Reporting System quality measures data.

EHR data submission vendors that wish to submit 2012 quality measures data obtained from an eligible professional's EHR product to CMS on the eligible professional's behalf must submit test data in late 2012 followed by the submission of the eligible professional's actual 2012 Physician Quality Reporting System data in early 2013.

For data submission vendors wishing to qualify for participation in the 2012 Physician Quality Reporting System-Medicare Incentive Pilot for the Medicare EHR Incentive Program (discussed in section VI.H. of this final rule with comment period), these data submission vendors must undergo a separate, accelerated vetting process for EHR data submission vendors. Although the requirements for becoming a qualified EHR data submission vendor are different than becoming a qualified EHR product for direct EHR-based reporting, the vetting process will be the same process as the vetting process for EHR vendor products for the 2012 Physician Quality Reporting System that is currently underway. We will begin the vetting process for these EHR data submission vendors in the beginning of 2012 and anticipate that the vetting process will be completed by Summer/Fall 2012.

Any EHR data submission vendor interested in being ''qualified'' to submit quality data extracted from an EHR to CMS on eligible professionals' behalf for the 2012 Physician Quality Reporting System is required to self-nominate. We anticipate that the self-nomination deadline will occur no later than December 31, 2011. We expect to post instructions for self-nomination by the 4th quarter of CY 2011 on the Physician Quality Reporting System section of CMS Web site.

EHR data submission vendors who wish to submit 2012 Physician Quality Reporting System quality measure data must also meet the following qualification requirements:

- Not be in a beta test form.
- Be in existence as of January 1, 2012
- Have at least 25 active users.
- Participate in ongoing Physician Quality Reporting mandatory support conference calls hosted by CMS (approximately one call per month). Failure to attend more than one call per year would result in the removal of the EHR data submission vendor from the 2012 EHR qualification process.
- Have access to the identity management system specified by CMS (such as, but not limited to, the Individuals Authorized Access to CMS Computer Systems, or IACS) to submit clinical quality data extracted to a CMS clinical data warehouse.
- Submit a test file containing dummy Medicare clinical quality data to a CMS clinical data warehouse via an identity management system specified by CMS during a timeframe specified by CMS. In 2011, the requirement to submit a test file could have contained real or dummy data. However, for privacy reasons, we have decided to only provide for the submission of test files containing dummy data. We have finalized revisions to 42 CFR 414.90 to reflect this change.
- Submit a file containing the eligible professional's 2012 Physician Quality Reporting System Medicare clinical quality data extracted from the EHR for the entire 12-month reporting period via the CMS-specified identify management system during the timeframe specified by us in early 2013.
- Provide at least 1 feedback report, based on the data submitted to them for the 2012 Physician Quality Reporting System incentive reporting period, but if technically feasible, provide at least 2 feedback reports throughout the year to participating eligible professionals.
- Be able to collect all needed data elements and transmit to CMS the data at the beneficiary level.
- Be able to separate out and report on Medicare Part B FFS patients.

• Provide the measure numbers for the quality measures on which the data submission vendor is reporting.

• Be able to transmit this data in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA).

• Comply with a CMS-specified secure method for data submission, such as submitting the EHR data submission vendor's data in an XML file through an identity management system specified by CMS or another approved method, such as use of appropriate Nationwide Health Information Network specifications, if technically feasible.

• Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the data submission vendor's receipt of patient-specific data from the eligible professionals, as well as the data submission vendor's disclosure of patient-specific data on Medicare beneficiaries on behalf of eligible professionals who wish to participate in the Physician Quality Reporting System.

• Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the data submission vendor has authorized the data submission vendor to submit patient-specific data on Medicare beneficiaries to CMS for the purpose of Physician Quality Reporting System participation. This documentation must be obtained at the time the eligible professional signs up with the data submission vendor to submit Physician Quality Reporting System quality measures data to the data submission vendor and must meet any applicable laws, regulations, and contractual business associate agreements.

• Provide CMS access (upon request for health oversight purposes like validation) to review the Medicare beneficiary data on which 2012 Physician Quality Reporting System EHR-based submissions are founded or provide to CMS a copy of the actual data (upon request).

• Provide CMS a signed, written attestation statement via mail or email which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete.

• Use Physician Quality Reporting System measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated. CMS will provide EHR data submission vendors a standard set of logic to calculate each measure and/or measures group they intend to report in 2012.

• Provide a calculated result using the CMS supplied measure calculation logic and XML file for each measure that the EHR data submission vendor intends to calculate. The data submission vendors will be required to show that they can calculate the proper measure results (that is, reporting and performance rates) using the CMS-supplied logic and send the calculated data back to CMS in the specified format.

For EHR data submission vendors participating in the Physician Quality Reporting System-Medicare EHR Incentive Pilot for 2012 (discussed in section VI.H. of this final rule with comment period) and wish to also submit Medicare clinical quality data extracted from an EHR for the purposes of the 2012 Physician Quality Reporting System incentive, these EHR data submission vendors must meet the following requirements in addition to the requirements stated previously:

• Be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level.

• Be able to calculate and submit measure-level reporting rates or, upon request, the data elements needed to calculate the reporting rates by TIN/NPI.

• Be able to calculate and submit, by TIN/NPI, a performance rate (that is, the percentage of a defined population who receive a particular process of care or achieve a particular outcome based on a calculation of the measure's numerator and denominator specifications) for each measure on which the TIN/NPI reports or, upon request the Medicare beneficiary data elements needed to calculate the reporting rates.

• Report the number of eligible instances (reporting denominator).

• Report the number of instances a quality service is performed (reporting numerator).

• Report the number of performance exclusions, meaning the quality action was not performed for a valid reason as defined by the measure specification.

• Report the number of reported instances, performance not met (eligible professional receives credit for reporting, not for performance), meaning the quality action was not performed for no valid reason as defined by the measure specification.

• Be able to transmit this data in a CMS-approved XML format.

• Submit an acceptable ''validation strategy'' to CMS by March 31, 2012. A validation strategy ascertains whether eligible professionals have submitted accurately and on at least the minimum number (80 percent) of their eligible patients, visits, procedures, or episodes for a given measure, which, as described in section VI.F.1.e.2. of this final rule with comment period, is the minimum percentage of patients on which an eligible professional must report on any given measure. Acceptable validation strategies often include such provisions as the EHR data submission vendor being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method.

• Perform the validation outlined in the strategy and send the results to CMS by June 30, 2013 for the 2012 reporting year's data.

• Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the data submission vendor's receipt of patient-specific data from the eligible professionals, as well as the data submission vendor's disclosure of quality measure results and numerator and denominator data on Medicare beneficiaries on behalf of eligible professionals who wish to participate in the Physician Quality Reporting System.

• Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the data submission vendor has authorized the data submission vendor to submit quality measure results and numerator and denominator data on Medicare beneficiaries to CMS for the purpose of Physician Quality Reporting System participation. This documentation must be obtained at the time the eligible professional signs up with the data submission vendor to submit Physician Quality Reporting System quality measures data to the data submission vendor and must meet any applicable laws, regulations, and contractual business associate agreements.

• Use Physician Quality Reporting System measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated.

• Provide a calculated result using the CMS supplied measure calculation logic and XML file for each measure that the EHR data submission vendor intends to calculate. The data submission vendors are required to show that they can calculate the proper measure results (that is, reporting and performance rates) using the CMS-supplied logic and send the calculated data back to CMS in the specified format.

For 2012, the EHR data submission vendor must submit clinical quality data on Medicare beneficiaries extracted from eligible professionals' EHRs to our designated database for the Physician Quality Reporting System using a CMS-specified record layout, which will be provided to the EHR data submission vendor by CMS. In addition, for purposes of also reporting 2012 Physician Quality Reporting System quality measures, the EHR data submission vendor must to submit patient level Medicare clinical quality data extracted from the eligible professional's EHR using the same CMS-specified record layout that qualified EHR products must be able to produce for purposes of an eligible professional directly submitting the 2012 Physician Quality Reporting System EHR measures to CMS.

(C) Qualification Requirements for Direct EHR-Based Reporting Data Submission Vendors and Their Products for the 2013 Physician Quality Reporting System

As in prior years, unlike the qualification process for registries, EHR vendors, which include vendors that provide EHR products that qualify for direct EHR-based reporting and EHR data submission vendors, are tested for qualification a year ahead of the program year in which the EHR vendor intends to submit Physician Quality Reporting System quality measures on behalf of individual eligible professionals or where its product(s) are available for use by eligible professionals to submit Physician Quality Reporting System measures directly to CMS.

We proposed EHR vendor testing for the 2013 Physician Quality Reporting System program year to qualify new EHR vendors and EHR data submission vendors and their EHR products for submission of Medicare beneficiary quality data extracted from EHR products to the CMS Medicare clinical quality data warehouse for the 2013 Physician Quality Reporting System.

In order for EHR vendors to be qualified to report 2013 Physician Quality Reporting System data to CMS, we proposed that EHR vendors would be required to meet the following requirements:

- Not be in a beta test form.
- Be in existence as of January 1, 2012.
- Have at least 25 active users.
- Participate in ongoing Physician Quality Reporting mandatory support conference calls hosted by CMS (approximately one call per month). Failure to attend more than one call per year would result in the removal of the EHR data submission vendor from the 2012 EHR qualification process.
- Indicate the reporting option the vendor seeks to qualify for its users to submit in addition to individual measures.
- Have access to the identity management system specified by CMS (such as, but not limited to, the Individuals Authorized Access to CMS Computer Systems, or IACS) to submit Medicare clinical quality data extracted to a CMS clinical data warehouse.
- Submit a test file containing dummy Medicare clinical quality data to a CMS clinical data warehouse via an identity management system specified by CMS during a timeframe specified by CMS. In 2011, the requirement to submit a test file could have contained real or dummy data. However, for privacy reasons, we have decided to only provide for the submission of test files containing dummy data. We proposed revisions to 42 CFR 414.90 to reflect this change.
- Submit a file containing the eligible professional's 2012 Physician Quality Reporting System Medicare clinical quality data extracted from the EHR for the entire 12-month reporting period via the CMS-specified identify management system during the timeframe specified by us in early 2013.
- Provide at least 1 feedback report, based on the data submitted to them for the 2012 Physician Quality Reporting System incentive reporting period, and if technically feasible, provide at least two feedback reports throughout the year to participating eligible professionals.
- Be able to collect all needed data elements and transmit to CMS the data at the beneficiary level.
- Be able to separate out and report on Medicare Part B FFS patients.
- Provide the measure numbers for the quality measures on which the data submission vendor is reporting.
- Be able to transmit this data in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA).
- Comply with a CMS-specified secure method for data submission, such as submitting the EHR vendor's data in an XML file through an identity management system specified by CMS or another approved method, such as use of appropriate Nationwide Health Information Network specifications, if technically feasible.
- Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the data submission vendor's receipt of patient-specific data from the eligible professionals, as well as the data submission vendor's disclosure of patient-specific data on Medicare beneficiaries on behalf of eligible professionals who wish to participate in the Physician Quality Reporting System.
- Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the data submission vendor has authorized the data submission vendor to submit patient-specific data on Medicare beneficiaries to CMS for the purpose of Physician Quality Reporting System participation. This documentation must be obtained at the time the eligible professional signs up with the data submission vendor to submit Physician Quality Reporting System quality measures data to the data submission vendor and must meet any applicable laws, regulations, and contractual business associate agreements.
- Provide CMS access (upon request for health oversight purposes like validation) to review the Medicare beneficiary data on which 2012 Physician Quality Reporting System EHR-based submissions are founded or provide to CMS a copy of the actual data (upon request).
- Provide CMS a signed, written attestation statement via mail or email which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete.
- Use Physician Quality Reporting System measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated. CMS would provide EHR vendors a standard set of logic to calculate each measure and/or measures group they intend to report in 2012.
- Provide a calculated result using the CMS supplied measure calculation logic and XML file for each measure that the EHR vendor intends to calculate. The data submission vendors would be required to show that they can calculate the proper measure results (that is, reporting and performance rates) using the CMS-supplied logic and send the calculated data back to CMS in the specified format.

This is the same self-nomination process described in the ''Requirements for Electronic Health Record (EHR) Vendors to Participate in the 2012 Physician Quality Reporting System EHR Program,'' posted on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.gov/*

PQRS/20_AlternativeReporting Mechanisms.asp#TopOfPage. For 2013, we proposed that these requirements would apply not only for the purpose of a vendor's EHR product being qualified so that the product's users may submit 2013 Medicare beneficiary data extracted from the EHR for the 2013 Physician Quality Reporting System in 2014, but also for the purpose of a vendor's EHR product being qualified to electronically submit Medicare beneficiary data extracted from the EHR for reporting the electronic prescribing measure for the eRx Incentive Program 2013 incentive and 2014 payment adjustment. Similarly, we proposed that these requirements would apply not only for the purposes of an EHR data submission vendor being qualified to submit 2013 Medicare beneficiary data from eligible professionals' EHRs for the 2013 Physician Quality Reporting System in 2014 but also for the purpose of an EHR data submission vendor being qualified to electronically submit Medicare beneficiary data extracted from the EHR for reporting the electronic prescribing measure for the eRx Incentive Program 2013 incentive and 2014 payment adjustment.

We also proposed that if an EHR vendor misses more than one mandatory support call or meeting, the vendor and their product and/or EHR data submission vendor would be disqualified for the Physician Quality Reporting System reporting year, which is covered by the call.

For the 2013 Physician Quality Reporting System, we proposed that previously qualified and new vendors and/or EHR data submission vendors would need to incorporate any new EHR measures (that is, electronically-specified measures), as well as update their electronic measure specifications and data transmission schema should either or both change, finalized for the Physician Quality Reporting System for 2013 if they wish to maintain their Physician Quality Reporting System qualification.

We invited public comment related to our proposed qualification requirements for EHR direct and data submission vendors and their products for the 2013 Physician Quality Reporting System. The comments received regarding this proposal have been addressed previously.

Based on the comments received and for the reasons previously stated, we are finalizing the qualification requirements for EHR direct and data submission vendors and their products for the 2013 Physician Quality Reporting System.

Any EHR vendor interested in having one or more of their EHR products ''qualified'' to submit quality data extracted from their EHR products to the CMS Medicare clinical quality data warehouse for the 2013 Physician Quality Reporting System must submit their self-nomination statement by January 31, 2012. Whereas, in prior program years, EHR vendors have submitted self-nomination statements via mail, we proposed to have EHR vendors submit self-nomination statements via a web-based tool, if technically feasible for us to develop such a tool. However, at this time, it is not technically feasible to collect self-nomination statements via a web-based tool. Therefore, as we proposed as an alternative, we will accept self-nomination statements from EHR vendors that wish to be qualified for the 2013 Physician Quality Reporting System via email. We expect to post instructions for submitting the self-nomination statement and the 2013 EHR vendor requirements in the 4th quarter of CY 2011. Specifically, for the 2013 Physician Quality Reporting System, in order to ensure EHR vendors' interest in participating in the 2013 Physician Quality Reporting System, only EHR vendors that self-nominate by January 31, 2012 to participate in the EHR Program testing during calendar year 2012 will be considered qualified EHR vendors for the 2013 Physician Quality Reporting System.

e. Incentive Payments for the 2012 Physician Quality Reporting System

In accordance with 42 CFR 414.90(c)(3), eligible professionals that satisfactorily report 2012 Physician Quality Reporting System measures can qualify for an incentive equal to 0.5 percent of the total estimated part B allowed charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice participating in the GPRO, the group practice) during the applicable reporting period. We proposed (76 FR 42850) modifying the incentive payment language in 42 CFR 414.90(c) so that the language is more consistent with section 1848 of the Act. We are finalizing this proposal. We are also making technical changes to renumber the clauses under 42 CFR 414.90(c).

(1) Criteria for Satisfactory Reporting of Individual Quality Measures for Individual Eligible Professionals via Claims

Section 1848(m)(3)(A) of the Act established the criteria for satisfactorily submitting data on individual quality measures as submitting data on at least three measures in at least 80 percent of the cases in which the measure is applicable. For claims-based reporting, if fewer than three measures are applicable to the services of the professional, the professional may meet the criteria by submitting data on one or two measures for at least 80 percent of applicable cases where the measures are reportable. For years after 2009, section 1848(m)(3)(D) of the Act authorizes the Secretary, in consultation with stakeholders and experts, to revise the criteria for satisfactorily reporting data on quality measures.

Accordingly, we proposed (76 FR 42850) the following criteria for satisfactory reporting via the claims-based reporting mechanism for individual eligible professionals specializing in internal medicine, family practice, general practice, or cardiology:

- Report on at least one Physician Quality Reporting System core measure as identified in Table 46 of this proposed rule.
- Report on at least two additional measures that apply to the services furnished by the professional.
- Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

We proposed the requirement of the reporting of Physician Quality Reporting System core measures for certain specialties to introduce measures reporting according to specialty for eligible professionals specializing in internal medicine, family practice, general practice, or cardiology. However, we did not propose this core measure requirement for all other specialties. Therefore, for all other specialties, we proposed (76 FR 42851) to retain similar reporting criteria as finalized for the in the 2011 MPFS final rule. Specifically, we proposed the following criteria for satisfactory reporting via the claims-based reporting mechanism:

- Report on at least three measures that apply to the services furnished by the professional; and
- Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

To the extent that an eligible professional has fewer than three Physician Quality Reporting System measures that apply to the eligible professional's services and the eligible professional is reporting via the claims-based reporting mechanism, we proposed (76 FR 42851) that the eligible

professional would be able to meet the criteria for satisfactorily reporting data on individual quality measures by meeting the following two criteria—

- Report on all measures that apply to the services furnished by the professional (that is one to two measures); and
- Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

As in prior years, we also proposed (76 FR 42851) that, for 2012, an eligible professional who reports on fewer than three measures through the claims-based reporting mechanism may be subject to the Measure Applicability Validation (MAV) process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures. This process was applied in prior years, including the 2011 Physician Quality Reporting System. We proposed that these criteria for satisfactorily reporting data on fewer than three individual quality measures would apply for the claims-based reporting mechanism only because, unlike registry and EHR-based reporting, the reporting of Physician Quality Reporting System quality measures via claims is not handled by an intermediary but rather directly by the eligible professional.

For 2012, in order to encourage reporting on measures that are applicable to the eligible professional's practice as well as encourage eligible professionals to perform the clinical quality actions specified in the measures, we proposed (76 FR 42851) not to count measures that are reported through claims that have a zero percent performance rate. That is, if the recommended clinical quality action, as indicated in the numerator of the quality measure, is not performed on at least one patient for a particular measure or measures group reported by the eligible professional via claims, we will not count the measure (or measures group) as a measure (or measures group) reported by an eligible professional. This requirement is also consistent with the registry and EHR-based reporting criteria for satisfactory reporting in section VI.F.1.e of this final rule with comment period.

We invited and received public comments on our proposed 2012 criteria for satisfactory reporting of data on individual Physician Quality Reporting System quality measures for individual eligible professionals via claims. We also sought public comment as to whether geriatricians should be included as a specialty required to report on 2012 Physician Quality Reporting System core measures. In addition, we sought public comment on whether other specialties should be included in the 2012 Physician Quality Reporting System core measure reporting requirement. The following is a summary of the comments we received regarding these proposals.

Comment: Some commenters supported our proposal to require the reporting of the 2012 Physician Quality Reporting System core measures. One commenter asked whether nurse practitioners and physician assistants working in family practice, internal medicine, general practice, and cardiology would be required to report on at least 1 Physician Quality Reporting System core measure. Other commenters suggested that we include geriatricians as a specialty required to report on at least 1 Physician Quality Reporting System core measure, whereas others did not. One commenter suggested that hospitalists also be required to report on the 2012 Physician Quality Reporting System core measures, whereas one commenter stated that hospitalists cannot report on the 2012 Physician Quality Reporting System core measures.

Response: We appreciate the commenters' feedback and question. We continue to recognize the importance of and encourage reporting on these Physician Quality Reporting System core measures, which are aimed at promoting cardiovascular care. However, due to some operational limitations, such as having insufficient time to properly update our analysis systems to check for an eligible professional's specialty, we are not finalizing our proposed requirement that physicians practicing in internal medicine, family practice, general practice, and cardiology report on at least 1 Physician Quality Reporting System core measure. Therefore, eligible professionals specializing in these specialties may still report on these measures under the program, but are not required to meet the proposed reporting criterion regarding the core measures. For purposes of earning a 2012 incentive, we are only finalizing the claims based reporting criteria for satisfactory reporting that we proposed for all other individual eligible professionals. Therefore, individual eligible professionals practicing in internal medicine, family practice, general practice and cardiology must meet that criterion for satisfactory reporting for the claims-based mechanism.

Comment: Some commenters opposed our proposal to require eligible professionals practicing in internal medicine, family practice, general practice, and cardiology to report on the 2012 Physician Quality Reporting System core measures as it posed an additional reporting burden on these eligible professionals.

Response: We appreciate the commenters' feedback but respectfully disagree. As these measures are those that we expect eligible professionals practicing in internal medicine, family practice, general practice, and cardiology to report as they address high priority care areas for eligible professionals practicing in these specialties, we do not believe requiring these eligible professionals to report on at least 1 2012 Physician Quality Reporting System core measure would have posed an additional reporting burden on these eligible professionals. However, as described previously, due to operational limitations, we are not finalizing this criterion for satisfactory reporting and therefore, we are not requiring these specialties to report on the 2012 Physician Quality Reporting System core measures. However, we still encourage these specialties to report on these Physician Quality Reporting System core measures when appropriate.

Comment: A few commenters supported our proposal to lower the reporting threshold from 80 to 50 percent of the eligible professional's Medicare Part B PFS patients seen during the reporting period to which the measure applies.

Response: We appreciate the commenter's feedback and are finalizing this reporting threshold of 50 percent of the eligible professional's Medicare Part B PFS patients seen during the reporting period to which the measure applies for claims-based reporting.

Comment: One commenter opposed our proposal to not count measures reported via claims with a zero percent performance rate, because it is sufficient that eligible professionals make the effort to report Physician Quality Reporting System measures.

Response: We appreciate the commenter's feedback. However, we are interested in moving away from pro forma reporting. We are interested in concentrating on the collection of meaningful data. Therefore, for the reasons we stated previously, we are finalizing our proposal to not count measures reported via claims with a zero percent performance rate.

Comment: One commenter opposed our proposal to require eligible professionals that report on less than 3

measures to undergo the MAV process, particularly since the program has not specifically identified which measures may be applicable to eligible professionals' respective practices.

Response: We provided this process as a way for eligible professionals to participate in the Physician Quality Reporting System when they may not have 3 measures applicable to their practice (which is the minimum number of measures eligible professionals must otherwise report). We believe it is important to have a process to check instances where eligible professionals report on less than 3 measures to ensure the that the minimum reporting requirement of reporting at least 3 measures is, in fact, impracticable.

Based on the comments received and for the reasons stated previously, we are finalizing the 2012 criteria for satisfactory reporting of data on individual Physician Quality Reporting System quality measures via claims, described in Table 40. As we indicate above, Table 40 reflects the criteria for satisfactory reporting of data on Physician Quality Reporting System quality measures via claims for all eligible professionals.

TABLE 40: 2012 CRITERIA FOR SATISFACTORY REPORTING OF DATA ON INDIVIDUAL PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES VIA CLAIMS

Reporting Mechanism	Reporting Criteria	Reporting Period
Claims	Report at least three Physician Quality Reporting System measures; OR If less than three measures apply to the eligible professional, 1-2 measures; AND Report each measure for at least 50% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0% performance rate will not be counted.	Jan 1, 2012 – Dec 31, 2012

In addition, an eligible professional who reports on fewer than three measures through the claims-based reporting mechanism may be subject to the Measure Applicability Validation (MAV) process, which will allow us to determine whether an eligible professional should have reported quality data codes for additional measures. Under the MAV process, when an eligible professional reports on fewer than 3 measures, we will perform a review to determine whether there are other closely related measures (such as those that share a common diagnosis or those that are representative of services typically provided by a particular type of eligible professional). If an eligible professional who reports on fewer than 3 measures in 2012 reports on a measure that is part of an identified cluster of closely related measures and does not report on any other measure that is part of that identified cluster of closely related measures, then the eligible professional will not qualify as a satisfactory reporter in the 2012 Physician Quality Reporting System or earn an incentive payment.

(2) 2012 Criteria for Satisfactory Reporting of Individual Quality Measures for Individual Eligible Professionals via Registry

Under our authority of section 1848(m)(3)(D) of the Act to revise the reporting criteria for the satisfactory reporting of measures, we proposed (76 FR 42852) the following criteria for satisfactory reporting via the registry-based reporting mechanism: (1) criteria for individual eligible professionals practicing in internal medicine, family practice, general practice, or cardiology and (2) criteria for all other eligible professionals. For the reasons stated previously, we distinguished eligible professionals in internal medicine, family practice, general practice, or cardiology from all other eligible professionals for the purposes of establishing criteria for satisfactory reporting. Therefore, for eligible professionals specializing in internal medicine, family practice, general practice, or cardiology, we proposed (76 FR 42852) the following criteria for satisfactory reporting—

- Report on at least one Physician Quality Reporting System core measure as identified in Table 28 of the proposed rule (76 FR 42863);
- Report on at least two additional measures that apply to the services furnished by the professional; AND
- Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

For the same reasons stated for establishing different reporting criteria for all other eligible professionals under the claims-based reporting mechanism, we proposed the following criteria for satisfactory reporting via the registry-based reporting mechanism—

- Report on at least three measures that apply to the services furnished by the professional; AND
- Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

In addition, as in prior years, for 2012, we proposed not to count measures that are reported through registries that have a zero percent performance rate, calculated by dividing the measure's numerator by the measure's denominator. That is, if the recommended clinical quality action, that is the action denoted in the quality measure's numerator, is not performed on at least one patient for a particular measure or measures group reported by the eligible professional via registry, we will not count the measure (or measures group) as a measure (or measures group) reported by an eligible professional. We proposed to disregard measures (or measures groups) that are reported through a registry that have a zero percent performance rate in the 2012 Physician Quality Reporting System, because we are assuming that the measure was not applicable to the eligible professional and was likely reported from EHR-derived data (or from data mining) and was unintentionally submitted from the registry to us. We also sought to avoid the possibility of intentional submission of spurious data solely for the purpose

of receiving an incentive payment for reporting.

We invited public comment on the proposed criteria for satisfactory reporting of individual quality measures for individual eligible professionals via registry. The following is a summary of the comments we received. We also sought public comment as to whether geriatricians should be included as a specialty required to report all 2012 Physician Quality Reporting System core measures. In addition, we sought public comment on whether other specialties should be included in the 2012 Physician Quality Reporting System core measure reporting requirement. The following is a summary of the comments we received.

Comment: One commenter stated that eligible professionals reporting via registry should report on quality scores on a sample drawn from all the eligible professional's patients.

Response: We appreciate the commenter's feedback. However, as we may collect information on Medicare Part B FFS patients via claims, we are only requiring that eligible professionals who report on Physician Quality Reporting System quality measure via registry report on their Medicare Part B FFS patients.

Based on the comments received and for the reasons stated previously, we are finalizing the 2012 criteria for satisfactory reporting of data on individual Physician Quality Reporting System quality measures for individual eligible professionals via registry described in Table 41. However, for the same operational reasons we discussed previously regarding claims-based reporting, we are not finalizing the criteria for satisfactory reporting that we proposed for eligible professionals practicing in internal medicine, family practice, general practice, and cardiology. Therefore, Table 41 reflects the criteria for satisfactory reporting of data on Physician Quality Reporting System quality measures via registry for all eligible professionals.

TABLE 41: 2012 CRITERIA FOR SATISFACTORY REPORTING OF DATA ON INDIVIDUAL PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES VIA REGISTRY

Reporting Mechanism	Reporting Criteria	Reporting Period
Registry	• Report at least three Physician Quality Reporting System measures, AND • Report each measure for at least 80% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0% performance rate will not be counted.	Jan 1,2012 – Dec 31, 2012

(3) Criteria for Satisfactory Reporting of Individual Quality Measures for Individual Eligible Professionals via EHR

Section 1848(m)(3)(A) of the Act established the criteria for satisfactorily submitting data on individual quality measures as at least three measures in at least 80 percent of the cases in which the measure is applicable. For years after 2009, section 1848(m)(3)(D) of the Act authorizes the Secretary, in consultation with stakeholders and experts, to revise the criteria for satisfactorily reporting data on quality measures. Accordingly, we proposed the following options for satisfactory reporting of individual quality measures by individual eligible professionals participating in the 2012 Physician Quality Reporting System via the EHR-based reporting mechanism:

First, we proposed (76 FR 42854) that an eligible professional would meet the criteria for satisfactory reporting under the Physician Quality Reporting System if the eligible professional, using a Physician Quality Reporting System ''qualified'' EHR product (if the eligible professional is also participating in the EHR Incentive Program via the Physician Quality Reporting System-EHR Incentive Pilot discussed in section VI.H. of this final rule with comment period, the eligible professional's EHR product must also be Certified EHR Technology), reports on three core measures for 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which each measure applies as identified in Table 28 of the proposed rule (76 FR 42863), which are identical to the Medicare EHR Incentive Program core measures included in Table 7 of the Medicare and Medicaid EHR Incentive Program final rule (75 FR 44410). For all core measures identified in Table 28 of the proposed rule except for the measures titled ''Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up'' and ''Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention'', insofar as the denominator for one or more of the core measures is 0, implying that the eligible professional's patient population is not addressed by these measures, we proposed (76 FR 42854) that eligible professionals would be required to report up to three alternate core measures as identified in Table 28 of the proposed rule and which are identical to the Medicare EHR Incentive Program alternate core measures included in Table 7 of the Medicare and Medicaid EHR Incentive Program final rule, (75 FR 44410). In addition, we proposed that the eligible professional would be required to report on three additional measures of their choosing that are available for the Medicare EHR Incentive Program in Table 6 of the Medicare and Medicaid EHR Incentive Program final rule (75 FR 44398 through 44408) (as identified in 29 of the proposed rule).

Section 1848(m)(7) of the Act (''Integration of Physician Quality Reporting and EHR Reporting''), as added by section 3002(d) of the Affordable Care Act, requires us to move towards the integration of EHR measures with respect to the Physician Quality Reporting System. Section 1848(m)(7) of the Act specifies that by

no later than January 1, 2012, the Secretary shall develop a plan to integrate reporting on quality measures under the Physician Quality Reporting System with reporting requirements under subsection (o) of section 1848 of the Act relating to the meaningful use of EHRs. Such integration shall consist of the following:

(A) The selection of measures, the reporting of which both would demonstrate—

(i) Meaningful use of an EHR for purposes of the Medicare EHR Incentive Program; and

(ii) Quality of care furnished to an individual; and

(B) Such other activities as specified by the Secretary.

We proposed the aforementioned criteria for satisfactory reporting via an EHR, which is identical to the criteria for achieving meaningful use for reporting clinical quality measures under the EHR Incentive Program as finalized in the Medicare and Medicaid Electronic Health Record Incentive Program final rule (75 FR 44409 through 44411), in an effort to align the Physician Quality Reporting System with the Medicare EHR Incentive Program.

In addition to the reporting criteria proposed (76 FR 42854) previously, we proposed alternative reporting criteria for satisfactory reporting using the EHR-based reporting mechanism that is similar to the criteria finalized in the CY 2011 MPFS Final Rule with comment period (75 FR 73497 through 73500). For the reasons set forth for establishing different criteria for satisfactory reporting via claims and registry, we proposed to adopt two different criteria for satisfactory reporting, depending on an eligible professional's specialty. For eligible professionals specializing in internal medicine, family practice, general practice, and cardiology, we proposed the following criteria:

- Report on ALL Physician Quality Reporting System core measure as identified in Table 28 of the proposed rule (76 FR 42863) AND
- Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

We understood that by requiring eligible professionals specializing in internal medicine, family practice, general practice, and cardiology to report all Physician Quality Reporting System core measures, we would be requiring such professionals to report more measures than eligible professionals who do not practice within those specialties. We believe, however, that requiring these specialists to report on all Physician Quality Reporting System core measures would not add an additional burden to these eligible professionals because the reporting of measures is done entirely through the EHR. Furthermore, because we are proposing to require these specialties to report on all Physician Quality Reporting System core measures and recognize that some of the Physician Quality Reporting System core measures may not be applicable to all of these eligible professionals' specialties, we proposed to allow the reporting of these Physician Quality Reporting System core measures with a zero percent performance rate. That is, the reporting of a Physician Quality Reporting System core measure that is not applicable to the eligible professional's practice in this instance will not preclude an eligible professional from meeting the criteria for satisfactory reporting.

For the reasons we stated previously for creating separate reporting criteria for all other eligible professionals for claims and registry reporting, we proposed (76 FR 42854) the following criteria for satisfactory reporting using the EHR-based reporting mechanism—

- Report on at least three Physician Quality Reporting System EHR measures of the eligible professional's choosing; AND
- Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

We invited public comment on the proposed criteria for satisfactory reporting of individual quality measures by individual eligible professionals via an EHR-based reporting mechanism in the 2012 Physician Quality Reporting System. We also sought public comment as to whether geriatricians should be included as a specialty required to report all 2012 Physician Quality Reporting System core measures. In addition, we sought public comment on whether other specialties should be included in the 2012 Physician Quality Reporting System core measure reporting requirement. In addition to the comments summarized and addressed previously regarding our proposal to require certain specialties to report on core measures, the following is a summary of the remaining comments we received regarding these proposals.

Comment: Several commenters supported the proposed criteria for EHR-based reporting for the 2012 Physician Quality Reporting System that aligns with the EHR Incentive Program. In general, the commenters supported our efforts to align the Physician Quality Reporting System and EHR Incentive Program.

Response: Aligning the Physician Quality Reporting System and EHR Incentive Program is a top priority, as we seek to minimize the reporting burden that the various CMS quality reporting programs may pose on eligible professionals who choose to participate in more than one program.

After considering the comments and for the reasons we stated previously, we are only finalizing the criteria for satisfactory reporting via EHR for the 2012 Physician Quality Reporting System described in Table 42. For the operational reasons discussed previously, we are not finalizing the criteria for satisfactory reporting via EHR that we proposed for eligible professionals practicing in internal medicine, family practice, general practice, and cardiology. Therefore, Table 42 reflects the criteria for satisfactory reporting of data on Physician Quality Reporting System quality measures via EHR for all eligible professionals.

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TABLE 42: 2012 CRITERIA FOR SATISFACTORY REPORTING OF DATA ON INDIVIDUAL PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES VIA EHR

Reporting Mechanism	Reporting Criteria	Reporting Period
EHR – Aligning with the Medicare EHR Incentive Program*	Report on ALL three Medicare EHR Incentive Program core measures (as identified in Table 48 of this final rule with comment period). If the denominator for one or more of the Medicare EHR Incentive Program core measures is 0, report on up to three Medicare EHR Incentive Program alternate core measures (as identified in Table 48 of this final rule with comment period); AND Report on three (of the 38) additional measures available for the Medicare EHR Incentive Program.	Jan 1, 2012 – Dec 31, 2012
EHR – Direct EHR-based reporting & EHR data submission vendor	Report at least three Physician Quality Reporting System measures AND Report each measure for at least 80% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0% performance rate will not be counted	Jan 1, 2012 – Dec 31, 2012

* As stated previously, insofar as the denominator for one or more of the core measures identified in Table M 9 is 0, implying that the eligible professional's patient population is not addressed by these measures, eligible professionals must report up to three alternate core measures as identified in Table 48 in this section of this final rule with comment period and which are identical to the Medicare EHR Incentive Program alternate core measures included in Table 7 of the Medicare and Medicaid EHR Incentive Program final rule (75 FR 44410).

However, with respect to reporting on the measure titled "Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up", listed in Table 48 of this final rule with comment period, there are two parameters in the measure denominator description: Age 65 and older BMI and Age 18-64 BMI. For the purpose of reporting this measure under the Physician Quality Reporting System, we will count the reporting of this measure if at least one of the two parameters does not contain a zero percent performance rate. In addition, with respect to reporting on the measure titled "Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention", also listed in Table 48 of this final rule with comment period, the measure is divided into two pairs: a. Tobacco Use Assessment and b. Tobacco Cessation Intervention. For the purpose of reporting this measure under the Physician Quality Reporting System, we will count the reporting of this measure if at least one of the two pairs does not contain a zero percent performance rate.

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(4) Criteria for Satisfactory Reporting of Measures Groups via Claims—Individual Eligible Professionals

Under § 414.90(b), ''measures group'' is defined as ''a subset of four or more Physician Quality Reporting System measures that have a particular clinical condition or focus in common.'' For 2012 and beyond, we proposed that individual eligible professionals have the option to report measures groups in addition to individual quality measures to qualify for the Physician Quality Reporting System incentive, using claims or registries.

For the reasons we proposed (76 FR 42855) different criteria for satisfactorily reporting individual quality measures depending on specialty, specifically our desire to introduce core measures applicable to certain specialties and promote cardiovascular care, we proposed two different criteria for

satisfactorily reporting measures groups. We proposed the following criteria for satisfactory reporting of 2012 Physician Quality Reporting System measures groups:

We proposed that eligible professionals specializing in internal medicine, family practice, general practice, and cardiology may meet the criteria for satisfactory reporting of Physician Quality Reporting System measures groups via claims by reporting in the following manner:

- Report at least one Physician Quality Reporting System measures group; AND
- If the measures group does not contain at least one Physician Quality Reporting System core measure, then one Physician Quality Reporting System core measure; AND
- For each measures group and, if applicable, Physician Quality Reporting System core measure reported, report on at least 30 Medicare Part B FFS patients for each measures group that is reported.
- Measures groups containing a measure with a zero percent performance rate will not be counted.

We also proposed that eligible professionals specializing in internal medicine, family practice, general practice, and cardiology may meet the criteria for satisfactorily reporting Physician Quality Reporting System measures groups via claims by reporting in the following manner:

- Report at least one Physician Quality Reporting System measures group; BUT
- If the measures group does not contain at least one Physician Quality Reporting System core measure, then one Physician Quality core measure.
- For each measures group and, if applicable, Physician Quality Reporting System core measure reported, report on at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; but report no less than 15 Medicare Part B PFS patients for each measures group reported.
- Measures groups containing a measure with a zero percent performance rate will not be counted.

For all other eligible professionals, in order to meet the criteria for satisfactory reporting of Physician Quality Reporting measures groups via claims, we proposed that the eligible professional must:

- Report at least one Physician Quality Reporting System measures group; AND
- Report on at least 30 Medicare Part B FFS patients for each measures group that is reported.
- Measures groups containing a measure with a zero percent performance rate will not be counted.

Alternatively, eligible professionals not specializing in internal medicine, family practice, general practice, and cardiology may meet the criteria for satisfactorily reporting Physician Quality Reporting System measures groups via claims by reporting in the following manner:

- Report at least one Physician Quality Reporting System measures group; AND
- For each measures group reported, report each on at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT
- Report no less than 15 Medicare Part B PFS patients for each measures group reported.
- Measures groups containing a measure with a zero percent performance rate will not be counted.

Aside from the Physician Quality Reporting System core measure reporting requirement for eligible professionals specializing in internal medicine, family practice, general practice, or cardiology, we proposed to retain the same criteria for satisfactory reporting of measures groups via claims as the 2011 criteria for satisfactory reporting of measures groups via claims for the 12-month reporting period that was finalized in the 2011 MPFS Final Rule with comment period, because we believe consistent reporting criteria will in turn lead to a greater chance that eligible professionals meet the criteria for satisfactory reporting (76 FR 42854). Therefore, as in 2011, we proposed that an eligible professional must satisfactorily report on all individual measures within the measures group in order to meet the criteria for satisfactory reporting via measures groups.

For 2012, in order to ensure that the Physician Quality Reporting System measures on which eligible professionals report are applicable to their respective practices, we proposed (76 FR 42854) not to count measures within measures groups that are reported through claims or registry that have a zero percent performance rate. That is, if the recommended clinical quality action is not performed on at least one patient for a particular measure reported by the eligible professional via claims or registry, we will not count the measures group as a measures group reported by an eligible professional. Furthermore, this proposed requirement is consistent with the reporting options for individual quality measures, which are discussed previously. Since we proposed to retain the requirement that an eligible professional must satisfactorily report on all individual measures contained within a measures group in order to meet the criteria for satisfactory reporting via measures groups, if an eligible professional reports a measure contained within a measures group with a zero percent performance rate, the eligible professional will fail to meet the criteria for the satisfactory reporting of measures groups.

We invited public comment on the 2012 criteria for satisfactory reporting on measures groups via claims for individual eligible professionals. We also sought public comment as to whether geriatricians should be included as a specialty required to report at least 1 proposed 2012 Physician Quality Reporting System core measure for measures group reporting. In addition, we sought public comment on whether other specialties should be included in the 2012 Physician Quality Reporting System core measure reporting requirement for measures groups. The following is a summary of the comments we received.

Comment: One commenter was opposed to the proposed criterion that measures with a zero percent performance rate will not be counted.

Response: We appreciate the commenter's feedback. However, as we stated previously, we are interested in moving away from pro forma reporting. We are interested in concentrating on the collection of meaningful data. Therefore, for the reasons we stated previously, we are finalizing our proposal to only count measures reported via claims, registry, and EHR with a zero percent performance rate.

Based on the comments received and for the reasons stated previously, we are finalizing the 2012 criteria for satisfactory reporting of measures groups via claims for individual eligible professionals described in Table 43. For the operational reasons discussed previously, however, we are not finalizing our proposals for eligible professionals practicing in internal medicine, family practice, general practice, and cardiology. Therefore, Table 43 reflects the final criteria for satisfactory reporting of data on Physician Quality Reporting System quality measures groups via claims for all eligible professionals.

TABLE 43: 2012 CRITERIA FOR SATISFACTORY REPORTING ON MEASURES GROUPS VIA CLAIMS

Reporting Mechanism	Reporting Criteria	Reporting Period
Claims	Report at least 1 Physician Quality Reporting System measures group; AND Report each measures group for at least 30 Medicare Part B FFS patients. Measures groups containing a measure with a 0% performance rate will not be counted.	Jan 1, 2012– Dec 31, 2012
Claims	Report at least 1 Physician Quality Reporting System measures group; AND Report each measures group for at least 50 % of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT Report each measures group on no less than 15 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. Measures groups containing a measure with a 0% performance rate will not be counted.	Jan 1, 2012 – Dec 31,2012

An eligible professional could also potentially qualify for the Physician Quality Reporting System incentive payment by satisfactorily reporting both individual measures and measures groups. However, only one incentive payment will be made to the eligible professional.

(5) 2012 Criteria for Satisfactory Reporting of Measures Groups via Registry—Individual Eligible Professionals

As with the reporting of measures groups via claims, we proposed (76 FR 42857) different criteria for the satisfactory reporting of Physician Quality Reporting System measures groups via registry depending on the eligible professional's specialty. For eligible professionals specializing in internal medicine, family practice, general practice, or cardiology, in order to meet the criteria for the satisfactory reporting of Physician Quality Reporting measures groups via registry, during the 12-month reporting period, we proposed that the eligible professional must—

- Report at least 1 Physician Quality Reporting System measures group; AND
- If the measures group does not contain at least 1 Physician Quality Reporting System core measure, then 1 Physician Quality Reporting System core measure; AND
- Report on at least 30 Medicare Part B FFS patients for each measures group and, if applicable, Physician Quality Reporting System core measure reported.
- Measures groups containing a measure with a zero percent performance rate will not be counted.

Alternatively, we proposed that the eligible professional specializing in internal medicine, family practice, general practice, or cardiology may meet the criteria for the satisfactory reporting of Physician Quality measures groups via registry by doing the following during the 12-month reporting period:

- Report at least one Physician Quality Reporting System measures group; AND
- If the measures group does not contain at least 1 Physician Quality Reporting System core measure, then 1 Physician Quality Reporting System core measure; AND
- Report each measures group and, if applicable, Physician Quality Reporting System core measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT
- Report each measures group on no less than 15 Medicare Part B FFS patients seen during the reporting period to which the measures group applies.
- Measures groups containing a measure with a zero percent performance rate will not be counted.

In order to meet the criteria for the satisfactory reporting of Physician Quality Reporting measures groups via registry, during the 6-month reporting period, we proposed that the eligible professional must—

- Report at least one Physician Quality Reporting System measures group; AND
- If the measures group does not contain at least 1 Physician Quality core measure, then 1 Physician Quality core measure; AND
- Report each measures group and, if applicable, Physician Quality Reporting System core measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT
- Report each measures group on no less than 8 Medicare Part B FFS patients seen during the reporting period to which the measures group applies.
- Measures groups containing a measure with a zero percent performance rate will not be counted.

For all other eligible professionals, in order to meet the criteria for the satisfactory reporting of Physician Quality Reporting System measures groups via registry, we proposed that, during the 12-month reporting period, the eligible professional must—

- Report at least 1 Physician Quality Reporting System measures group; AND
- Report each measures group for at least 30 Medicare Part B FFS patients.
- Measures groups containing a measure with a zero percent performance rate will not be counted.

Alternatively, we proposed that an eligible professional not specializing in internal medicine, family practice, general practice, or cardiology may meet the criteria for the satisfactory reporting of Physician Quality Reporting System measures groups via registry by doing the following during the 12-month reporting period:

- Report at least one Physician Quality Reporting System measures group; AND
- For each measures group reported, report on at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT
- Report no less than 15 patients for each measures group reported.
- Measures groups containing a measure with a zero percent performance rate will not be counted.

For all other eligible professionals, in order to meet the criteria for the satisfactory reporting of Physician Quality Reporting System measures groups via registry during the 6-month reporting period, we proposed that, during the proposed 6-month reporting period, the eligible professional must—

- Report at least 1 Physician Quality Reporting System measures group; AND
- For each measures group reported, report on at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT
- Report each measures group on no less than least 8 Medicare Part B FFS patients for each measures group reported.
- Measures groups containing a measure with a zero percent performance rate will not be counted.

Aside from the Physician Quality Reporting System core measure reporting requirement for eligible professionals specializing in internal medicine, family practice, general practice, or cardiology, we proposed to retain the same criteria for satisfactory reporting of measures groups via registry as the 2011 criteria for satisfactory reporting of measures groups via registry finalized in the 2011 MPFS Final Rule with comment period. Therefore, as in 2011, an eligible professional must satisfactorily report on all individual measures within the measures group in order to meet the criteria for satisfactory reporting via measures groups. We proposed to retain the same criteria, because, since eligible professionals are already familiar with this reporting criteria, we believe having consistent reporting criteria will in turn lead to a greater chance that eligible professionals meet the criteria for satisfactory reporting.

For 2012, in order to ensure that the Physician Quality Reporting System measures on which eligible professionals report are applicable to their respective practices, we proposed not to count measures within measures groups that are reported through claims or registry that have a zero percent performance rate. That is, if the recommended clinical quality action is not performed on at least one patient for a particular measure reported by the eligible professional via claims or registry, we will not count the measures groups as a measures group reported by an eligible professional. Furthermore, this requirement is consistent with the reporting options for individual quality measures, which were discussed previously. Since we proposed to retain the requirement that an eligible professional must satisfactorily report on all individual measures contained within a measures group in order to meet the criteria for satisfactory reporting via measures groups, if an eligible professional reports a measure contained within a measures group with a zero percent performance rate, the eligible professional will fail to meet the criteria for the satisfactory reporting of measures groups.

We also sought public comment as to whether geriatricians should be included as a specialty required to report at least 1 proposed 2012 Physician Quality Reporting System core measure for measures group reporting. In addition, we sought public comment on whether other specialties should be included in the 2012 Physician Quality Reporting System core measure reporting requirement for measures groups. The summary of these comments and our responses was discussed previously in this final rule with comment period.

We invited but received no public comment on the proposed 2012 criteria for satisfactory reporting on measures groups via registry for individual eligible professionals. Therefore, for the reasons stated previously, we are finalizing the 2012 criteria for satisfactory reporting of data on measures groups via registry described in Table 44. However, for the operational reasons discussed previously, we are not finalizing our proposals regarding eligible professionals practicing in internal medicine, family practice, general practice, and cardiology. Therefore, Table 42 reflects the final criteria for satisfactory reporting of data on Physician Quality Reporting System quality measures via EHR for all eligible professionals.

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TABLE 44: 2012 CRITERIA FOR SATISFACTORY REPORTING ON MEASURES GROUPS VIA REGISTRY

Reporting Mechanism	Reporting Criteria	Reporting Period
Registry	Report at least 1 Physician Quality Reporting System measures group; AND Report each measures group for at least 30 Medicare Part B FFS patients. Measures groups containing a measure with a 0% performance rate will not be counted.	Jan 1, 2012 – Dec 31, 2012
Registry	Report at least 1 Physician Quality Reporting System measures group; AND Report each measures group for at least 80 % of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT Report each measures group on at least 15 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. Measures groups containing a measure with a 0% performance rate will not be counted.	Jan 1, 2012 – Dec 31, 2012
Registry	Report at least 1 Physician Quality Reporting System measures group; AND Report each measures group for at least 80 % of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT Report each measures group on no less than 8 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. Measures groups containing a measure with a 0% performance rate will not be counted.	Jul 1, 2012 – Dec 31, 2012

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An eligible professional could also potentially qualify for the Physician Quality Reporting System incentive payment by satisfactorily reporting both individual measures and measures groups. However, only one incentive payment will be made to the eligible professional.

(6) 2012 Criteria for Satisfactory Reporting on Physician Quality Reporting System Measures by Group Practices Under the Group Practice Reporting Option (GPRO)

Instead of participating as an individual eligible professional, an eligible professional in a group practice may participate in the Physician Quality Reporting System under the Physician Quality Reporting System GPRO. However, an individual eligible professional who is affiliated with a group practice participating in the Physician Quality Reporting System GPRO that satisfactorily submits Physician Quality Reporting System quality measures will only be able to earn an incentive as part of the group practice and not as an individual eligible professional.

We proposed (76 FR 42859) that group practices interested in participating in GPRO must self-nominate. As stated in section VI.F.1.e.6. of this final rule with comment period, for group practices selected to participate in the Physician Quality Reporting System GPRO for 2012, we finalized a 12-month reporting period beginning January 1, 2012. For 2012, we proposed (76 FR 32859) to use the same GPRO reporting methods that we have used in prior years. Specifically, we proposed that group practices participating in GPRO submit information on measures within a common set of 30 NQF-endorsed quality measures using a web interface based on the GPRO web interface used in the 2011 Physician Quality Reporting System GPRO. As part of the data submission process for 2012 GPRO, we proposed that during 2012, each group practice would be required to report quality measures with respect to services furnished during the 2012 reporting period (that is, January 1, 2012, through December 31, 2012) on an

assigned sample of Medicare beneficiaries. Once the beneficiary assignment has been made for each group practice, which we anticipated would be done during the fourth quarter of 2012, we proposed to provide each group practice selected to participate in the Physician Quality Reporting System GPRO with access to a web interface that would include the group's assigned beneficiary samples and the final GPRO quality measures. We proposed to pre-populate the web interface with the assigned beneficiaries' demographic and utilization information based on all of their Medicare claims data. The group practice would be required to populate the remaining data fields necessary for capturing quality measure information on each of the assigned beneficiaries.

In 2011, to distinguish the criteria in GPRO I and II for satisfactory reporting between small vs. large groups, we established different reporting criteria dependent on the group's size. Although we are consolidating the GPRO for 2012, we still recognize the need to equalize the reporting burden by establishing different reporting criteria for small vs. large groups. Therefore, we proposed to establish the following two criteria for the satisfactory reporting of Physician Quality Reporting System quality measures under the 2012 GPRO, based on the size of the group practice:

- For group practices comprised of 25–99 eligible professionals participating in the GPRO, we proposed that the group practice must report on all GPRO measures included in the web interface (listed in Table 55 of the proposed rule (76 FR 42880)). During the submission period, the group practice will need to access the web interface and populate the data fields necessary for capturing quality measure information on each of the assigned beneficiaries up to 218 beneficiaries (with an over-sample of 327 beneficiaries) for each disease module and preventive care measure. We further proposed that if the pool of eligible assigned beneficiaries for any disease module or preventive care measure is less than 218, then the group practice would need to populate the remaining data files for 100 percent of eligible assigned beneficiaries for that disease module or preventive care measure. For each disease module or preventive care measure, we proposed that the group practice must report information on the assigned patients in the order in which they appear in the group's sample (that is, consecutively).
- For group practices comprised of 100 or more eligible professionals, we proposed that the group practices must report on all Physician Quality Reporting System GPRO quality measures. During the submission period, the group practice would need to populate the remaining data fields in the web interface necessary for capturing quality measure information on each of the assigned beneficiaries up to 411 beneficiaries (with an over-sample of 616 beneficiaries) for each disease module and preventive care measure. We further proposed that if the pool of eligible assigned beneficiaries for any disease module or preventive care measure is less than 411, then the group practice must populate the remaining data fields for 100 percent of eligible assigned beneficiaries for that disease module or preventive care measure. For each disease module or preventive care measure, we proposed that the group practice must report information on the assigned patients in the order in which they appear in the group's sample (that is, consecutively). In determining the appropriate reporting criteria for group practices comprised of 100 or more eligible professionals, we sought to use the same criteria we finalized in the 2011 MPFS Final Rule with comment period for GPRO I (75 FR 73506) because group practices are already familiar with this reporting process. We hope that establishing the same process for reporting under the GPRO as used in prior years will provide a likelier chance for meeting the criteria for satisfactory reporting under the GPRO. In addition, we sought to align the criteria for satisfactory reporting under the Physician Quality Reporting System with CMS' PGP demonstration, which collects data from large group practices in an effort to coordinate the overall care delivered to Medicare patients.

As we discussed previously with our definition of group practice, we allow for fluctuation of the group practice's size throughout the reporting period, provided that the group size contains at least 25 eligible professionals, which is the minimum group practice size for participation in the Physician Quality Reporting System GPRO. However, as we established in 2011, for purposes of determining which reporting criteria the group must satisfy, a group practice's size will be the size of the group at the time the group's participation is approved by CMS (75 FR 73504). For example, if a group practice is comprised of 100 eligible professionals at the time it self-nominates for participation as a GPRO in 2012, and the group practice's size then drops to 99 eligible professionals at the time the group practice's participation is approved by CMS, the group practice would need to meet the reporting criteria for a group size of 99.

We invited public comment on the proposed requirements for satisfactory reporting via the Physician Quality Reporting System GPRO reporting option. The following is a summary of the comments we received that were related to the proposed 2012 criteria for satisfactory reporting for group practices in the Physician Quality Reporting System GPRO.

Comment: Some commenters urged us to modify the GPRO web interface to minimize burden of use of the web interface, particularly by minimizing the manual processes required to populate the remaining fields.

Response: The patient data can be extracted from an EHR and uploaded into the web interface, which eliminates the need for manual abstraction. CMS will continue development efforts to enhance tool so that there is decreased burden on group practices reporting via the web interface.

After considering the comments and for the reasons stated previously, we are finalizing all of the proposed 2012 criteria for satisfactory reporting for group practices participating in the Physician Quality GPRO. Table 45 summarizes the criteria for the satisfactory reporting of data on quality measures by group practice under the 2012 Physician Quality Reporting GPRO. Group practices participating in the 2012 Physician Quality Reporting System GPRO, regardless of size, are required to report on all of the measures listed in Table 71 of this final rule with comment period. These quality measures are grouped into preventive care measures and five disease modules: heart failure, diabetes, coronary artery disease, hypertension, and chronic obstructive pulmonary disease (COPD).

TABLE 45: 2012 CRITERIA FOR SATISFACTORY REPORTING FOR GROUP PRACTICES PARTICIPATING IN THE PHYSICIAN QUALITY REPORTING SYSTEM GROUP PRACTICE REPORTING OPTION (GPRO)

Group Practice Size	Reporting Mechanism	Reporting Criteria	Reporting Period
25-99 Eligible Professionals	A submission web interface provided by CMS	Report on all measures included in the web interface; AND Populate data field for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample (with an over-sample of 327) for each disease module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100% of assigned beneficiaries.	Jan 1, 2012 – Dec 31, 2012
100+ Eligible Professionals	A submission web interface provided by CMS	Report on all measures included in the web interface; AND Populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample (with an over-sample of 616) for each disease module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100% of assigned beneficiaries.	Jan 1, 2012 – Dec 31, 2012

Furthermore, although we are requiring that the group practices participating in the GPRO to report on a certain number of consecutive patients, such as either 218 or 411 beneficiaries depending on the group's size, we will allow the ''skipping'' of patients for valid reasons, such as a beneficiary's medical records not being found or not being able to confirm a diagnosis. However, excessive skipping of patients may cause us to question the accuracy or validity of the data being reported to us by the group practices. Due to the variance in group patterns, measures, and disease modules, however, it is difficult to establish a ''skip threshold'' for the satisfactory reporting of GPRO measures. Therefore, it is our intent to examine each group practice's skip patterns. We may request the group to provide additional information to help explain or support the skips to help better inform us on what levels of skipping could potentially be considered excessive skipping in a future year.

We intend to post the final 2012 Physician Quality Reporting System GPRO participation requirements for group practices, including instructions for submitting the self-nomination statement and other requested information, on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.gov/PQRS* by November 15, 2011 or shortly thereafter.

The Physician Quality Reporting System GPRO web interface will be updated as needed to include the 2012 Physician Quality Reporting System GPRO measures (that is, to eliminate measures that have been retired as well as add additional measures that will be finalized for 2012). We intend to provide the selected physician groups with access to this pre-populated database by no later than the first quarter of 2012. For purposes of pre-populating this GPRO web interface, we will assign beneficiaries to each group practice using a patient assignment methodology modeled after the patient assignment methodology used in the PGP & MCMP demonstrations. We will use Medicare Part B claims data for dates of service on or after January 1, 2011, and submitted and processed by approximately October 31, 2011, to assign Medicare beneficiaries to each group practice. Assigned beneficiaries will be limited to those Medicare Part B FFS beneficiaries with Medicare Parts A and B claims for whom Medicare is the primary payer. Assigned beneficiaries will not include Medicare Advantage enrollees. A beneficiary will be assigned to the group practice that provides the plurality of a beneficiary's office or other outpatient office evaluation and management allowed charges. Beneficiaries with only one office visit to the group practice will be eliminated from the group practice's assigned patient sample for purposes of the 2012 Physician Quality Reporting System GPRO. We will pre-populate the GPRO web interface with the assigned beneficiaries' demographic and utilization information based on their Medicare claims data.

f. 2012 Physician Quality Reporting System Measures

(1) Statutory Requirements for the Selection of the Final 2012 Physician Quality Reporting System Measures

Under section 1848(k)(2)(C)(i) of the Act, the Physician Quality Reporting System quality measures shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under subsection 1890(a) of

the Act (currently, that is the National Quality Forum, or NQF). 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 NQF, section 1848(k)(2)(C)(ii) of the Act authorizes the Secretary to 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, such as the AQA alliance. In light of these statutory requirements, we believe that, except in the circumstances specified in the statute, each 2012 Physician Quality Reporting System quality measure must be endorsed by the NQF. Additionally, section 1848(k)(2)(D) of the Act requires that for each 2012 Physician Quality Reporting System quality measure, ''the Secretary shall ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish.''

The statutory requirements under section 1848(k)(2)(C) of the Act, subject to the exception noted previously, require only that the measures be selected from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) (that is, the NQF) and are silent with respect to how the measures that are submitted to the NQF for endorsement were developed. The basic steps for developing measures applicable to physicians and other eligible professionals prior to submission of the measures for endorsement may be carried out by a variety of different organizations. We do not believe there needs to be any special restrictions on the type or make-up of the organizations carrying out this basic process of development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the basic development of quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards for purposes of the Physician Quality Reporting System.

The following is a summary of comments we received.

Comment: Several commenters suggested that we only include NQF-endorsed measures for reporting for the 2012 Physician Quality Reporting System. Some of these commenters strongly urged that all new measures finalized for inclusion in the 2012 Physician Quality Reporting System be submitted to the NQF for endorsement. Other commenters stated that, should we include quality measures for reporting under the 2012 Physician Quality Reporting System that are not NQF-endorsed, we ensure that these quality measures undergo a review process similar to NQF's endorsement procedures.

Response: We agree that endorsement of measures by the NQF is an important criterion for inclusion in the 2012 Physician Quality Reporting System. However, section 1848(k)(2)(C)(ii) of the Act provides an exception to the requirement that measures be endorsed by the NQF. We may exercise this exception authority in a specified area or medical topic for which a feasible and practical measure has not been endorsed by the NQF, so long as due consideration is given to measures that have been endorsed by the NQF. For this reason, we retain the ability to include non-NQF endorsed measures in the Physician Quality Reporting System. We encourage the measure owners to submit all non-NQF measures that are included in the 2012 Physician Quality Reporting System for endorsement by the NQF, if the measures have not already been submitted for endorsement. In future years, we may consider removing a measure from the program if the measure owner has opportunities to submit the measure to the NQF for review but does not do so.

(2) Other Considerations for the Selection of 2012 Physician Quality Reporting System Measures

In addition to reviewing the 2011 Physician Quality Reporting System measures for purposes of developing the 2012 Physician Quality Reporting System measures, we reviewed and considered measure suggestions for the 2012 Physician Quality Reporting System.

With respect to the selection of new measures, we applied the following considerations, which include many of the same considerations applied to the selection of 2009, 2010 and 2011 Physician Quality Reporting System quality measures proposed (76 FR 42864) for inclusion in the 2012 Physician Quality Reporting System quality measure set previously described:

- High Impact on Healthcare.

++ Measures that are high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. These current and long term priority topics include the following: prevention; chronic conditions; high cost and high volume conditions; elimination of health disparities; healthcare-associated infections and other conditions; improved care coordination; improved outcomes; 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.

++ Measures that are included in, or facilitate alignment with, other Medicare, Medicaid, and CHIP programs in furtherance of overarching healthcare goals.

++ NQF Endorsement.

++ Measures must be NQF-endorsed by August 15, 2011, in order to be considered for inclusion in the 2012 Physician Quality Reporting System quality measure set except, as provided under section 1848(k)(2)(C)(ii) of the Act.

++ Section 1848(k)(2)(C)(ii) of the Act provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF).

- Address Gaps in the Physician Quality Reporting System Measure Set.

++ Measures that increase the scope of applicability of the Physician Quality Reporting System measures to services furnished to Medicare beneficiaries and expand opportunities for eligible professionals to participate in the Physician Quality Reporting System.

- Measures of various aspects of clinical quality including outcome measures, where appropriate and feasible, process measures, structural measures, efficiency measures, and measures of patient experience of care.

Other considerations that we applied to the selection of proposed measures for 2012, regardless of whether the measure was a 2011 Physician Quality Reporting System measure or not, were—

- Measures that are functional, which is to say measures that can be technically implemented within the capacity of the CMS infrastructure for data collection, analysis, and calculation of reporting and performance rates;
- Measures that address gaps in the quality of care delivered to Medicare beneficiaries;
- Measures impacting chronic conditions (chronic kidney disease, diabetes mellitus, heart failure, hypertension and musculoskeletal);
- Measures involving care coordination;
- Measures applicable across care settings (such as, outpatient, nursing facilities, domiciliary, etc.);

• Measures conducive to leveraging capabilities of an electronic health record (EHR);
• Measures whose detailed specifications will be completed and ready for implementation in the 2012 Physician Quality Reporting System;
• Broadly applicable measures that could be used to create a core measure set required of all participating eligible professionals; and
• Measures groups that reflect the services furnished to beneficiaries by a particular specialty.

In the 2012 Physician Quality Reporting System, as in the 2011 Physician Quality Reporting System, for some measures that are useful, but where data submission is not feasible through all otherwise available Physician Quality Reporting System reporting mechanisms, we proposed that a measure may be included for reporting solely through specific reporting mechanism(s) in which its submission is feasible.

However, we stress that inclusion of measures that are not NQF endorsed or AQA adopted is an exception to the requirement under section 1848(k)(2)(C)(i) of the Act that measures be endorsed by the NQF. We may exercise this exception authority in a specified area or medical topic for which a feasible and practical measure has not been endorsed by NQF, so long as due consideration is given to measures that have been endorsed by the NQF.

We invited comments on our proposed approach in selecting measures. The following is a summary of the comments we received regarding other considerations we have taken into account with regard to selecting 2012 Physician Quality Reporting System measures.

Comment: Several commenters supported the inclusion of proposed 2012 Physician Quality Reporting System measures that are either not endorsed by NQF or pending NQF-endorsement. However, some commenters suggested that we properly vet these non-NQF-endorsed measures prior to including them for reporting under the 2012 Physician Quality Reporting System.

Response: For measures that we finalize that are not currently NQF-endorsed, we are exercising our authority under section 1848(k)(2)(C)(i) of the Act to, among other reasons, address gaps in a specified area or medical topic. We note that, prior to rulemaking, we review these submitted measures with the measure owners prior to including these measures for reporting under the 2012 Physician Quality Reporting System. Among other factors, we examine the utility of each quality measure that was submitted, the feasibility of reporting the measure, as well as our ability to analyze the data provided by the reporting of the measure.

Comment: One commenter stated that the following measures should be retired from reporting in the 2012 Physician Quality Reporting System, because they have been retired by the measure owner or are no longer applicable for quality reporting purposes:
• #135: Chronic Kidney Disease (CKD): Influenza Immunization.
• #79: End Stage Renal Disease (ESRD): Influenza immunization in Patients with ESRD.
• #175: Pediatric Stage Renal Disease (ESRD): Influenza Immunization.

The commenter stated that Physician Quality Reporting System measure no. 110 titled ''Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old'' has been updated to incorporate the influenza immunization measures. Therefore, the commenter encouraged reporting of Physician Quality Reporting System measure no. 110 in lieu of these retired measures. Another commenter also supported retiring Physician Quality Reporting System measure #79.

Response: We agree and are not finalizing those measures for reporting under the 2012 Physician Quality Reporting System.

Comment: One commenter suggested that we retire Physician Quality Reporting System measure #199 titled ''Heart Failure: Patient Education'' because this measure is no longer available for quality reporting.

Response: We agree and are not finalizing this measure for reporting under the 2012 Physician Quality Reporting System.

Comment: One commenter suggested that we implement a ''test measure'' process, whereby a measure would be tested for validity, feasibility, and reliability prior to being included for reporting under the Physician Quality Reporting System.

Response: Although we do not currently employ such a ''test measure'' process, we note that we review all quality measures submitted for inclusion for reporting under the Physician Quality Reporting System prior to proposing these measures for inclusion. We also note that we view implementation of a measure in the Physician Quality Reporting System as a vehicle for testing measures.

Comment: One commenter stated that, as the number of measures and available reporting options have grown substantially since the implantation of the Physician Quality Reporting System in 2007, we should look at the long-term value of the measures we finalize for inclusion as 2012 Physician Quality Reporting System measures.

Response: We appreciate and agree with the commenter's feedback. For example, when selecting measures for inclusion in the 2012 Physician Quality Reporting System, we took into consideration medical topics or areas not addressed in the 2011 Physician Quality Reporting System quality measures set, as well as which measures would encourage reporting by a broader scope of eligible professionals.

Comment: Some commenters stated that the process of submitting, reviewing, proposing, and finalizing measures for inclusion in the 2012 Physician Quality Reporting System is too slow. One commenter urged us to work with the NQF and measure developers to make the measure selection process more efficient.

Response: We understand that there is a need for measures to be reviewed, tested, and endorsed by the NQF in a timely fashion. We are committed to working with the NQF and measure owners to ultimately meet this goal. We welcome suggestions on how to improve the process for selecting measures for inclusion under the Physician Quality Reporting System.

Comment: One commenter suggested that we collaborate more with medical specialty boards when developing measures.

Response: We note that we typically do not develop measures. Rather, we solicit measures that have been developed by other measure developers for possible inclusion for reporting in the Physician Quality Reporting System through an annual Call for Measures. The Call for Measures for the 2013 program year has passed. However, information about our annual Call for Measures is typically posted on our Web site at *http://www.cms.gov/PQRS/15_MeasuresCodes.asp#TopOfPage.* We encourage all medical specialty boards to submit measure suggestions during our future Call for Measures sessions.

Comment: Some commenters were opposed to including quality measures for reporting under the 2012 Physician Quality Reporting System that were not developed by physicians.

Response: We appreciate the commenters' feedback but respectfully disagree. Although we welcome measures developed by physicians, we do not believe there needs to be any restrictions on the type of professional or organizations carrying out the basic

development of measures for physicians and other eligible professionals, such as restricting the initial development to physician-controlled organizations. While we agree that expertise in measure development is important in the measure development and consensus processes, any such restriction would unduly limit the basic development of quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards. To ensure that all measures may be appropriately reported under the Physician Quality Reporting System, we review all measures prior to proposing these measures for reporting. In addition, we note that physicians are not the only types of professionals eligible to participate in the Physician Quality Reporting System.

Comment: One commenter supported the inclusion of NQF-endorsed measures related to influenza, pneumococcal, Hepatitis A, and Hepatitis B vaccinations as we have recognized the importance of collection care information related to these diseases.

Response: We appreciate the commenter's support and are finalizing measures that are related to influenza, pneumococcal disease, Hepatitis A, and Hepatitis B vaccinations for the 2012 Physician Quality Reporting System. As described in the following further detail, measures involving these diseases are available for reporting as individual measures under the claims, registry, and EHR-based reporting mechanism.

Comment: One commenter supported the inclusion of Hepatitis C measures available for reporting under the 2012 Physician Quality Reporting System. However, the commenter notes that only a subset of eligible professionals is able to report on these measures.

Response: We appreciate the commenter's support of the finalized Hepatitis C measures. We encourage the commenter, as well as other professional organizations and measure developers, to submit additional Hepatitis C measures that cover a broader scope of eligible professionals during the Physician Quality Reporting System Call for Measures for future program years.

Comment: Several commenters suggested other considerations that we should take into account when selecting Physician Quality Reporting System measures, such as—

- Focusing on including measures that are related to the following medical topics: anesthesia, hematology, cardiology, abdominal aortic aneurysm (AAA) screening, pelvic prolapsed, gynecologic cancer, chronic obstructive pulmonary disease (COPD), elevated blood pressure, and gastroenterology;
- Whether measures test an eligible professional's basic competencies, rather than providing meaningful data on patient care; and
- Whether measures focus on care coordination.

Response: We appreciate the commenters' suggestions and will take these other considerations into account in future program years. We note that we largely depend on the development of measures by professional organizations and other measure developers and encourage professional organizations and other measure developers to fund and develop measures that address the priority areas identified by the commenters. In addition, if there are specific measures that commenters would like us to consider for future years to address these areas, measure suggestions may be submitted during our annual Call for Measures. Although the deadline to submit new measures via this year's Call for Measures for suggesting possible measures for the 2012 Physician Quality Reporting System has passed, measure suggestions may be submitted for consideration for possible inclusion under the 2014 Physician Quality Reporting System and beyond.

We typically host a Call for Measures each year and consider the measures provided for the next program year. However, we note that next year, we will not host a Call for Measures for measures to be included in the 2013 program year. This is due our need to concentrate our efforts to convert International Classification of Diseases (ICD) codes (which classify all diagnoses, symptoms, and procedures recording in conjunction with care in the United States) from ICD–9 to ICD–10. This conversion affects quality measures included in the Physician Quality Reporting System, as these measures currently contain ICD–9 codes. We believe that the transition from ICD–9 to ICD–10 is necessary to update care classifications. However, we urge these commenters to submit these specific measure suggestions for consideration in a future Call for Measures. Information on the Call for Measures will be available on the Physician Quality Reporting System Web site at *http://www.cms.gov/PQRS//* when it becomes available.

Comment: One commenter suggested that we provide feedback in instances where measures or measures groups that were submitted for inclusion for reporting for the 2012 Physician Quality Reporting System were not ultimately proposed as 2012 Physician Quality Reporting System quality measures or measures groups.

Response: We agree and believe that such feedback will be invaluable to measure developers and owners with regard to developing and suggesting quality measures to be included in future program years. We usually provide this feedback to measure developers for those individual measures and measures groups that were submitted for inclusion but ultimately not proposed as 2012 Physician Quality Reporting System individual measures or measures groups.

Comment: Some commenters noted that, at times, although CMS has allowed for certain measures to be reported under various CMS programs, the description of some of these measures (for example, measure titles) may vary across the various CMS programs. CMS suggested that we synthesize the measure information we provide, such as measure title and number, with other various CMS programs.

Response: We appreciate the commenters' feedback and agree with the commenters. We understand that consistent displays of information on reportable measures across various CMS programs will facilitate greater ease of reporting for those eligible professionals who participate in programs other than the Physician Quality Reporting System. However, we note that we are faced with operational limitations that prevent us from posting consistent measure information, such as varied rulemaking and measure review timeframes. When possible, we provide measure information that is consistent with other CMS programs.

Comment: Several commenters asked that the finalized 2012 Physician Quality Reporting System individual measures be grouped according to medical specialty applicability. Commenters believed that grouping measures in this way would make it easier for eligible professionals to decide on which measures to report. Commenters also noted the importance of identifying clusters of measures prior to potentially subjecting eligible professionals to the Measure Applicability Validation (MAV) process.

Response: We understand the importance of providing guidance on which measures to report. Although the measures that we are finalizing in this final rule with comment period are not listed according to medical specialty, we note that that we provide further guidance on disease clusters in subregulatory guidance on our Web site

at *http://www.cms.gov/PQRS//*. For example, the Physician Quality Reporting System 2009 Reporting Experience, which includes information on some measures available for reporting in 2012, provides information on top measures on which certain specialties have reported in past program years. Information on the MAV process is available in our ''2011 Physician Quality Reporting System Measure-Applicability Validation Process'' document available at *http://www.cms.gov/PQRS/25_AnalysisAndPayment.asp#TopOfPage.* Eligible professionals are also encouraged to contact the QualityNet Help Desk for guidance on satisfactory reporting. Furthermore, eligible professionals who are participating in the Physician Quality Reporting System for the first time may find it helpful to visit the ''How to Get Started'' section of our Web site, available at *http://www.cms.gov/PQRS/03_How_To_Get_Started.asp#TopOfPage,* which provides detailed information on all Physician Quality Reporting System quality measures available for reporting.

Comment: Several commenters proposed new measures and measures topics for inclusion in the 2012 Physician Quality Reporting System that were not specifically proposed in the proposed rule.

Response: We appreciate the commenters' suggestions on new measures and measure topics. However, as we stated in the proposed rule (76 FR 42862), section 1848(k)(2)(D) of the Act requires that the public have the opportunity to provide input during the selection of measures. We also are required to provide an opportunity for public comment on provisions of policy or regulation that are established via notice and comment rulemaking. Measures that are not included in this final rule with comment period for inclusion in the 2012 Physician Quality Reporting System that are recommended to us via comments on the proposed rule have not been placed before the public to comment on the selection of those measures within the rulemaking process. Even when measures have been published in the **Federal Register**, but in other contexts and not specifically proposed as Physician Quality Reporting System measures, we do not believe that such publication provides the best opportunity for public comment on those measures' potential inclusion in the Physician Quality Reporting System. Thus, such additional measures recommended for selection for the 2012 Physician Quality Reporting System via comments on the CY 2012 PFS proposed rule are not included in the 2012 measure set. As such, while we welcomed all constructive comments and suggestions, and may consider such recommended measures for inclusion in future measure sets for the Physician Quality Reporting System and other programs to which such measures may be relevant, we are not able to consider such additional measures for inclusion in the final 2012 Physician Quality Reporting System measure set.

In addition, as in prior years, we again note that we do not use notice and comment rulemaking as a means to update or modify measure specifications. Quality measures that have completed the consensus process have a designated party (usually, the measure developer/owner) who has accepted responsibility for maintaining the measure. In general, it is the role of the measure owner, developer, or maintainer to make changes to a measure. Therefore, comments requesting changes to a specific Physician Quality Reporting System measure's title, definition, and detailed specifications or coding should be directed to the measure developer identified in Tables 52 through 55. Contact information for the 2011 Physician Quality Reporting System measure developers is listed in the ''2011 Physician Quality Reporting System Quality Measures List,'' which is available on the CMS Web site at *http://www.cms.gov/PQRS/15_MeasuresCodes.asp#TopOfPage.*

Based on the criteria previously discussed, we proposed (76 FR 42862 and 42863) to include the individual measures listed in Tables 29 through 31 in the 2012 Physician Quality Reporting System individual quality measure set. We believe that each measure we proposed and are finalizing for reporting under the 2012 Physician Quality Reporting System meets at least one criterion for the selection of Physician Quality Reporting System measures described previously. We are also proposed (76 FR 42873) to include 24 measures groups in the 2012 Physician Quality Reporting System quality measure set, which were listed in Tables 32 through 55 of the proposed rule. The proposed individual measures selected for the 2012 Physician Quality Reporting System were categorized as follows—

- 2012 Physician Quality Reporting System Core Measures Available for Either Claims, Registry, and/or EHR-based Reporting;
- 2012 Physician Quality Reporting System Individual Quality Measures Available for Either Claims-based Reporting and/or Registry-based Reporting; and
- 2012 Physician Quality Reporting System Measures Available for EHR-based Reporting.

Please note that some individual measures we proposed in Tables 32 through 55 of the proposed rule for reporting for the 2012 Physician Quality Reporting System may be available for reporting in other CMS programs, such as the Medicare and Medicaid EHR Incentive Program as well as the Medicare Shared Savings Program. Please note that, in some instances, we have made technical changes in measure titles because the respective measure owners have updated these measure titles. We note that measure titles, in some instances, may vary from program to program. If an eligible professional intends to report the same measures for multiple CMS programs, it is important to check the full measure specifications, NQF measure number (if applicable), as well as any other identifying measure features to determine whether the measures are the same.

(3) 2012 Physician Quality Reporting System Individual Measures

This section focuses on the 2012 Physician Quality Reporting System Individual Measures available for reporting via claims, registry, and/or EHR-based reporting. For the proposed 2012 Physician Quality Reporting System measures that were selected for reporting in 2011, please note that detailed measure specifications, including the measure's title, for the 2012 individual Physician Quality Reporting System quality measures may have been updated or modified during the NQF endorsement process or for other reasons prior to 2012. The 2012 Physician Quality Reporting System quality measure specifications for any given individual quality measure may, therefore, be different from specifications for the same quality measure used in prior years. Specifications for all 2012 individual Physician Quality Reporting System quality measures, whether or not included in the 2011 Physician Quality Reporting System program, must be obtained from the specifications document for 2012 individual Physician Quality Reporting System quality measures, which will be available on the Physician Quality Reporting System section of the CMS Web site on or before December 31, 2011.

The following is a summary of general comments received that were related to the proposed 2012 Physician Quality Reporting System individual quality measures.

Comment: Some commenters were pleased to note that the proposed 2012 Physician Quality Reporting System individual measures include ample measures from which certain specialties may report, such as vascular surgeons, and audiologists.

Response: We appreciate the commenter's feedback and are pleased that the 2012 Physician Quality Reporting System provides many measures on which these eligible professionals can report.

Comment: Some commenters suggested that measures that have been updated or retired by the respective measure owners be excluded from the 2012 Physician Quality Reporting System.

Response: We update and retire measures that have been either updated or retired by the respective measure owners.

Comment: Several commenters suggested specific quality measures and/or measure topics be included in the 2012 Physician Quality Reporting System that we did not propose in the proposed rule, such as—

- NQF #492: Participation in a practice-based or individual quality database registry with a standard measure set (NQF #492);
- NEQ #493: Participation by a physician or other clinician in systematic clinical database registry that includes consensus endorsed quality measures;
- Measures related to fluid management; and
- Measures related to oncology.

Response: We appreciate the commenters' feedback. However, we are obligated by section 1848(k)(2)(D) of the Act to give eligible professionals an opportunity to provide input on measures recommended for selection, which we do via the proposed rule. Since the specific measures suggested previously were not proposed for inclusion, these additional measures and/or measure topics cannot be included for reporting under the 2012 Physician Quality Reporting System. However, we will take these measure suggestions into consideration for future program years.

We describe the individual quality measures we are finalizing for the 2012 Physician Quality Reporting System as follows: (The measures specifications for all finalized 2012 Physician Quality Reporting System measures will be available at *http://www.cms.gov/PQRS/15_MeasuresCodes.asp#TopOfPage.*)

(A) 2012 Physician Quality Reporting System Core Measures Available for Claims, Registry, and/or EHR-Based Reporting

The prevention of cardiovascular conditions is a top priority for CMS and HHS. In fact, in 2011, HHS launched the Million Hearts campaign, which is aimed at preventing 1 million heart attacks and strokes across the next 5-years through clinical- and community-based prevention strategies. Therefore, in conjunction with the Million Hearts campaign and in an effort to encourage eligible professionals to monitor their performance with respect to the prevention of cardiovascular conditions, we proposed (76 FR 42863) to adopt a 2012 Physician Quality Reporting System set of core measures, identified in Table 28 of the proposed rule, aimed at promoting cardiovascular care.

We invited public comment on the proposed 2012 Physician Quality Reporting System core measures available for claims, registry, and/or EHR-based reporting. The following is a summary of those comments.

Comment: Several commenters supported the proposed set of 2012 Physician Quality Reporting System core measures. While commenters generally supported the development of a set of Physician Quality Reporting System core measures, some of these commenters urge us to create additional core measure sets related to other disease modules (such as diabetes) for future program years.

Response: We appreciate the commenters' feedback and are finalizing all proposed 2012 Physician Quality Reporting System core measures. We will explore the development of additional Physician Quality Reporting System core measure sets for future program years.

Comment: Some commenters opposed the inclusion of the following two measures as 2012 Physician Quality Reporting System core measures, because they are not NQF-endorsed—

- Preventive Care and Screening: Blood Pressure Measurement; and
- Preventive Care: Cholesterol-LDL test performed.

Response: We appreciate the commenters' feedback. However, as stated previously, we believe these measures address important gaps in the Physician Quality Reporting System quality measure set and are integral to the Million Hearts campaign goal of preventing heart attacks and strokes.

Comment: Several commenters provided suggestions for other measures that should be included as a 2012 Physician Quality Reporting System core measure, such as—

- Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD
- Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus
- Coronary Artery Disease (CAD): Lipid Control

Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up

- A lipid profile measure

Response: We appreciate the commenters' feedback. However, we did not propose these measures for inclusion in the 2012 Physician Quality Reporting System as core measures. We are obligated by section 1848(k)(2)(D) of the Act to give eligible professionals an opportunity to provide input on measures recommended for selection, which we do via the proposed rule. Therefore, we are not finalizing these additional measures that commenters suggested for reporting under the 2012 Physician Quality Reporting System as core measures. However, since these measures are otherwise still generally reportable under the Physician Quality Reporting System via the claims, registry, and/or EHR-based reporting mechanisms, we encourage eligible professionals to report on these measures.

Comment: Some commenters suggested we establish a Physician Quality Reporting System core measure set addressing other medical topics, such as heart failure, ophthalmology, gastroenterology, and coronary artery disease.

Response: We appreciate the commenters' feedback and we are interested in developing measure sets that focus on other medical areas. We will take these core measures suggestions into consideration for future program years.

Based on the comments received and for the reasons stated previously, we are finalizing the 2012 Physician Quality Reporting System core measures listed in the following Table 46. Please note that the measure titled ''Proportion of adults 18-years and older who have had their BP measured within the preceding 2-years'' has been updated to ''Preventive Care and Screening: Blood Pressure Measurement.'' Therefore, this new measure title, when listed, will be used in Tables 47 through 72.

As stated previously, we are not requiring that eligible professionals report on these core measures. However, we view the reporting of these measures as a top priority to report and strongly encourage all eligible professionals to report on these measures. We are also listing these finalized Physician Quality

Reporting System core measures in Tables 48 and 49.

TABLE 46: 2012 PHYSICIAN QUALITY REPORTING SYSTEM CORE MEASURES AVAILABLE FOR CLAIMS, REGISTRY, AND/OR EHR-BASED REPORTING

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
204	Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic	0068	NCQA	Claims, Registry, EHR
236	Controlling High Blood Pressure	0018	NCQA	Claims, Registry, EHR
2	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus	0064	NCQA	Claims, Registry, EHR
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention	0028	AMA-PCPI	Claims, Registry, EHR
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100	0075	NCQA	Claims, Registry, EHR
TBD	Preventive Care and Screening: Blood Pressure Measurement	N/A	CMS	Claims, Registry, EHR
TBD	Preventive Care: Cholesterol-LDL test performed	N/A	CMS	EHR

(B) 2012 Physician Quality Reporting System Individual Measures for Claims and Registry Reporting

For 2012, we proposed (76 FR 42863) to retain all measures currently used in the 2011 Physician Quality Reporting System. We believe these 2011 Physician Quality Reporting System measures meet the statutory considerations as well as other factors we used in determining which measures to include for reporting under the 2012 Physician Quality Reporting System. The retention of these measures also promotes program consistency. These proposed measures included 55 registry-only measures currently used in the 2011 Physician Quality Reporting System, and 144 individual quality measures for either claims-based reporting or registry-based reporting (75 FR 40186 through 40190, and 52489 through 52490). These proposed measures do not include any measures that were proposed to be included as part of the following measures groups: Back Pain, COPD, IBD, Sleep Apnea, Epilepsy, Dementia, Parkinson's, Elevated Blood Pressure, and Cataracts.

As we stated in the proposed rule (76 FR 42864), in 2011, Physician Quality Reporting System measure #197 was titled ''Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL–Cholesterol.'' For 2012, we are changing the title of measure #197 to ''Coronary Artery Disease: Lipid Control'', because the measure owner, AMA–PCPI, has changed the title of the measure. Aside from the title change, measure #197's NQF number as well as its NQF-endorsement status has not changed. However, as noted previously, eligible professionals should check the measure specifications for measure #197, as the specifications on how to report on measure #197 for the 2012 Physician Quality Reporting System may change from 2011.

In addition, we proposed (76 FR 42864) the 26 new individual measures for inclusion in the 2012 Physician Quality Reporting System in order to provide eligible professionals with more Physician Quality Reporting System quality measures on which they can select from to report. The following 2 proposed measures are NQF-endorsed:

- Anticoagulation for Acute Pulmonary Embolus Patients.
- Pregnancy Test for Female Abdominal Pain Patients.

The remaining 24 measures we proposed (76 FR 42864) were either pending NQF endorsement or would have to be adopted under the exception to NQF endorsement provided under section 1848(k)(2)(C)(ii) of the Act. In selecting these proposed measures, we took into account other considerations listed in section VI.F.1.f.2.. of the proposed rule. Specifically, fwe proposed to include the following measures for reporting under the 2012 Physician Quality Reporting System because the measures impact chronic conditions:

- Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers.
- Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers.
- Hypertension: Blood Pressure Control.

We proposed the following measures because these measures involve care coordination:

• Coronary Artery Disease (CAD): Symptom Management.

We proposed the following measures for reporting under the Physician Quality Reporting System because these measures are applicable across care settings:

• Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence.

• Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence.

• Cardiac Rehabilitation Patient Referral From an Outpatient Setting.

We proposed (76 FR 42864) the following measures because we believe the measures address gaps in the Physician Quality Reporting System measure set:

• Barrett's Esophagus.

• Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain.

• Rh Immunoglobulin (Rhogam) for Rh Negative Pregnant Women at Risk of Fetal Blood Exposure.

• Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR).

• Referral for Otology Evaluation for Patients with Acute or Chronic Dizziness.

• Image Confirmation of Successful Excision of Image–Localized Breast Lesion.

• Improvement in Patient's Visual Function within 90–Days Following Cataract Surgery.

• Patient Satisfaction within 90–Days Following Cataract Surgery.

We proposed the following measures because we believe the measures increase the scope of applicability of the Physician Quality Reporting System measures to services furnished to Medicare beneficiaries and expand opportunities for eligible professionals to participate in the Physician Quality Reporting System:

• Radical Prostatectomy Pathology Reporting.

• Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients .

We proposed the following measures because the measures are high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries.

• Statin Therapy at Discharge after Lower Extremity Bypass (LEB).

• Rate of Open AAA Repair without Major Complications (discharged to home no later than post-operative day #7).

• Rate of EVAR without Major Complications (discharged to home no later than POD #2).

• Rate of Carotid Endarterectomy for Asymptomatic Patients, without Major Complications (discharged to home no later than post-operative day #2).

We proposed the following measures because the measures have a high impact on health care:

• Preoperative Diagnosis of Breast Cancer.

• Sentinel Lymph Node Biopsy for Invasive Breast Cancer.

• Biopsy Follow-up.

Of these newly proposed 26 measures, 13 would be reportable via registry-only. The remaining 13 measures would be available for claims and registry reporting. Although we proposed to designate certain measures as registry-only measures, we indicated we could not guarantee that there would be a registry qualified to submit each registry-only measure for 2012. We rely on registries to self-nominate and identify the measures for which they would like to be qualified to submit quality measures results and numerator and denominator data on quality measures. If no registry self-nominates to submit measure results and numerator and denominator data on a particular measure for 2012, then an eligible professional would not be able to report that particular measure.

We believe that the addition of Physician Quality Reporting System quality measures will encourage eligible professionals to participate in the Physician Quality Reporting System, as there are more measures that may be applicable to eligible professionals.

We invited public comment on the proposed 2012 Physician Quality Reporting System individual quality measures that are available for claims and/or registry-based reporting identified in Table 30 of the proposed rule (76 FR 42865). The following is a summary of the comments we received.

Comment: One commenter supported the inclusion of all 2011 Physician Quality Reporting System individual quality measures available for claims and registry-based reporting. Several commenters supported the following proposed 2012 Physician Quality Reporting System individual measures available for claims and/or registry-based reporting that were available for reporting in 2011:

• End Stage Renal Disease (ESRD): Influenza Immunization in Patients with ESRD.

• End Stage Renal Disease (ESRD): Plan of Care for Inadequate Hemodialysis in ESRD Patients.

• End Stage Renal Disease (ESRD): Plan of Care for Inadequate Peritoneal Dialysis.

• Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairments.

• Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lower Leg, Foot or Ankle Impairments.

• Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lumbar Spine Impairments.

• Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments.

• Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Elbow, Wrist or Hand Impairments.

• Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Neck, Cranium, Mandible, Thoracic Spine, Ribs, or Other General Orthopedic Impairments.

• Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients.

• Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula.

• Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear.

• Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention.

• Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old.

• Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus.

• Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus.

• Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus.

• Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).

• Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI).

• Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older.

• Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD.

• Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).

• Coronary Artery Disease (CAD): Lipid Control.

• Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation.

• Ischemic Vascular Disease (IVD): Blood Pressure Management.

• Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.

• Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.

One commenter was opposed to the measure titled ''End Stage Renal Disease (ESRD): Influenza Immunization in Patients with ESRD'' because the commenter believes reporting of this measure will create a higher burden for dialysis facility staff.

Response: We are finalizing all of the measures commenters supported, except for the following measure, because, as stated previously, the measure is being retired by the respective measure owner:

• End Stage Renal Disease (ESRD): Influenza Immunization in Patients with ESRD

Comment: Several commenters supported the inclusion of all 26 newly introduced individual measures for reporting under the 2012 Physician Quality Reporting System via the claims and/or registry-based reporting mechanisms. Some commenters supported specific newly proposed 2012 Physician Quality Reporting System individual quality measures available for claims and/or registry-based reporting, such as—

• Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence;

• Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence;

• Cardiac Rehabilitation Patient Referral From an Outpatient Setting;

• Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients;

• Image Confirmation of Successful Excision of Image-Localized Breast Lesion;

• Preoperative Diagnosis of Breast Cancer;

• Sentinel Lymph Node Biopsy for Invasive Breast Cancer;

• Biopsy Follow-up;

• Barrett's Esophagus;

• Radical Prostatectomy Pathology Reporting;

• Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients;

• Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence; and

• Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence.

Response: We appreciate the commenters' support and are finalizing these newly-proposed 26 measures specified previously as 2012 Physician Quality Reporting System quality measures available for claims and/or registry-based reporting.

Comment: A few commenters noted that the following measures that we indicated were not NQF-endorsed in the proposed rule (76 FR 42864), in fact, received NQF endorsement:

• Cardiac Rehabilitation Patient Referral From an Outpatient Setting.

• Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain.

• Rh Immunoglobulin (Rhogam) for Rh Negative Pregnant Women at Risk of Fetal Blood Exposure.

One commenter also requested that the measure titled ''Rh Immunoglobulin (Rhogam) for Rh Negative Pregnant Women at Risk of Fetal Blood Exposure'' be also be reported via claims, rather than only via the registry-based reporting mechanism.

Response: We appreciate the commenters' comment and note that these measures are endorsed by the NQF. Therefore, we are finalizing these measures for reporting via the claims and/or registry-based reporting mechanism for the 2012 Physician Quality Reporting System. The corresponding NQF numbers for these measures are indicated in the following Table 47. Furthermore, 'since we agree with the commenter, we are allowing the reporting of the measure titled ''Rh Immunoglobulin (Rhogam) for Rh Negative Pregnant Women at Risk of Fetal Blood Exposure'' to also be reported via claims as well as registry.

Comment: With respect to the measure titled ''Patient Satisfaction within 90 Days Following Cataract Surgery'', one commenter wondered whether there was an alternative NQF-endorsed measure that may be reported to indicate patient satisfaction.

Response: An alternative NQF-endorsed measure addressing patient satisfaction was not submitted for possible inclusion in the 2012 Physician Quality Reporting System. We also note that the measure is to be reported whether or not the patient was satisfied with their care. Rather, the measure analytics will calculate the percentage of patients who were satisfied or not satisfied with their care.

Comment: Some commenters suggested that all measures be reportable via claims, at least for the first year in which the measure is introduced for reporting in the Physician Quality Reporting System. One commenter suggested that we reconsider the inclusion of measures that are only reportable via a registry that is only open to certain eligible professionals.

Response: We appreciate the commenters' feedback. However, some measures are not conducive to collection via claims because they may require data that is not available at the time a claim form is submitted. For example, some outcome measures that look at complications which may occur within a specific post-operative period would be difficult to collect from claims. In bundled or global payments, there may not be additional claims coming to CMS with charges in which the eligible professional could report a complication. Other measures can be difficult to collect via claims due to their complexity. Additionally, each year one or more registries request being vetted (qualified) to report on any and all Physician Quality Reporting System measures which would give a specific specialty an opportunity to report any new measures.

In addition, we understand the concern that certain eligible professionals may not be able to report on registry-only measures. However, we believe it is beneficial that we provide as many measures as possible on which eligible professionals may report so as to increase participation and eligible professionals' reporting success rates. We believe the inclusion of registry-only measures provides a greater set of measures on which to satisfactorily report.

Comment: One commenter suggested that we update the following 2011 Physician Quality Reporting System measure titles to reflect their new measure titles:

• Measure #7: Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40 percent).

• Measure #53: Asthma: Pharmacologic Therapy for Persistent Asthma.

• Measure #64: Asthma: Assessment of Asthma Control.

• Measure #81: Adult Kidney Disease: Hemodialysis Adequacy: Solute.

• Measure #82: Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute.

• Measure #32: Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy.

• Measure #36: Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered.

• Measure #224: Melanoma: Overutilization of Imaging Studies in Melanoma.

• Measure #121: Adult Kidney Disease: Laboratory Testing (Lipid Profile).

• Measure #122: Adult Kidney Disease: Blood Pressure Management.
• Measure #123: Adult Kidney Disease: Patients on Erythropoiesis-Stimulating Agent (ESA) Hemoglobin Level > 12.0 g/dL.
• Measure #197: Coronary Artery Disease (CAD): Lipid Control.
• Measure #110: Preventive Care and Screening: Influenza Immunization.

Response: We appreciate the commenter's feedback and are finalizing these measures for reporting under the Physician Quality Reporting System. The updated measure titles for Physician Quality Reporting System measure #s 7, 53, 64, 81, 82, 32, 36, 224, and 121 are provided in our final list of measures identified in Tables 48 and 49 as well as in Tables 50 through 71, which contain our final 2012 Physician Quality Reporting System measures groups.

Comment: One commenter expressed concern that we are retiring the measure titled ''End Stage Renal Disease (ESRD): Plan of Care for Inadequate Hemodialysis in ESRD Patients'' due to its lack of endorsement by the NQF.

Response: We are not retiring this measure, which is Physician Quality Reporting System measure # 81. As we stated previously, however, we are updating the title of this measure to ''Adult Kidney Disease: Hemodialysis Adequacy: Solute.''

Comment: One commenter suggested that we correct the title to Physician Quality Reporting System measure # 186 as the measure is titled ''Chronic Wound Care: Use of Compression System in Patients with Venous Ulcers.''

Response: We appreciate the commenter's feedback and are updating this measure title in our list of finalized measures in the following Table 47.

Comment: One commenter suggested that we update Physician Quality Reporting System measures # 5, 8, and 198 to reflect new joint copyright between the AMA–PCPI and ACC. Another commenter suggested that we update Physician Quality Reporting System measures # 53, 64, 224, and 231 to reflect new joint copyright ownership between the AMA–PCPI and NCQA. Another commenter suggested that we update Physician Quality Reporting System measures # 6, 7, 118, 196, and 197 to reflect new joint copyright ownership between the AMA–PCPI and AHA.

Response: We appreciate the commenter's' feedback will reflect these changes in copyright ownership in all of these measures, which are listed in Tables 48 and 49.

Comment: One commenter suggested that we update the description of Physician Quality Reporting System measure # 108 and # 117 to reflect the correct measure developers, who are AMA–PCPI/NCQA and NCQ respectively.

Response: We appreciate the commenter's feedback and are updating the measure descriptions of Physician Quality Reporting System measures # 108 and # 117 accordingly.

Comment: One commenter stated that Physician Quality Reporting System measures # 67, 68, 69, and 70 state the measures' clinical topic, hematology.

Response: We appreciate the commenter's feedback and will include the measures' clinical topic, hematology, in the measure titles for Physician Quality Reporting System measures # 108 and 117 in the finalized measures listed in the following Tables 48 and 49.

Comment: One commenter suggested that we retire the following measure that we proposed for reporting via claims, registry, and/or EHR-based reporting under the 2012 Physician Quality Reporting System: Physician Quality Reporting System #200: Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation because the commenter claims the use of warfarin therapy to treat Atrial Fibrillation is no longer consistent with evidence-based clinical guidelines.

Response: We agree that the Physician Quality Reporting System quality measure #200 is no longer consistent with the evidence-based clinical guidelines. However, we believe it is important to retain this measure for the EHR-based reporting mechanism for the 2012 Physician Quality Reporting System in order to align with the EHR Incentive Program. Therefore, as specified in the following Table 48, we are only finalizing this measure for reporting under the EHR-based reporting mechanism only. We note that the measure owner has modified the measure specifications of Physician Quality Reporting System quality measure #200 to allow for the use of additional therapies that are more consistent with the updated guidelines. We note that, for future program years, we will revisit the inclusion of this measure in the Physician Quality Reporting System and EHR Incentive Program. We emphasize our belief that eligible professionals should follow standard clinical guidelines related to the treatment of Atrial Fibrillation.

Comment: One commenter suggested that we retire the following measure that we proposed for reporting via claims and/or registry under the 2012 Physician Quality Reporting System: Measure #6, which the commenter described as ''Use of High Risk-Medications in the Elderly,'' because the commenter believes that the measure may not represent the most up-to-date evidence-based clinical guidelines.

Response: We appreciate the commenter's feedback. However, Physician Quality Reporting System measure #6 is ''Coronary Artery Disease (CAD): Antiplatelet Therapy,'' not ''Use of High Risk-Medications in the Elderly.'' ''Use of High Risk-Medications in the Elderly'' is not a measure that we proposed for inclusion in the 2012 Physician Quality Reporting System. For 2012, we are finalizing Physician Quality Reporting System measure #6 for reporting via claims and/or registry.

Comment: One commenter opposed the inclusion of the following newly proposed 2012 Physician Quality Reporting System individual measures:

• Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers.
• Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers.

The commenter believes that these measures will encourage eligible professionals to use more expensive dressings without improving quality of care.

Response: We appreciate the commenter's feedback. However, we believe these measures will create a positive impact to on providing care to patients with chronic wounds. We encourage the commenter to review the revised measure specifications within the Physician Quality Reporting System. These measures are calculated as ''inverse'' measures. Therefore, a lower rate indicates a better performance/control or quality indicator.

For the reasons stated previously, we proposed to include, but are not finalizing, the following measures for claims and/or registry-based reporting in the 2012 Physician Quality Reporting System:

• # 135: Chronic Kidney Disease (CKD): Influenza Immunization.
• # 79: End Stage Renal Disease (ESRD): Influenza immunization in Patients with ESRD.
• # 175: Pediatric Stage Renal Disease (ESRD): Influenza Immunization.

Furthermore, as shown in the following Table 47, we are not finalizing the following measures for the following reasons:

• Physician Quality Reporting System measure #94 titled ''Otitis Media with Effusion (OME): Diagnostic Evaluation—Assessment of Tympanic Membrane Mobility'': this measure underwent NQF review, but did not receive endorsement from the NQF.

• Physician Quality Reporting System measure #153 titled ''Chronic Kidney Disease (CKD): Referral for Arteriovenous (AV) Fistula'': this measure owner has removed this measure for purposes of quality reporting.

• Physician Quality Reporting System measure #202 titled ''Ischemic Vascular Disease (IVD): Complete Lipid Profile'' and Physician Quality Reporting System measure #203 titled ''Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL–C) Control'': these measures have been combined into a single measure titled ''Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100.'' This combined measure was listed in Table 55 of the proposed rule. This new individual measure (see Table 47) titled ''Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100'' will be available for claims and registry-based reporting.

Based on the comments received and for the reasons stated previously, we are finalizing all measures in Table 47 for claims and/or registry-based reporting in the 2012 Physician Quality Reporting System. We proposed (76 FR 42877) an Epilepsy measures group for inclusion in the 2012 Physician Quality Reporting System. As described in further detail later in this section, we are not finalizing the proposed Epilepsy measures group. However, we are still finalizing three of the measures from this measures group for reporting as individual measures. Table 47 lists a total of 240 individual measures available for claims and/or registry-based reporting under the 2012 Physician Quality Reporting System.

We note that the final measures available for claims and/or registry-based reporting listed in Table 47 that do not have NQF measure numbers (as indicated by ''N/A'') are not currently endorsed by the NQF. These measures are awaiting review and endorsement by the NQF. Therefore, for these measures, for reasons previously explained, we are exercising our authority under section 1848(k)(2)(C)(i) of the Act to include these measures for reporting via the claims and/or registry-based reporting mechanisms.

The 2012 Physician Quality Reporting System individual measures for either claims-based reporting or registry-based reporting are listed in Table 47 by their Physician Quality Reporting System Measure Number (to the extent the measure is part of the 2011 Physician Quality Reporting System measure set) and Title, along with the name of the measure's developer/owner and NQF measure number, if applicable. The Physician Quality Reporting System Measure Number is a unique identifier assigned by CMS to all measures in the Physician Quality Reporting System measure set. Once a Physician Quality Reporting System Measure Number is assigned to a measure, it will not be used again to identify a different measure, even if the original measure to which the number was assigned is subsequently retired from the Physician Quality Reporting System measure set. A description of the measures listed in Table 47 can be found in the ''2011 Physician Quality Reporting System Quality Measures List,'' which is available on the Measures and Codes page of the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.hhs.gov/PQRS* to the extent the measure is part of the 2011 Physician Quality Reporting System measure set. New measures that we are adding to the Physician Quality Reporting System measure set for 2012 are designated with a Physician Quality Reporting System Measure Number of ''TBD.'' As we stated previously, the final 2012 Physician Quality Reporting System core measures are also listed in Table 47.

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TABLE 47: 2012 PHYSICIAN QUALITY REPORTING SYSTEM INDIVIDUAL QUALITY MEASURES AVAILABLE FOR EITHER CLAIMS-BASED REPORTING AND/OR REGISTRY-BASED REPORTING

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus	0059	NCQA	Claims, Registry
2	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus	0064	NCQA	Claims, Registry
3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus	0061	NCQA	Claims, Registry
5	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0081	AMA-PCPI/ACC	Registry
6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD	0067	AMA-PCPI/AHA	Claims, Registry
7	Coronary Artery Disease (CAD): Beta-Blocker Therapy- Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40 percent)	0070	AMA-PCPI/AHA	Registry
8	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD < 40%)	0083	AMA-PCPI/ACC	Registry
9	Major Depressive Disorder (MDD): Antidepressant Medication During Acute Phase for Patients with MDD	0105	NCQA	Claims, Registry
10	Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports	00246	AMA-PCPI/NCQA	Claims, Registry
12	Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation	0086	AMA-PCPI	Claims, Registry
14	Age-Related Macular Degeneration (AMD): Dilated Macular Examination	0087	AMA-PCPI/NCQA	Claims, Registry
18	Diabetic Retinopathy	0088	AMA-PCPI	Claims, Registry
19	Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care	0089	AMA-PCPI	Claims, Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
20	Perioperative Care: Timing of Antibiotic Prophylaxis – Ordering Physician	0270	AMA-PCPI/NCQA	Claims, Registry
21	Perioperative Care: Selection of Prophylactic Antibiotic	0268	AMA-PCPI/NCQA	Claims, Registry
22	Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures)	0271	AMA-PCPI/NCQA	Claims, Registry
23	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients)	0239	AMA-PCPI/NCQA	Claims, Registry
24	Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older	0045	AMA-PCPI/NCQA	Claims, Registry
28	Aspirin at Arrival for Acute Myocardial Infarction (AMI)	0092	AMA-PCPI/NCQA	Claims, Registry
30	Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics	0270	AMA-PCPI/NCQA	Claims, Registry
31	Stroke and Stroke Rehabilitation: Deep Vein Thrombosis Prophylaxis (DVT) for Ischemic Stroke or Intracranial Hemorrhage	0240	AMA-PCPI/NCQA	Claims, Registry
32	Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy	0325	AMA-PCPI/NCQA	Claims, Registry
33	Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge	0241	AMA-PCPI/NCQA	Registry
35	Stroke and Stroke Rehabilitation: Screening for Dysphagia	0243	AMA-PCPI/NCQA	Claims, Registry
36	Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered	0244	AMA-PCPI/NCQA	Claims, Registry
39	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older	0046	AMA-PCPI/NCQA	Claims, Registry
40	Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older	0045	AMA-PCPI/NCQA	Claims, Registry
41	Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older	0049	AMA-PCPI/NCQA	Claims, Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
43	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery	0516	STS	Claims, Registry
44	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery	0235	STS	Claims, Registry
45	Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures)	0637	AMA-PCPI/NCQA	Claims, Registry
46	Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility	0097	AMA-PCPI/NCQA	Claims, Registry
47	Advance Care Plan	0326	AMA-PCPI/NCQA	Claims, Registry
48	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	0098	AMA-PCPI/NCQA	Claims, Registry
49	Urinary Incontinence: Characterization of Urinary Incontinence in Women Aged 65 Years and Older	0099	AMA-PCPI/NCQA	Claims, Registry
50	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	0100	AMA-PCPI/NCQA	Claims, Registry
51	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation	0091	AMA-PCPI	Claims, Registry
52	Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy	0102	AMA-PCPI	Claims, Registry
53	Asthma: Pharmacologic Therapy for Persistent Asthma	0047	AMA-PCPI/NCQA	Claims, Registry,
54	12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain	0090	AMA-PCPI/NCQA	Claims, Registry
55	12-Lead Electrocardiogram (ECG) Performed for Syncope	0093	AMA-PCPI/NCQA	Claims, Registry
56	Community-Acquired Pneumonia (CAP): Vital Signs	0232	AMA-PCPI/NCQA	Claims, Registry
57	Community-Acquired Pneumonia (CAP): Assessment of Oxygen Saturation	0094	AMA-PCPI/NCQA	Claims, Registry
58	Community-Acquired Pneumonia (CAP): Assessment of Mental Status	0234	AMA-PCPI/NCQA	Claims, Registry
59	Community-Acquired Pneumonia (CAP): Empiric Antibiotic	0096	AMA-PCPI/NCQA	Claims, Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
64	Asthma: Assessment of Asthma Control	0001	AMA-PCPI/NCQA	Claims, Registry
65	Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use	0069	NCQA	Claims, Registry
66	Hematology: Appropriate Testing for Children with Pharyngitis	0002	NCQA	Claims, Registry
67	Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow	0377	AMA-PCPI/ASH	Claims, Registry
68	Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy	0378	AMA-PCPI/ASH	Claims, Registry
69	Hematology: Multiple Myeloma: Treatment with Bisphosphonates	0380	AMA-PCPI/ASH	Claims, Registry
70	Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry	0379	AMA-PCPI/ASH	Claims, Registry
71	Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	0387	AMA-PCPI/ ASCO/NCCN	Claims, Registry
72	Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients	0385	AMA-PCPI/ ASCO/NCCN	Claims, Registry
76	Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol	0464	AMA-PCPI	Claims, Registry
81	Adult Kidney Disease: Hemodialysis Adequacy: Solute	0323	AMA-PCPI	Registry
82	Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute	0321	AMA-PCPI	Registry
83	Hepatitis C: Testing for Chronic Hepatitis C – Confirmation of Hepatitis C Viremia	0393	AMA-PCPI	Registry
84	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment	0395	AMA-PCPI	Claims, Registry,
85	Hepatitis C: HCV Genotype Testing Prior to Treatment	0396	AMA-PCPI	Claims, Registry
86	Hepatitis C: Antiviral Treatment Prescribed	0397	AMA-PCPI	Claims, Registry
87	Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment	0398	AMA-PCPI	Claims, Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
89	Hepatitis C: Counseling Regarding Risk of Alcohol Consumption	0401	AMA-PCPI	Claims, Registry
90	Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy	0394	AMA-PCPI	Claims, Registry
91	Acute Otitis Externa (AOE): Topical Therapy	0653	AMA-PCPI	Claims, Registry
92	Acute Otitis Externa (AOE): Pain Assessment	N/A	AMA-PCPI	Claims, Registry
93	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use	0654	AMA-PCPI	Claims, Registry
99	Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade	0391	AMA-PCPI/CAP	Claims, Registry
100	Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade	0392	AMA-PCPI/CAP	Claims, Registry
102	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients	0389	AMA-PCPI	Claims, Registry
104	Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Prostate Cancer Patients	0390	AMA-PCPI	Claims, Registry
105	Prostate Cancer: Three-Dimensional (3D) Radiotherapy	0388	AMA-PCPI	Claims, Registry
106	Major Depressive Disorder (MDD): Diagnostic Evaluation	0103	AMA-PCPI	Claims, Registry
107	Major Depressive Disorder (MDD): Suicide Risk Assessment	0104	AMA-PCPI	Claims, Registry
108	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy	0054	AMA-PCPI/NCQA	Claims, Registry
109	Osteoarthritis (OA): Function and Pain Assessment	0050	AMA-PCPI	Claims, Registry
110	Preventive Care and Screening: Influenza Immunization	0041	AMA-PCPI	Claims, Registry
111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older	0043	NCQA	Claims, Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
112	Preventive Care and Screening: Screening Mammography	0031	NCQA	Claims, Registry
113	Preventive Care and Screening: Colorectal Cancer Screening	0034	NCQA	Claims, Registry
116	Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use	0058	NCQA	Claims, Registry
117	Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient	0055	NCQA	Claims, Registry
118	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)	0066	AMA-PCPI/AHA	Registry
119	Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients	0062	NCQA	Claims, Registry
121	Adult Kidney Disease: Laboratory Testing (Lipid Profile)	N/A	AMA-PCPI	Claims, Registry
122	Adult Kidney Disease: Blood Pressure Management	AQA adopted	AMA-PCPI	Claims, Registry
123	Adult Kidney Disease: Patients on Erythropoiesis-Stimulating Agent (ESA) Hemoglobin Level > 12.0 g/dL	AQA adopted	AMA-PCPI	Claims, Registry
124	Health Information Technology (HIT): Adoption/Use of Electronic Health Records (EHR)	0488	CMS/QIP	Claims, Registry
126	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	0417	APMA	Claims, Registry
127	Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear	0416	APMA	Claims, Registry
128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up	0421	CMS/QIP	Claims, Registry
130	Documentation of Current Medications in the Medical Record	0419	CMS/QIP	Claims, Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
131	Pain Assessment Prior to Initiation of Patient Therapy and Follow-Up	0420	CMS/QIP	Claims, Registry
134	Screening for Clinical Depression and Follow-Up Plan	0418	CMS/QIP	Claims, Registry
137	Melanoma: Continuity of Care – Recall System	0650	AMA-PCPI/NCQA	Registry
138	Melanoma: Coordination of Care	0561	AMA-PCPI/NCQA	Registry
140	Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement	0566	AMA-PCPI/NCQA	Claims, Registry
141	Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care	0563	AMA-PCPI/NCQA	Claims, Registry
142	Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-Counter (OTC) Medications	0051	AMA-PCPI	Claims, Registry
143	Oncology: Medical and Radiation – Pain Intensity Quantified	0384	AMA-PCPI	Registry
144	Oncology: Medical and Radiation – Plan of Care for Pain	0383	AMA-PCPI	Registry
145	Radiology: Exposure Time Reported for Procedures Using Fluoroscopy	0510	AMA-PCPI/NCQA	Claims, Registry
146	Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening	0508	AMA-PCPI/NCQA	Claims, Registry
147	Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy	0511	AMA-PCPI	Claims, Registry
154	Falls: Risk Assessment	AQA adopted	AMA-PCPI/NCQA	Claims, Registry
155	Falls: Plan of Care	AQA adopted	AMA-PCPI/NCQA	Claims, Registry
156	Oncology: Radiation Dose Limits to Normal Tissues	0382	AMA-PCPI	Claims, Registry
157	Thoracic Surgery: Recording of Clinical Stage for Lung Cancer and Esophageal Cancer Resection	0455	STS	Claims, Registry
158	Carotid Endarterectomy: Use of Patch During Conventional Carotid Endarterectomy	0466	SVS	Claims, Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
159	HIV/AIDS: CD4+ Cell Count or CD4+ percentage	0404	AMA-PCPI/NCQA	Registry
160	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis	0405	AMA-PCPI/NCQA	Registry
161	HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy	0406	AMA-PCPI/NCQA	Registry
162	HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy	0407	AMA-PCPI/NCQA	Registry
163	Diabetes Mellitus: Foot Exam	0056	NCQA	Claims, Registry
164	Coronary Artery Bypass Graft (CABG): Prolonged Intubation (Ventilation)	0129	STS	Registry
165	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate	0130	STS	Registry
166	Coronary Artery Bypass Graft (CABG): Stroke/Cerebrovascular Accident (CVA)	0131	STS	Registry
167	Coronary Artery Bypass Graft (CABG): Postoperative Renal Insufficiency	0114	STS	Registry
168	Coronary Artery Bypass Graft (CABG): Surgical Re-exploration	0115	STS	Registry
169	Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge	0237	STS	Registry
170	Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge	0238	STS	Registry
171	Coronary Artery Bypass Graft (CABG): Lipid Management and Counseling	0118	STS	Registry
172	Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula	0259	SVS	Claims, Registry
173	Preventive Care and Screening: Unhealthy Alcohol Use – Screening	AQA adopted	AMA-PCPI	Claims, Registry
176	Rheumatoid Arthritis (RA): Tuberculosis Screening	AQA adopted	AMA-PCPI/NCQA	Claims, Registry
177	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity	AQA adopted	AMA-PCPI/NCQA	Claims, Registry
178	Rheumatoid Arthritis (RA): Functional Status Assessment	AQA adopted	AMA-PCPI/NCQA	Claims, Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
179	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis	AQA adopted	AMA-PCPI/NCQA	Claims, Registry
180	Rheumatoid Arthritis (RA): Glucocorticoid Management	AQA adopted	AMA-PCPI/NCQA	Claims, Registry
181	Elder Maltreatment Screen and Follow-Up Plan	AQA adopted	CMS/QIP	Claims, Registry
182	Functional Outcome Assessment in Chiropractic Care	AQA adopted	CMS/QIP	Claims, Registry
183	Hepatitis C: Hepatitis A Vaccination in Patients with HCV	0399	AMA-PCPI	Claims, Registry
184	Hepatitis C: Hepatitis B Vaccination in Patients with HCV	0400	AMA-PCPI	Claims, Registry
185	Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	0659	AMA-PCPI/NCQA	Claims, Registry
186	Chronic Wound Care: Use of Compression System in Patients with Venous Ulcers	AQA adopted	AMA-PCPI/NCQA	Claims, Registry
187	Stroke and Stroke Rehabilitation: Thrombolytic Therapy	0437	AHA/ASA/TJC	Registry
188	Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear	N/A	AQC	Claims, Registry
189	Referral for Otologic Evaluation for Patients with History of Active Drainage From the Ear Within the Previous 90 Days	N/A	AQC	Claims, Registry
190	Referral for Otologic Evaluation for Patients with a History of Sudden or Rapidly Progressive Hearing Loss	N/A	AQC	Claims, Registry
191	Cataracts: 20/40 or Better Visual Acuity Within 90 Days Following Cataract Surgery	0565	AMA-PCPI/NCQA	Registry
192	Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures	0564	AMA-PCPI/NCQA	Registry
193	Perioperative Temperature Management	0454	AMA-PCPI	Claims, Registry
194	Oncology: Cancer Stage Documented	0386	AMA-PCPI/ASCO	Claims, Registry
195	Radiology: Stenosis Measurement in Carotid Imaging Studies	0507	AMA-PCPI/NCQA	Claims, Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
196	Coronary Artery Disease (CAD): Symptom and Activity Assessment	0065	AMA-PCPI/AHA	Registry
197	Coronary Artery Disease (CAD): Lipid Control	0074	AMA-PCPI/AHA	Registry
198	Heart Failure: Left Ventricular Function (LVF) Assessment	0079	AMA-PCPI/ACC	Registry
201	Ischemic Vascular Disease (IVD): Blood Pressure Management Control	0073	NCQA	Claims, Registry
204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic	0068	NCQA	Claims, Registry
205	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea	0409	AMA-PCPI/NCQA	Registry
206	HIV/AIDS: Screening for High Risk Sexual Behaviors	0413	AMA-PCPI/NCQA	Registry
207	HIV/AIDS: Screening for Injection Drug Use	0415	AMA-PCPI/NCQA	Registry
208	HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis	0410	AMA-PCPI/NCQA	Registry
209	Functional Communication Measure - Spoken Language Comprehension	0445	ASHA	Registry
210	Functional Communication Measure - Attention	0449	ASHA	Registry
211	Functional Communication Measure - Memory	0448	ASHA	Registry
212	Functional Communication Measure - Motor Speech	0447	ASHA	Registry
213	Functional Communication Measure - Reading	0446	ASHA	Registry
214	Functional Communication Measure - Spoken Language Expression	0444	ASHA	Registry
215	Functional Communication Measure - Writing	0442	ASHA	Registry
216	Functional Communication Measure - Swallowing	0443	ASHA	Registry
217	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Knee Impairments	0422	FOTO	Registry
218	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairments	0423	FOTO	Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
219	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lower Leg, Foot or Ankle Impairments	0424	FOTO	Registry
220	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lumbar Spine Impairments	0425	FOTO	Registry
221	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments	0426	FOTO	Registry
222	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Elbow, Wrist or Hand Impairments	0427	FOTO	Registry
223	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Neck, Cranium, Mandible, Thoracic Spine, Ribs, or Other General Orthopedic Impairments	0428	FOTO	Registry
224	Melanoma: Overutilization of Imaging Studies in Melanoma	0562	AMA-PCPI/NCQA	Registry
225	Radiology: Reminder System for Mammograms	0509	AMA-PCPI/NCQA	Claims, Registry
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention	0028	AMA-PCPI	Claims, Registry
228	Heart Failure (HF): Left Ventricular Function (LVF) Testing	0079	CMS	Registry
231	Asthma: Tobacco Use: Screening - Ambulatory Care Setting	N/A	AMA-PCPI/NCQA	Claims, Registry
232	Asthma: Tobacco Use: Intervention - Ambulatory Care Setting	N/A	AMA-PCPI/NCQA	Claims, Registry
233	Thoracic Surgery: Recording of Performance Status Prior to Lung or Esophageal Cancer Resection	0457	STS	Registry
234	Thoracic Surgery: Pulmonary Function Tests Before Major Anatomic Lung Resection (Pneumonectomy, Lobectomy, or Formal Segmentectomy)	0458	STS	Registry
235	Hypertension (HTN): Plan of Care	0017	AMA-PCPI	Claims, Registry
TBD	Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers	N/A	ASPS-PCPI-NCQA	Claims, Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
TBD	Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers	N/A	ASPS-PCPI-NCQA	Claims, Registry
TBD	Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence	AQA adopted	ASPS-PCPI-NCQA	Claims, Registry
TBD	Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence	AQA adopted	ASPS-PCPI-NCQA	Claims, Registry
TBD	Coronary Artery Disease (CAD): Symptom Management	N/A	ASPS-PCPI-NCQA	Registry
TBD	Cardiac Rehabilitation Patient Referral From an Outpatient Setting	0643	ACCF-AHA	Registry
TBD	Hypertension: Blood Pressure Control	N/A	ACC-AHA-PCPI	Registry
TBD	Barrett's Esophagus	N/A	CAP	Claims, Registry
TBD	Radical Prostatectomy Pathology Reporting	N/A	CAP	Claims, Registry
TBD	Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients	N/A	College of American Pathologists	Claims, Registry
TBD	Anticoagulation for Acute Pulmonary Embolus Patients	0503	ACEP	Claims, Registry
TBD	Pregnancy Test for Female Abdominal Pain Patients	0502	ACEP	Claims, Registry
TBD	Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain	0651	ACEP	Claims, Registry
TBD	Rh Immunoglobulin (Rhogam) for Rh Negative Pregnant Women at Risk of Fetal Blood Exposure	0652	ACEP	Claims, Registry
TBD	Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR	N/A	SVS	Registry
TBD	Statin Therapy at Discharge after Lower Extremity Bypass (LEB)	N/A	SVS	Registry
TBD	Rate of Open AAA Repair without Major Complications (discharged to home no later than post-operative day #7)	N/A	SVS	Registry
TBD	Rate of EVAR without Major Complications (discharged to home no later than POD #2)	N/A	SVS	Registry
TBD	Rate of Carotid Endarterectomy for Asymptomatic Patients, without Major Complications (discharged to home no later than post-operative day #2)	N/A	SVS	Registry

Physician Quality Reporting System Measure Number	Measure Title	NQF Measure Number	Measure Developer	Reporting Mechanism
TBD	Referral for Otology Evaluation for Patients with Acute or Chronic Dizziness	N/A	AQC	Claims, Registry
TBD	Image Confirmation of Successful Excision of Image–Localized Breast Lesion	N/A	ASBS	Claims, Registry
TBD	Preoperative Diagnosis of Breast Cancer	N/A	ASBS	Claims, Registry
TBD	Sentinel Lymph Node Biopsy for Invasive Breast Cancer	N/A	ASBS	Registry
TBD	Biopsy Follow-up	N/A	AAD	Registry
TBD	Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	N/A	AAO	Registry
TBD	Patient Satisfaction within 90 Days Following Cataract Surgery	N/A	AAO	Registry
TBD	Seizure Type(s) and Current Seizure Frequency(ies)	N/A	AAN/AMA-PCPI	Claims, Registry
TBD	Documentation of Etiology of Epilepsy or Epilepsy Syndrome	N/A	AAN/AMA-PCPI	Claims, Registry
TBD	Counseling for Women of Childbearing Potential with Epilepsy	N/A	AAN/AMA-PCPI	Claims, Registry
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100	0075	**NCQA**	Claims, Registry
TBD	Preventive Care and Screening: Blood Pressure Measurement	N/A	**CMS**	Claims, Registry
TBD	Preventive Care: Cholesterol-LDL test performed	N/A	**CMS**	Claims, Registry
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100*	0075	NCQA	Claims, Registry

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(C) 2012 Measures Available for EHR-Based Reporting

For 2012, we proposed (76 FR 42871) to again accept Physician Quality Reporting System data from EHRs for a limited subset of 2012 Physician Quality Reporting System quality measures.

Section 1848(m)(7) of the Act (''Integration of Physician Quality Reporting and EHR Reporting''), as added by section 3002(d) of the Affordable Care Act, requires that by no later than January 1, 2012, the Secretary shall develop a plan to integrate reporting on quality measures under the Physician Quality Reporting System with reporting requirements under the EHR Incentive Program under section 1848(o) of the Act relating to the meaningful use of EHRs. Such integration shall consist of the following:

(A) The selection of measures, the reporting of which would both demonstrate—

(i) Meaningful use of an EHR for purposes of the Medicare EHR Incentive Program; and

(ii) Quality of care furnished to an individual; and

(B) Such other activities as specified by the Secretary.

To align the Physician Quality Reporting System with the Medicare EHR Incentive Program, we proposed (76 FR 42871) to include all clinical quality measures available for reporting under the Medicare EHR Incentive Program (75 FR 44398 through 44408) -in the 2012 Physician Quality Reporting System for purposes of reporting data on quality measures under the EHR-based reporting option. In 2011, we included 14 of the 44 EHR Incentive Program measures under the 2011 Physician Quality Reporting System EHR reporting mechanism. In order to better align Physician Quality Reporting System measures with those under the EHR Incentive Program, for 2012, we proposed to have the rest of the 44 clinical quality measures in the Medicare EHR Incentive Program available for EHR-based reporting under the 2012 Physician Quality Reporting System.

Furthermore, for 2012, we proposed to retain the following 6 additional measures that were available for reporting under the EHR-based reporting mechanism under the 2011 Physician Quality Reporting System:

- Measure # 39: Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older.
- Measure # 47: Advance Care Plan.
- Measure # 48: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older.

• Measure # 124: Health Information Technology (HIT): Adoption/Use of Electronic Health Records (EHR).

• Measure # 173: Preventive Care and Screening: Unhealthy Alcohol Use—Screening.

• Measure # 238: Drugs to be Avoided in the Elderly.

We believe these measures meet the criteria listed previously for inclusion for reporting under the Physician Quality Reporting System.

We invited public comment on the proposed EHR-based individual quality measures available for reporting under the 2012 Physician Quality Reporting System. The following is a summary of the comments we received.

Comment: Several commenters support the inclusion of all 44 EHR measures that are also available for reporting under the EHR Incentive Program in order to align reporting requirements and options for the Physician Quality Reporting System and EHR Incentive Program.

Response: We appreciate the commenters' support and are finalizing the inclusion of all 44 EHR measures that are also available for reporting under the EHR Incentive Program as 2012 Physician Quality Reporting System measures available for EHR-based reporting.

Comment: Some commenters supported the following specific proposed 2012 Physician Quality Reporting System measures available for EHR-based reporting as they address important medical topics:

• Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up

• Hypertension (HTN): Blood Pressure Measurement

• Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention

• Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old

• Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus

• Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

• Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD

• Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation

• Ischemic Vascular Disease (IVD): Blood Pressure Management

• Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic

Response: We appreciate the commenters' feedback and are finalizing all of the measures commenters supported for EHR-based reporting for the 2012 Physician Quality Reporting System.

Comment: One commenter suggested that we collaborate with NQF to develop health information technology-based quality measures.

Response: With respect to EHR measures that we have adopted from the EHR Incentive Program, we note that we are collaborating with NQF to develop these quality measures.

Comment: One commenter suggested that all commonly reported Physician Quality Reporting System measures be available for EHR-based reporting.

Response: We appreciate the commenter's feedback. However, each measure's method of reporting is determined by the measure owners and developers. Therefore, we cannot affect the method in which measures may be reported.

We proposed to include but are not finalizing the following measure for EHR-based reporting in the 2012 Physician Quality Reporting System, because we believe that use of electronic health records is already addressed in most of the measures we are finalizing:

• ''Health Information Technology: Adoption/Use of Electronic Health Records''

Based on the comments received and for the reasons stated previously, we are finalizing the 70 measures identified in Table 48 for EHR-based reporting under the 2012 Physician Quality Reporting System. As we stated previously, the final 2012 Physician Quality Reporting System core measures are also listed in Table 48.

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TABLE 48: 2012 PHYSICIAN QUALITY REPORTING SYSTEM MEASURES AVAILABLE FOR EHR-BASED REPORTING

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
MEASURES THAT ARE ALSO EHR INCENTIVE PROGRAM CORE MEASURES			
128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up**	0421	CMS/QIP
237	Hypertension (HTN): Blood Pressure Measurement	0013	AMA-PCPI
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention ***	0028	AMA-PCPI
MEASURES THAT ARE ALSO EHR INCENTIVE PROGRAM ALTERNATE CORE MEASURES			
110	Preventive Care and Screening: Influenza Immunization	0041	AMA-PCPI
239	Weight Assessment and Counseling for Children and Adolescents	0024	NCQA
TBD	Childhood Immunization Status	0038	NCQA
MEASURES THAT ARE ALSO EHR INCENTIVE PROGRAM MEASURES			
1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus	0059	NCQA
2	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus	0064	NCQA
3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus	0061	NCQA
5	Heart Failure: Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0081	AMA-PCPI/ACC
6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD	0067	AMA-PCPI/AHA
7	Coronary Artery Disease (CAD): Beta-Blocker Therapy- Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40 percent)	0070	AMA-PCPI/AHA
8	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0083	AMA-PCPI/ACC
9	Anti-depressant medication management: (a) Effective Acute Phase Treatment, (b) Effective Continuation Phase Treatment	0105	NCQA
12	Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation	0086	AMA-PCPI
18	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy	0088	AMA-PCPI

19	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care	0089	AMA-PCPI
53	Asthma: Pharmacologic Therapy for Persistent Asthma	0047	AMA-PCPI/NCQA
64	Asthma: Assessment of Asthma Control	0001	AMA-PCPI/NCQA
66	Appropriate Testing for Children with Pharyngitis	0002	NCQA
71	Oncology Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	0387	AMA-PCPI
72	Oncology Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients	0385	AMA-PCPI
102	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0389	AMA-PCPI
111	Preventive Care and Screening: Screening Mammography	0043	NCQA
112	Preventive Care and Screening: Colorectal Cancer Screening	0031	NCQA
113	Colorectal Cancer Screening	0034	NCQA
114 & 115	Smoking and Tobacco Use Cessation, Medical Assistance: a. Advising Smokers to Quit, b. Discussing Smoking and Tobacco Use Cessation Medications, c. Discussing Smoking and Tobacco Use Cessation Strategies	0027	NCQA
117	Diabetes: Eye Exam	0055	NCQA
119	Diabetes: Urine Screening	0062	NCQA
163	Diabetes: Foot Exam	0056	NCQA
197	Coronary Artery Disease (CAD): Lipid Control	0074	AMA-PCPI/AHA
200	Heart Failure: Warfarin Therapy Patients with Atrial Fibrillation	0084	AMA-PCPI
201	Ischemic Vascular Disease (IVD): Blood Pressure Management	0073	NCQA
204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic	0068	NCQA
TBD	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement	0004	NCQA
TBD	Prenatal Care: Screening for Human Immunodeficiency Virus (HIV)	0012	AMA-PCPI
TBD	Prenatal Care: Anti-D Immune Globulin	0014	AMA-PCPI
236	Controlling High Blood Pressure	0018	NCQA
TBD	Cervical Cancer Screening	0032	NCQA
TBD	Chlamydia Screening for Women	0033	NCQA
240	Use of Appropriate Medications for Asthma	0036	NCQA
TBD	Low Back Pain: Use of Imaging Studies	0052	NCQA
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control	0075	NCQA
TBD	Diabetes: Hemoglobin A 1 c Control (<8.0%)	0575	NCQA
OTHER PHYSICIAN QUALITY REPORTING SYSTEM EHR MEASURES			
39	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older	0046	AMA-PCPI/NCQA

47	Advance Care Plan	0326	AMA-PCPI/NCQA
48	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	0098	AMA-PCPI/NCQA
173	Preventive Care and Screening: Unhealthy Alcohol Use – Screening	AQA Adopted	AMA-PCPI
238	Drugs to be Avoided in the Elderly	0022	NCQA
TBD	Preventive Care: Cholesterol-LDL test performed	N/A	CMS
TBD	Preventive Care and Screening: Blood Pressure Measurement	N/A	**CMS**

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(4) 2012 Physician Quality Reporting System Measures Groups

We proposed (76 FR 42873) to retain the following 14 2011 Physician Quality Reporting System measures groups for the 2012 Physician Quality Reporting System: (1) Diabetes Mellitus; (2) Adult Kidney Disease (formerly CKD); (3) Preventive Care; (4) CABG; (5) Rheumatoid Arthritis; (6) Perioperative Care; (7) Back Pain; (8) CAD; (9) Heart Failure; (10) IVD; (11) Hepatitis C; (12) HIV/AIDS; (13) CAP, and (14) Asthma. For 2012, we proposed that the CABG, CAD, Heart Failure, and HIV/AIDS measures groups would continue to be reportable through the registry-based reporting mechanism only, while the remaining Diabetes Mellitus, CKD, Preventive Care, Rheumatoid Arthritis, Perioperative Care, Back Pain, IVD, Hepatitis C, CAP, and Asthma measures groups would continue to be reportable through either claims-based reporting or registry-based reporting. We proposed to retain these measures groups for the 2012 Physician Quality Reporting System particularly because we believe the measures groups reflect the services furnished to beneficiaries by a particular specialty. We also believe that retaining these measures groups would provide consistency from program year to program year.

In addition to the 14 measures groups previously discussed, we proposed (76 FR 42873 through 42879) the following 10 new measures groups for 2012 to provide eligible professionals with more measures groups on which to report:

- Chronic Obstructive Pulmonary Disease (COPD).
- Inflammatory Bowel Disease.
- Sleep Apnea.
- Epilepsy.
- Dementia.
- Parkinson's.
- Elevated Blood Pressure.
- Radiology.
- Cardiovascular Prevention, which contains individual measures from the Physician Quality Reporting System core measure set previously discussed.
- Cataracts.

These are the measures groups that were presented to us by measure owners and developers for inclusion for reporting under the 2012 Physician Quality Reporting System. Section 1848(k)(2)(C)(ii) of the Act provides an exception to the requirement that measures be endorsed by the NQF. We may exercise this exception authority in a specified area or medical topic for which a feasible and practical measure has not been endorsed by NQF, so long as due consideration is given to measures that have been endorsed by the NQF. For the measures contained within these measures groups that are not currently NQF-endorsed, we proposed to exercise this authority due to our interest in all of the proposed 10 measures group's topics. We believe that each of these additional measures groups address gaps in the Physician Quality Reporting System measures groups and will also allow for greater reporting options for individual eligible professionals, thereby increasing participation in the Physician Quality Reporting System.

Finally, as in previous program years, for 2012, we proposed (76 FR 42873) that the measures included in any proposed 2012 measures group be reportable either as individual measures or as part of a measures group, except for the Back Pain measures group, which would continue to be reportable only as part of a measures group and not as individual measures in 2012.

As with measures group reporting in prior program years, we proposed that each eligible professional electing to report a group of measures for 2012 must report all measures in the group that are applicable to each patient or encounter to which the measures group applies at least up to the minimum number of patients required by the applicable reporting criteria.

We invited public comment on our proposed retention of all 2011 Physician Quality Reporting System measures groups, as well as our newly proposed measures groups for the 2012 Physician Quality Reporting System. The following is a summary of the comments received that were related to the proposed 2012 Physician Quality Reporting System measures groups.

Comment: Some commenters supported our proposal to continue the measures group method of reporting.

Response: We believe that reporting measures in this manner will allow us to collect information on patient experience and care that related to a particular disease.

Comment: Some commenters supported the following measures groups for inclusion as a 2012 Physician Quality Reporting System measures group because they address important medical topics: Coronary Artery Disease; Heart Failure; Sleep Apnea; Hepatitis C; Elevated Blood Pressure; Epilepsy; Hypertension; Cardiovascular Prevention; Cataracts; Parkinson's; Diabetes; Dementia; and Radiology.

Response: We appreciate the commenters' feedback and are finalizing all of the proposed measures groups for the 2012 Physician Quality Reporting System, except for the Epilepsy measures group and Radiology measures group. With respect to the Epilepsy measures group, 2 of the proposed 5 measures under this measures group did not receive NQF-endorsement. Since these measures have undergone review by the NQF but did not receive endorsement, we are not finalizing these measures for the 2012 Physician Quality Reporting System. Because a measures group must contain at least 4 measures, we are not finalizing the Epilepsy measures group. However, we are retaining the remaining 3 measures in the proposed Epilepsy measures group for reporting as individual measures via the claims and/or registry-based reporting mechanisms. With respect to the Radiology measures group, the measure owner withdrew the measure group for consideration as a 2012

Physician Quality Reporting System measures group.

Furthermore, we note that, although we are finalizing the Parkinson's measures group, we are not finalizing the following measure contained within this measures group because the measure was reviewed by NQF but not endorsed: Parkinson's Disease Medical and Surgical Treatment Options.

Although we are finalizing the Elevated Blood Pressure measures group, we are not finalizing the following measures contained within this measures group because, because these measures differ from other Physician Quality Reporting System measures in that they are survey-based; therefore, it is not operationally feasible for us to analyze data collected under these measures:

- Overall Hypertension Care Satisfaction
- Patient Self-care Support

Comment: Some commenters made specific suggestions to the proposed 2012 Radiology measures group, such as renaming the Radiology measures group, reducing the number of measures contained within the Radiology measures group, reconsidering the measures contained with the Radiology measures group so that the measures contained in this measures group have similar denominators, and splitting the Radiology measures group into two Radiology measures groups.

Response: We appreciate the commenters' feedback. However, as we noted previously, we are not finalizing the Radiology measures group for 2012, because the Radiology measures group was withdrawn by the measure owner for consideration as a 2012 Physician Quality Reporting System measures group.

Comment: One commenter suggested that the Pulmonary Rehabilitation measures group that was submitted for possible inclusion as a 2012 Physician Quality Reporting System measures group be included as a 2012 Physician Quality Reporting System measures group.

Response: We reviewed all measures groups that were submitted for possible inclusion as a 2012 Physician Quality Reporting System measures group, including the Pulmonary Rehabilitation measures group. Upon review of the measures and feedback received from the NQF, 2 of the 5 proposed measures contained within the Pulmonary Rehabilitation measures group did not pass review, thereby leaving only 3 measures available for reporting under the Pulmonary Rehabilitation measures group. Since a Physician Quality Reporting System measures group must consist of at least 4 measures, the Pulmonary Rehabilitation measures group no longer contained enough measures to be classified as a Physician Quality Reporting System measures group. However, we are interested in including a pulmonary rehabilitation measures group and encourage professional organizations and measure developers to submit such a measures group for inclusion as a Physician Quality Reporting System in future program years.

Comment: One commenter suggested that the measure titled ''Counseling for Women'' be included in the Epilepsy measures group.

Response: We appreciate the commenter's feedback. However, as we stated previously, we are not finalizing the Epilepsy measures group inclusion under the 2012 Physician Quality Reporting System.

Comment: Several commenters urged us to have all measures contained within these measures groups also available for reporting as individual measures. Some commenters requested that all measures contained within specific measures groups, such as Radiology and IBD, be reportable as individual Physician Quality Reporting System measures.

Response: We proposed (76 FR 42873) that measures included in the Back Pain measures group will not be available for reporting as individual measures. Although we proposed that measures contained within the proposed 2012 Physician Quality Reporting System measures groups also be available for individual reporting, except for the COPD measures group (which contains 2011 Physician Quality Reporting System measures that were previously available for reporting as individual measures), we are not allowing any measures contained in either the back pain measures group or any of the newly finalized 2012 Physician Quality Reporting System measures groups to be reportable as individual measures, unless a measure contained in a measures group has been identified as a 2012 Physician Quality Reporting System individual measure in Table 47. Some of the measures contained in the finalized measures groups do not lend themselves to reporting as individual measures. Therefore, for 2012, only measures contained in the following measures groups will be available for reporting as individual measures: Diabetes Mellitus; Adult Kidney Disease; Preventive Care; CABG; Rheumatoid Arthritis; Perioperative Care; CAD; Heart Failure; IVD; Hepatitis C; HIV/AIDS; CAP, Asthma; Cardiovascular Prevention; and COPD.

Comment: Some commenters suggested that all measures groups be reported via claims and registry, such as the Dementia measures group. One commenter suggested that the Parkinson's and Dementia measures groups be reportable via claims as well as registry, since there are currently no registries which report on these measures groups, at least until registries for these conditions become available.

Response: Reporting methods are chosen based on the most effective way to accurately collect data needed to calculate the measure. Due to the limitations of claims-based reporting, some measures are reportable only through a registry. Due to the way the measures within these measures groups are analyzed, the Dementia and Parkinson's measures groups fall within this category of measures groups that cannot be reported via claims. With respect to the Parkinson's and Dementia measures groups, although no registries are currently qualified to report on these measures groups, we anticipate that qualified registries will be available to report on these measures for the 2012 Physician Quality Reporting System. Therefore, the Dementia and Parkinson's measures groups may only be reportable via registry.

Comment: Some commenters suggested that we ensure that there is an analytically sound method to grouping measures within measures groups, particularly when measure denominators differ.

Response: We appreciate the commenters' feedback and agree that ensuring accurate reporting analysis is essential. As in prior years, the reporting rate calculations for the 2012 Physician Quality Reporting System will only include instances that qualify for the denominator of the respective measure. When denominators differ for measures within a measures group, eligible professionals will not be held accountable for reporting on measures that are not applicable for purposes of the requiring that eligible professionals report on measures with a performance rate other than zero. However, eligible professionals are still required to report on these measures. The performance rate calculation only includes denominator eligible and successfully reported instances, so the requirement to have each measure within the group have a performance rate above zero percent will not be adversely affected by instances that are not denominator eligible.

Comment: One commenter suggested that we remove the following measure from the Radiology measures group: Cumulative Count of Potential High

Dose Radiation Imaging Studies: CT Scans and Cardiac Nuclear Medicine Scans. The commenter believes that removing this measure will allow for the measure denominators of the measures contained within the Radiology measures group to consistent with the use of CT scans alone.

Response: We appreciate the commenter's feedback and interest in aligning the measure denominators contained within the Radiology measures group. However, because the measure owner has withdrawn this measures group for consideration for reporting under the 2012 Physician Quality Reporting System, we are not finalizing the proposed Radiology measures group.

Comment: Several commenters suggested that we include or develop other measures groups that were not proposed as a 2012 Physician Quality Reporting System measures group, such as: Oncology, Stroke, Cardiac Imaging, Colorectal Cancer, Thyroid Disease, Pain Management, Physical Therapy, Colorectal Cancer Screening, and Cancer Care.

Response: We appreciate the commenter's feedback. However, because we did not propose these measures groups for inclusion in the 2012 Physician Quality Reporting System and there was not opportunity for the public to comment on these measures, we are not finalizing any of these suggestions. However, we will take these measures group's suggestions into consideration for future program years.

Based on the comments received and for the reasons stated in our responses, we are finalizing the measures groups that are identified in Tables 50 through 71. As we explained previously, we are finalizing all proposed 2012 Physician Quality Reporting System measures groups, except for the Epilepsy and Radiology measures groups.

We also note that, although we are finalizing these measures groups, we have made the following changes to these final 2012 Physician Quality Reporting System measures groups:

- Adult Kidney Disease measures group: As indicated in Table 50, we are not finalizing Physician Quality Reporting System #153 titled ''Chronic Kidney Disease (CKD): Referral for Arteriovenous (AV) Fistula'' for reporting in this measures group because, as we stated previously, the measure owner has removed this measure for reporting in 2012. Instead, we are adding Physician Quality Reporting System measure #110 titled ''Preventive Care and Screening: Influenza Immunization'' for reporting within the Adult Kidney Disease measures group.
- IVD measures group: As indicated in Table 58, we are not finalizing Physician Quality Reporting System measures #202 titled ''Ischemic Vascular Disease (IVD): Complete Lipid Profile'' and #203 titled ''Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL–C)'' for reporting in the IVD measures group. As stated previously, these two measures have been combined into a single measure titled ''Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100.'' Therefore, instead of reporting measures #202 and #203, we are requiring that eligible professionals report on this new measure in the IVD measures group.
- IBD Measures Group: As indicated in Table 64, we are updating measure title ''Inflammatory Bowel Disease (IBD): Assessment of Inflammatory Bowel Disease Activity and Severity'' to ''Inflammatory Bowel Disease: Type Anatomic Location and Activity All Documented'' as the measure owner has updated the title of this measure.
- Parkinson's Measures Group: As indicated in Table 67, we are not finalizing the measure titled ''Parkinson's Disease Related Safety Issues Counseling'' for reporting within the Parkinson's measures group.
- Elevated Blood Pressure: As indicated in Table 68, we are not finalizing the measures titled ''Overall Hypertension Care Satisfaction'' and ''Patient Self-care Support'' for reporting within this measures group.

Some measures in the 2012 measures groups are also 2011 individual Physician Quality Reporting System measures. Specifically, measures contained in the following measures groups will be available for reporting as individual measures: Diabetes Mellitus; Adult Kidney Disease; Preventive Care; CABG; Rheumatoid Arthritis; Perioperative Care; CAD; Heart Failure; IVD; Hepatitis C; HIV/AIDS; CAP, and Asthma.

The title of each such measure is preceded with its Physician Quality Reporting System Measure Number in Tables 50 through 71. As stated previously, the Physician Quality Reporting System Measure Number is a unique identifier assigned by us to all measures in the Physician Quality Reporting System measure set. Once a Physician Quality Reporting System Measure Number is assigned to a measure, it will not be used again, even if the measure is subsequently retired from the Physician Quality Reporting System measure set. Measures that are not preceded by a number (in other words, those preceded by ''TBD'') in Tables 50 through 71 were never part of a Physician Quality Reporting System measure set prior to 2012. A number will be assigned to such measures for 2012. Furthermore, please note that, in some instances, the measure titles have been updated to reflect measure title updates by the respective measure owners.

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TABLE 49: MEASURES INCLUDED IN THE 2012 DIABETES MELLITUS MEASURES GROUP**

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus	0059	NCQA
2	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus	0064	NCQA
3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus	0061	NCQA
117	Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient	0055	NCQA
119	Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients	0062	NCQA
163	Diabetes Mellitus: Foot Exam	0056	NCQA

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 50: MEASURES INCLUDED IN THE 2012 ADULT KIDNEY DISEASE MEASURES GROUP**

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
121	Adult Kidney Disease: Laboratory Testing (Lipid Profile)	Not applicable	AMA-PCPI
122	Adult Kidney Disease: Blood Pressure Management	AQA adopted	AMA-PCPI
123	Adult Kidney Disease: Patients on Erythropoiesis-Stimulating Agent (ESA) Hemoglobin Level > 12.0 g/dL	AQA adopted	AMA-PCPI
110	Preventive Care and Screening: Influenza Immunization	0041	AMA-PCPI

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 51: MEASURES INCLUDED IN THE 2012 PREVENTIVE CARE MEASURES GROUP**

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
39	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older	0046	AMA-PCPI/ NCQA
48	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	0098	AMA-PCPI/ NCQA
110	Preventive Care and Screening: Influenza Immunization	0041	AMA-PCPI
111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older	0043	NCQA
112	Preventive Care and Screening: Screening Mammography	0031	NCQA
113	Preventive Care and Screening: Colorectal Cancer Screening	0034	NCQA
128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up	0421	CMS/QIP
173	Preventive Care and Screening: Unhealthy Alcohol Use – Screening	AQA adopted	AMA-PCPI
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention	0028	AMA-PCPI

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 52: MEASURES INCLUDED IN THE 2012 CABG MEASURES GROUP* **

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
43	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery	0516	STS
44	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery	0235	STS
164	Coronary Artery Bypass Graft (CABG): Prolonged Intubation (Ventilation)	0129	STS
165	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate	0130	STS
166	Coronary Artery Bypass Graft (CABG): Stroke/Cerebrovascular Accident (CVA)	0131	STS
167	Coronary Artery Bypass Graft (CABG): Postoperative Renal Insufficiency	0114	STS
168	Coronary Artery Bypass Graft (CABG): Surgical Re-exploration	0115	STS
169	Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge	0237	STS
170	Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge	0238	STS
171	Coronary Artery Bypass Graft (CABG): Lipid Management and Counseling	0118	STS

* This measures group is reportable through registry-based reporting only.

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 53: MEASURES INCLUDED IN THE 2012 RHEUMATOID ARTHRITIS MEASURES GROUP**

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
108	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy	0054	AMA-PCPI/ NCQA
176	Rheumatoid Arthritis (RA): Tuberculosis Screening	AQA adopted	AMA-PCPI /NCQA
177	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity	AQA adopted	AMA-PCPI /NCQA
178	Rheumatoid Arthritis (RA): Functional Status Assessment	AQA adopted	AMA-PCPI /NCQA
179	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis	AQA adopted	AMA-PCPI /NCQA
180	Rheumatoid Arthritis (RA): Glucocorticoid Management	AQA adopted	AMA-PCPI /NCQA

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 54: MEASURES INCLUDED IN THE 2012 PERIOPERATIVE CARE MEASURES GROUP**

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
20	Perioperative Care: Timing of Antibiotic Prophylaxis – Ordering Physician	0270	AMA-PCPI/NCQA
21	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin	0268	AMA-PCPI/NCQA
22	Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures)	0271	AMA-PCPI/NCQA
23	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients)	0239	AMA-PCPI/NCQA

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 55: MEASURES INCLUDED IN THE 2012 BACK PAIN MEASURES GROUP

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
148	Back Pain: Initial Visit	0322	NCQA
149	Back Pain: Physical Exam	0319	NCQA
150	Back Pain: Advice for Normal Activities	0315	NCQA
151	Back Pain: Advice Against Bed Rest	0313	NCQA

TABLE 56: MEASURES INCLUDED IN THE 2012 CAD MEASURES GROUP*

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD	0067	AMA-PCPI/AHA
196	Coronary Artery Disease (CAD): Symptom and Activity Assessment	0065	AMA-PCPI
197	Coronary Artery Disease (CAD): Lipid Control	0074	AMA-PCPI
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention	0028	AMA-PCPI

* This measures group is reportable through registry-based reporting only.

TABLE 57: MEASURES INCLUDED IN THE 2012 HEART FAILURE MEASURES GROUP* **

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
5	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0081	AMA-PCPI/ACC
8	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0083	AMA-PCPI/ACC
198	Heart Failure: Left Ventricular Function (LVF) Assessment	0079	AMA-PCPI/ACC
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	0028	AMA-PCPI

* This measures group is reportable through registry-based reporting only.

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 58: MEASURES INCLUDED IN THE 2012 IVD MEASURES GROUP**

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
201	Ischemic Vascular Disease (IVD): Blood Pressure Management Control	0073	NCQA
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100*	0075	NCQA
204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic	0068	NCQA
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention	0028	AMA-PCPI

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 59: MEASURES INCLUDED IN THE 2012 HEPATITIS C MEASURES GROUP**

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
84	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment	0395	AMA-PCPI
85	Hepatitis C: HCV Genotype Testing Prior to Treatment	0396	AMA-PCPI
86	Hepatitis C: Antiviral Treatment Prescribed	0397	AMA-PCPI
87	Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment	0398	AMA-PCPI
89	Hepatitis C: Counseling Regarding Risk of Alcohol Consumption	0401	AMA-PCPI
90	Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy	0394	AMA-PCPI
183	Hepatitis C: Hepatitis A Vaccination in Patients with HCV	0399	AMA-PCPI
184	Hepatitis C: Hepatitis B Vaccination in Patients with HCV	0400	AMA-PCPI

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 60: MEASURES INCLUDED IN THE 2012 HIV/AIDS MEASURES GROUP* **

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
159	HIV/AIDS: CD4+ Cell Count or CD4+ percentage	0404	AMA-PCPI/NCQA
160	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis	0405	AMA-PCPI/NCQA
161	HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy	0406	AMA-PCPI/NCQA
162	HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy	0407	AMA-PCPI/NCQA
205	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea	0409	AMA-PCPI/NCQA
206	HIV/AIDS: Screening for High Risk Sexual Behaviors	0413	AMA-PCPI/NCQA
207	HIV/AIDS: Screening for Injection Drug Use	0415	AMA-PCPI/NCQA
208	HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis	0410	AMA-PCPI/NCQA

* This measures group is selected to be reportable through registry-based reporting only.

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 61: MEASURES INCLUDED IN THE 2012 CAP MEASURES GROUP**

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
56	Community-Acquired Pneumonia (CAP): Vital Signs	0232	AMA-PCPI/NCQA
57	Community-Acquired Pneumonia (CAP): Assessment of Oxygen Saturation	0094	AMA-PCPI/NCQA
58	Community-Acquired Pneumonia (CAP): Assessment of Mental Status	0234	AMA-PCPI/NCQA
59	Community-Acquired Pneumonia (CAP): Empiric Antibiotic	0096	AMA-PCPI/NCQA

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 62: MEASURES INCLUDED IN THE 2012 ASTHMA MEASURES GROUP**

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
53	Asthma: Pharmacologic Therapy for Persistent Asthma	0047	AMA-PCPI
64	Asthma: Asthma Assessment	0001	AMA-PCPI
231	Asthma: Tobacco Use: Screening – Ambulatory Setting	N/A	AMA-PCPI/ NCQA
232	Asthma: Tobacco Use: Intervention – Ambulatory Screening	N/A	AMA-PCPI/ NCQA

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 63: MEASURES INCLUDED IN THE 2012 COPD MEASURES GROUP**

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
110	Preventive Care and Screening: Influenza Immunization	0041	AMA-PCPI
111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older	0043	AMA-PCPI
51	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation	0091	AMA-PCPI
52	Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy	0102	AMA-PCPI
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention	0028	AMA-PCPI

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 64: MEASURES INCLUDED IN THE 2012 IBD MEASURES GROUP*

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
TBD	Inflammatory Bowel Disease: Type, Anatomic Location and Activity All Documented	N/A	AGA/AMA-PCPI
TBD	Inflammatory Bowel Disease (IBD): Preventive Care: Steroid Sparing Therapy	N/A	AGA/AMA-PCPI
TBD	Inflammatory Bowel Disease (IBD): Preventive Care: Steroid Related Iatrogenic Injury – Bone Loss Assessment	N/A	AGA/AMA-PCPI
TBD	Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization	N/A	AGA/AMA-PCPI
TBD	Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization	N/A	AGA/AMA-PCPI
TBD	Inflammatory Bowel Disease (IBD): Screening for Latent TB Before Initiating Anti-TNF Therapy	N/A	AGA/AMA-PCPI
TBD	Inflammatory Bowel Disease (IBD): Hepatitis B Assessment Before Initiating Anti-TNF Therapy	N/A	AGA/AMA-PCPI
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention	0028	AMA-PCPI

* This measures group is reportable through registry-based reporting only.

TABLE 65: MEASURES INCLUDED IN THE 2012 SLEEP APNEA MEASURES GROUP*

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
TBD	Assessment of Sleep Symptoms	N/A	AMA/PCPI/AASM
TBD	Severity Assessment at Initial Diagnosis	N/A	AMA/PCPI/AASM
TBD	Positive Airway Pressure Therapy Prescribed	N/A	AMA/PCPI/AASM
TBD	Assessment of Adherence to Positive Airway Pressure Therapy	N/A	AMA/PCPI/AASM

* This measures group is reportable through registry-based reporting only.

TABLE 66: MEASURES INCLUDED IN THE 2012 DEMENTIA MEASURES GROUP*

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
TBD	Dementia: Staging of Dementia	N/A	AAN/AGS/AMDA/APA/ AMA-PCPI
TBD	Dementia: Cognitive Assessment	N/A	AAN/AGS/AMDA/APA/ AMA-PCPI
TBD	Dementia: Functional Status Assessment	N/A	AAN/AGS/AMDA/APA/ AMA-PCPI
TBD	Dementia: Neuropsychiatric Symptom Assessment	N/A	AAN/AGS/AMDA/APA/ AMA-PCPI
TBD	Dementia: Management of Neuropsychiatric Symptoms	N/A	AAN/AGS/AMDA/APA/ AMA-PCPI
TBD	Dementia: Screening for Depressive Symptoms	N/A	AAN/AGS/AMDA/APA/ AMA-PCPI
TBD	Dementia: Counseling Regarding Safety Concerns	N/A	AAN/AGS/AMDA/APA/ AMA-PCPI
TBD	Dementia: Counseling Regarding Risks of Driving	N/A	AAN/AGS/AMDA/APA/ AMA-PCPI
TBD	Dementia: Caregiver Education and Support	N/A	AAN/AGS/AMDA/APA/ AMA-PCPI

* This measures group is reportable through registry-based reporting only.

TABLE 67: MEASURES INCLUDED IN THE 2012 PARKINSON'S MEASURES GROUP*

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
TBD	Annual Parkinson's Disease Diagnosis Review	N/A	AAN
TBD	Psychiatric Disorders or Disturbances Assessment	N/A	AAN
TBD	Cognitive Impairment or Dysfunction Assessment	N/A	AAN
TBD	Querying about Sleep Disturbances	N/A	AAN
TBD	Parkinson's Disease Rehabilitative Therapy Options	N/A	AAN
TBD	Parkinson's Disease Medical and Surgical Treatment Options Reviewed	N/A	AAN

* This measures group is reportable through registry-based reporting only.

TABLE 68: MEASURES INCLUDED IN THE 2012 ELEVATED BLOOD PRESSURE MEASURES GROUP*

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
TBD	Aspirin or Other Anti-Platelet or Anti-Coagulant Therapy	N/A	ABIM
TBD	Complete Lipid Profile	N/A	ABIM
TBD	Urine Protein Test	N/A	ABIM
TBD	Annual Serum Creatinine Test	N/A	ABIM
TBD	Diabetes Documentation or Screen Test	N/A	ABIM
TBD	Counseling for Diet and Physical Activity	N/A	ABIM
TBD	Blood Pressure Control	N/A	ABIM
TBD	LDL Control	N/A	ABIM

* This measures group is reportable through registry-based reporting only.

TABLE 69: MEASURES INCLUDED IN THE 2012 CARDIOVASCULAR PREVENTION MEASURES GROUP**

Physician Quality Reporting System	Measure Title	NQF Measure Number	Measure Developer
204	Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic	0068	NCQA
236	Controlling High Blood Pressure	0018	NCQA
2	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus	0064	NCQA
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention	0028	AMA-PCPI
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100	0075	NCQA
TBD	Preventive Care and Screening: Blood Pressure Measurement	N/A	CMS

** The measures contained within this measures group are also available for reporting as individual measures.

TABLE 70: MEASURES INCLUDED IN THE 2012 CATARACTS MEASURES GROUP*

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
TBD	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	N/A	AAO
TBD	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	N/A	AAO
191	Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery	0565	AMA-PCPI/ NCQA
192	Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures	0564	AMA-PCPI/ NCQA

* This measures group is reportable through registry-based reporting only.

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As with measures group reporting in prior years of the Physician Quality Reporting System, each eligible professional electing to report a group of measures for 2012 must report all measures in the group that are applicable to each patient or encounter to which the measures group applies at least up to the minimum number of patients required by the applicable reporting criteria. We note that the specifications for measures groups do not necessarily contain all the specification elements of each individual measure making up the measures group. This is based on the need for a common set of denominator specifications for all the measures making up a measures group in order to define the applicability of the measures group. Therefore, the specifications and instructions for measures groups will be provided separately from the specifications and instructions for the individual 2012 Physician Quality Reporting System measures. We will post the detailed specifications and specific instructions for reporting measures groups on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.hhs.gov/PQRS* by no later than December 31, 2011.

Additionally, the detailed measure specifications and instructions for submitting data on these 2012 measures groups that were also included as 2011 Physician Quality Reporting System measures groups may be updated or modified by the measure developer prior to 2012. Therefore, the 2012 Physician Quality Reporting System measure specifications for any given measures group could be different from specifications and submission instructions for the same measures group used for 2011. For example, the measure developer may change the codes contained in the measure's denominator. These measure specification changes do not materially impact the intended meaning of the measures or the strength of the measures.

(5) 2012 Physician Quality Reporting System Quality Measures for Group Practices Selected To Participate in the GPRO (GPRO)

For 2012, we proposed (76 FR 42879) that group practices selected to participate in the 2012 Physician Quality Reporting System GPRO would be required to report on 41 proposed measures listed in Table 55 of the proposed rule. Specifically, for the 2012 Physician Quality Reporting System, we proposed to retain most of the measures available for reporting under the 2011 Physician Quality Reporting System GPRO because of our continued interest in the reporting of those measures, as well as to maintain program consistency from year to year. However, for 2012, we proposed to retire the following measures that were required under the 2010 and 2011 GPRO (that is, GPRO I for 2011):

- Diabetes Mellitus: Hemoglobin A1c Testing.
- Diabetes Mellitus: Lipid Profile
- Hypertension (HTN): Blood Pressure Measurement.

Furthermore, we proposed to add the following Physician Quality core measures that were not available for reporting via the GPRO for the 2011 Physician Quality Reporting System:

- Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic.
- Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention.
- Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100
- Proportion of adults 18 years and older who have had their blood pressure measured within the preceding 2-years.

In addition to adding the Physician Quality Reporting System core measures that were not available for reporting under the GPRO for the 2011 Physician Quality Reporting System, we proposed to add the following measures for reporting under the 2012 Physician Quality Reporting System GPRO:

- Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy.
- Adult Weight Screening and Follow-up.
- Ischemic Vascular Disease (IVD): Blood Pressure Management Control.

- Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation.
- 30 Day Post Discharge Physician Visit.
- Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility.
- Diabetes: Aspirin Use.
- Falls: Screening for Fall Risk.
- Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older.
- Diabetes Mellitus: Tobacco Non Use.
- Coronary Artery Disease (CAD): LDL-level < 100 mg/dl.
- Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus (less than 8 percent).
- Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received.
- Monthly International Normalized Ratio (INR) for Beneficiaries on Warfarin.

We proposed (76 FR 42879) these new measures because they are NQF-endorsed measures that are consistent with other CMS quality reporting initiatives. We believe it is in the stakeholders' interest to align measures in different initiatives. We proposed that group practices selected to participate in the Physician Quality Reporting System GPRO would be required to report on all measures listed in Table 55.

We invited public comment on the proposed 2012 Physician Quality Reporting System measures for group practices selected to participate in the 2012 Physician Quality Reporting System GPRO. The following is a summary of the comments we received.

Comment: Some commenters suggested we retain the following 3 measures that we proposed to retire for the 2012 Physician Quality Reporting System GPRO because they address important medical topics relevant to the commenters' respective specialties:

- Diabetes Mellitus: Hemoglobin A1c Testing;
- Diabetes Mellitus: Lipid Profile; and
- Hypertension (HTN): Blood Pressure Measurement.

Response: We appreciate the commenters' feedback. However, as stated previously, due to our desire to align these 2012 Physician Quality Reporting System GPRO measures with other CMS programs, we are retiring these measures.

Comments: Several commenters supported inclusion of the following measures as reportable measures for physician groups participating in the 2012 Physician Quality Reporting System GPRO because they either addressed important medical topics relevant to the commenters' respective specialties and/or they are measures included in other CMS programs:

- Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention.
- Ischemic Vascular Disease (IVD): Blood Pressure Management Control.
- Adult Weigh Screening and Follow-up.
- Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility.
- Diabetes: Aspirin Use.
- Diabetes Mellitus: Tobacco Non-Use.
- Coronary Artery Disease (CAD): LDL-level < 100 mg/dl.
- Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus (<8%).
- Monthly INR for Beneficiaries on Warfarin.
- Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient.
- Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI).
- Ischemic Vascular Disease (IVD): Blood Pressure Management.

Response: 'In an effort to reduce the number of measures group practices report under the GPRO we proposed so that the number of measures required for reporting are closer to 26, which is the number of measures available for reporting under the Physician Quality Reporting System GPRO I in 2011 (76 FR 73537), we are finalizing all of the measures for inclusion in the 2012 Physician Quality Reporting System GPRO measure set, except for the following measures:

- Ischemic Vascular Disease (IVD): Blood Pressure Management Control.
- Coronary Artery Disease (CAD): LDL-level < 100 mg/dl.
- Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI).

We are not retaining these measures because we seek to align the Physician Quality Reporting System GPRO with the Medicare Shared Savings Program. These measures were not included for reporting under the Medicare Shared Savings Program (''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations'' displayed in the October 20, 2011 **Federal Register** at *http://www.ofr.gov/OFRUpload/OFRData/2011-27461_PI.pdf.*

Also due to our desire to align the measures available for reporting under the 2012 Physician Quality Reporting System GPRO with the measures available for reporting under the Medicare Shared Savings Program, we are not finalizing the following measures in the 2012 Physician Quality Reporting System GPRO measure set:

- Diabetes Mellitus: Urine Screening for Microalbumin for Medical Attention for Nephropathy in Diabetic Patients.
- Heart Failure: Weight Measurement.
- Heart Failure: Patient Education.
- Hypertension (HTN): Plan of Care.
- Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation.
- Ischemic Vascular Disease (IVD): Use of Aspirin of another Antithrombotic.
- 30-Day Post Discharge Physician Visit.
- Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older.
- Coronary Artery Disease (CAD): LDL-level < 100 mg/dl.
- Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received.

We believe our effort to align various CMS programs will encourage participation in the Physician Quality Reporting System. Since increasing participation in the Physician Quality Reporting System is a top priority, we believe our desire to align various CMS programs outweighs our interest in maintaining measures that were previously available for reporting under the Physician Quality Reporting System. We further believe that the measures that we finalize for reporting under the 2012 Physician Quality Reporting System GPRO, as identified in Table 71, sufficiently address the conditions and care measured by the measures we are not finalizing.

Comment: One commenter stated that, since group practices participating in the Physician Quality Reporting System GPRO must report on all measures listed in Table 71, only NQF-endorsed measures should be included for reporting by physician groups participating in the 2012 Physician Quality Reporting System GPRO.

Response: We appreciate the commenter's feedback. We note that, unlike the criteria for satisfactory reporting for individual eligible professionals, group practices may report measures with a zero percent performance rate. Therefore, it does not harm group practices participating under the GPRO to report on the measures we are finalizing for the GPRO, regardless of whether the measures are NQF-endorsed. We also note that we have authority under section 1848(k)(2)(C)(ii) of the Act to select measures that are not NQF-

endorsed. We believe the non-NQF endorsed measures we are finalizing below address critical areas of health care.

Comment: One commenter urged us to minimize the reporting burden on group practices by reducing the number of measures on which group practices participating in the Physician Quality Reporting System may report.

Response: As stated previously, we are only finalizing 30 of the 40 measures we proposed. We hope this will notably reduce the reporting burden on group practices participating in the Physician Quality Reporting System GPRO.

Comment: One commenter was concerned that the reporting of the measure titled ''Monthly INR for Beneficiaries on Warfarin'' will have the unintended consequence of having eligible professionals avoid patients who are non-compliant with treatment recommendations.

Response: We agree that the personal preferences of beneficiaries play an important role in their health behaviors. However, the lack of patient adherence may also represent a legitimate dimension of care, as it could be indicative of poor communication between providers and their patients. As INR is important for patients on warfarin, we are retaining this measure as proposed. In addition, as discussed in the public reporting requirements in section VI.G. of this final rule with comment period, we believe publicly reporting certain measures provides greater incentive for providers to coordinate care and influence patient behavior.

Comment: One commenter opposed our proposal to retire the measure titled ''Plan of Care for Inadequate Hemodialysis'' because the retirement of this measure will only leave nephrologists with only one Physician Quality Reporting System measure on which to report.

Response: We understand the need to have adequate number of measures available under which eligible professionals practicing in many specialties report. In this instance, however, we do not believe that retiring this measure for reporting under the GPRO will affect the ability for eligible professionals to satisfactorily reporting. We note that group practices participating in the GPRO must report on all measures listed in Table 71, regardless of whether the measures are applicable to the group practice.

Comment: One commenter suggested that the measures available for reporting under the Physician Quality Reporting System GPRO include more measures that pertain to otolaryngologists.

Response: We appreciate the commenter's feedback. However, we give eligible professionals an opportunity to provide input on measures recommended for selection via the proposed rule, and therefore, additional measures and/or measure topics cannot be included for reporting under the 2012 Physician Quality Reporting System. However, we will take these GPRO measure suggestions into consideration for future program years.

Comment: Some commenters requested that the measure specifications for the proposed GPRO measures be available for review prior to its inclusion as GPRO measures.

Response: As we stated previously, we do not use notice and comment rulemaking as a means to update or modify measure specifications. Questions regarding measure specifications should be directed to the measure developers, who are all listed in Table 55 of the proposed rule (76 FR 42880). Contact information for the 2011 Physician Quality Reporting System measure developers is listed in the ''2011 Physician Quality Reporting System Quality Measures List,'' which is available on the CMS Web site at *http://www.cms.gov/PQRS/15_MeasuresCodes.asp#TopOfPage.*

Based on the comments received and for the reasons stated previously, we are finalizing the 29 measures for physician groups participating in the 2012 Physician Quality Reporting System GPRO listed in Table 71. Table 71 also indicates which measures are also available for reporting under the Medicare Shared Savings Program.

We also note that, in an effort to align the 2012 Physician Quality Reporting System GPRO measures with the measures available for group reporting under the Medicare Shared Savings Program, we are not finalizing the following measures for the 2012 Physician Quality Reporting System GPRO:

- Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI)
- Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients
- Heart Failure: Weight Measurement
- Hypertension (HTN): Plan of Care
- Ischemic Vascular Disease (IVD): Blood Pressure Management Control
- Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation
- 30–Day Post Discharge Physician Visit
- Osteoperosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older
- Coronary Artery Disease (CAD): LDL-level < 100 mg/dl
- Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received
- Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation

We are also not finalizing the measure titled ''Monthly INR for Beneficiaries on Warfarin'' because, as we stated with Physician Quality Reporting System measure #200, the use of Warfarin to treat heart disease is no longer consistent with clinical guidelines.

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TABLE 71: MEASURES FOR PHYSICIAN GROUPS PARTICIPATING IN THE 2012 PHYSICIAN QUALITY REPORTING SYSTEM GROUP PRACTICE REPORTING OPTION (GPRO)

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus(>9%)**	0059	NCQA
2	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus**	0064	NCQA
3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus**	0061	NCQA
5	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0081	AMA-PCPI
6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD	0067	AMA-PCPI
8	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)*	0083	AMA-PCPI
46	Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility*	0097	AMA-PCPI/NCQA
52	Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy	0102	AMA-PCPI
110	Preventive Care and Screening: Influenza Immunization*	0041	AMA-PCPI
111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older*	0043	NCQA
112	Preventive Care and Screening: Screening Mammography*	0031	NCQA
113	Preventive Care and Screening: Colorectal Cancer Screening*	0034	NCQA
117	Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient	0055	NCQA
118	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)*	0066	AMA-PCPI

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	Measure Developer
128	Adult Weight Screening and Follow-up*	421	CMS/QIP
163	Diabetes Mellitus: Foot Exam	0056	NCQA
197	Coronary Artery Disease (CAD): Lipid Control*	0074	AMA-PCPI
198	Heart Failure: Left Ventricular Function (LVF) Assessment	0079	AMA-PCPI
199	Heart Failure: Patient Education	0082	AMA-PCPI
204	Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic*	0068	NCQA
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention*	0028	AMA-PCPI
228	Heart Failure: Left Ventricular Function (LVF) Testing	N/A	CMS
236	Hypertension (HTN): Blood Pressure Control*	0018	NCQA
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100*	0075	NCQA
TBD	Preventive Care and Screening: Blood Pressure Measurement*	N/A	CMS
TBD	Diabetes: Aspirin Use*	0076	MN Community Measurement
TBD	Falls: Screening for Fall Risk*	0101	NCQA
TBD	Diabetes Mellitus: Tobacco Non-Use*	0729	MN Community Measurement
TBD	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus (<8%)*	0575	NCQA

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We intend to provide a separate measures specifications document and other supporting documents for group practices participating in the 2012 Physician Quality Reporting System GPRO. We anticipate that the group practice measures specifications document will be available by November 15, 2011 or shortly thereafter on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.hhs.gov/PQRS.*

g. Maintenance of Certification Program Incentive

Section 1848(k)(4) of the Act requires the Secretary to address a mechanism whereby an eligible professional may provide data on quality measures through a maintenance of certification program (Maintenance of Certification Program) operated by a specialty body of the American Board of Medical Specialties (ABMS). In addition, section 1848(m)(7) of the Act (''Additional Incentive Payment'') authorizes an additional 0.5 percent incentive payment for years 2011 through 2014 if certain requirements are met. In accordance with section 1848(m)(7)(B) of the Act governing the ''Additional Incentive Payment,'' in order to qualify for the additional incentive payment, an eligible professional must—

- Satisfactorily submit data on quality measures under the Physician Quality Reporting System for a year and have such data submitted—

++ On their behalf through a Maintenance of Certification Program that meets the criteria for a registry under the Physician Quality Reporting System; or

++ In an alternative form and manner determined appropriate by the Secretary; and

++ More frequently than is required to qualify for or maintain board certification status:

++ Participate in such a Maintenance of Certification Program for a year; and

++ Successfully completes a qualified Maintenance of Certification Program practice assessment for such year.

Section 1848(m)(7)(C)(i) of the Act defines ''Maintenance of Certification Program'' as a continuous assessment program, such as a qualified ABMS Maintenance of Certification Program, or an equivalent program (as determined by the Secretary), that advances quality and the lifelong learning and self-assessment of board certified specialty physicians by focusing on the competencies of patient care, medical knowledge, practice-based learning,

interpersonal and communications skills and professionalism. Such a program shall require a physician to do the following:

- Maintain a valid, unrestricted medical license in the United States.
- Participate in educational and self-assessment programs that require an assessment of what was learned.
- Demonstrate, through a formalized, secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.
- Successful completion of a qualified Maintenance of Certification Program practice assessment.

As defined in section 1848(m)(7)(C)(ii) of the Act, a ''qualified Maintenance of Certification Program practice assessment'' means an assessment of a physician's practice that—

- Includes an initial assessment of an eligible professional's practice that is designed to demonstrate the physician's use of evidence-based medicine;
- Includes a survey of patient experience with care; and
- Requires a physician to implement a quality improvement intervention to address a practice weakness identified in the initial assessment and then to remeasure to assess performance after such intervention.

To qualify for the additional incentive payment, section 1848(m)(7)(B)(iii) of the Act also requires the Maintenance of Certification Program to submit to CMS, on behalf of the eligible professional, information:

- In a form and manner specified by the Secretary, that the eligible professional more frequently than is required to qualify for or maintain board certification status, participates in the Maintenance of Certification Program for a year and successfully completes a qualified Maintenance of Certification Program practice assessment for such year;
- Upon request by the Secretary, information on the survey of patient experience with care; and
- As the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

In order to qualify for the additional 0.5 percent incentive payment in 2011, eligible professionals were required to participate more frequently in each of the following four parts of the Maintenance of Certification Program:

- Maintain a valid unrestricted license in the United States. For 2011, physicians simply needed to maintain a valid unrestricted license in the United States to meet the requirement for ''more frequent'' participation with respect to this part (75 FR 73541 through 73546).
- Participate in educational and self-assessment programs that require an assessment of what was learned.
- Demonstrate, through a formalized secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.
- Successfully complete a qualified maintenance of certification program practice assessment.

We received requests from the American Board of Medical Specialties, as well as various specialty organizations, to revise the criteria for satisfying the Maintenance of Certification Program additional incentive, because these entities believe that more frequent participation in all four parts of the Maintenance of Certification Program is too narrow. In the proposed rule, we noted that we further considered the language under section 1848(m)(7)(B)(ii)(I) of the Act and we believe it can be interpreted more broadly. In particular, we noted that the requirement that a professional ''more frequently than is required to qualify for or maintain board certification status participates in such a Maintenance of Certification Program'' could refer to the program as a whole, such that any element performed more frequently than is required satisfies the general requirement. The nature of the various components of the Maintenance of Certification Program also suggest that it is not necessary that each of the four elements of the program be performed more frequently. We previously stated we believe that the ''more frequently'' requirement does not apply to the first part, which states that a physician maintain a valid unrestricted license, as there is no way a physician may maintain a valid unrestricted license ''more frequently.'' As such, we believe that the more frequently requirement could be satisfied based on any of the other elements of the program (that is, educational and self-assessment program; secure examination; or practice assessment). Specifically, we believe that if a professional more frequently than is required satisfies one or more of those parts of a program, the more frequently requirement would be met. Accordingly, we proposed (76 FR 42881–42882) that in order to earn an additional 0.5 percent incentive for 2012 through 2014, for each respective year, an eligible professional must participate more frequently than is required in at least one of the following three parts of the Maintenance of Certification Program, as well as ''more frequent'' participation in the practice assessment component. With respect to how to assess whether a professional completes one of the elements of a program ''more frequently,'' we believe that this would be tied to the specific requirements of Board certification for the professional. Given that different specialties have different certification requirements (physician examination requirements to maintain Board certification varies widely depending on specialty), we do not believe it is appropriate to impose a uniform requirement for all professionals and therefore, we believe that the board could determine for a particular program element the more frequent requirement for the professional. However, we believe that a minimum threshold would need to be met such that the professional would have to do something more frequently or more than what is ordinarily required for a particular part of the program, as well as ''more frequent'' participation in the practice assessment component.

Therefore, in order to earn an additional 0.5 percent incentive for 2012 through 2014, an eligible professional would be required to participate more frequently than is required in at least one of the following three parts of the Maintenance of Certification Program, as well as ''more frequent'' successful completion of a qualified maintenance of certification program practice assessment:

- Maintain a valid unrestricted license in the United States. For 2011, physicians simply needed to maintain a valid unrestricted license in the United States to meet the requirement for ''more frequent'' participation with respect to this part (75 FR 73541 through 73546).
- Participate in educational and self-assessment programs that require an assessment of what was learned.
- Demonstrate, through a formalized secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.

Therefore, we proposed for 2012, 2013, and 2014 the following for each year (76 FR 42882 and 42883):

- An eligible professional wishing to be eligible for the additional Physician Quality Reporting System incentive payment of 0.5 percent must meet the requirements for satisfactory reporting for the Physician Quality Reporting

System, for the applicable program year (that is, to qualify for the additional 0.5 percent incentive payment for 2012, meet the 2012 requirements for satisfactory reporting), based on the 12-month reporting period (January 1 through December 31 of the respective program year).

• For purposes of satisfactory reporting under the Physician Quality Reporting System, we proposed (76 FR 42882) that the eligible professional may participate as an individual eligible professional using either individual Physician Quality Reporting System measures or measures groups and submitting the Physician Quality Reporting System data via claims, a registry, or an EHR or participate under the GPRO option. As an alternative to this reporting option, we proposed that eligible professionals may satisfactorily report under the Physician Quality Reporting System based on submission of Physician Quality Reporting System data by a Maintenance of Certification Program, provided that the Maintenance of Certification Program has qualified as a Physician Quality Reporting System registry for 2012. As indicated previously, an eligible professional would not necessarily have to qualify for the Physician Quality Reporting System through a Maintenance of Certification Program serving as a registry. Rather, we proposed that an eligible professional may qualify for the additional incentive, without regard to the method by which the eligible professional has met the basic requirement of satisfactory reporting under the Physician Quality Reporting System. We received no comments regarding our proposal to allow eligible professionals to qualify for the additional incentive without regard to the method by which the eligible professional has met the basic requirement of satisfactory reporting under the Physician Quality Reporting System and are therefore, we are finalizing this proposal.

• In addition to meeting the requirements for satisfactory reporting for the Physician Quality Reporting System for a program year, the eligible professional must have data with respect to the eligible professional's participation in a Maintenance of Certification Program submitted on his or her behalf by a qualified medical specialty board or other entity sponsoring a Maintenance of Certification Program. For each eligible professional that wishes to qualify for the Maintenance of Certification Program Incentive, the qualified medical specialty board or other entity sponsoring a Maintenance of Certification Program must submit data to CMS with respect to the following:

• An eligible professional must, more frequently than is required to qualify for or maintain board certification, participate in a Maintenance of Certification Program for a year and successfully complete a qualified Maintenance of Certification Program practice assessment for such year. With regard to the ''more frequently'' requirement as it applies to the elements of a Maintenance of Certification Program itself (other than completing a qualified Maintenance of Certification Program practice assessment), the Maintenance of Certification Program must certify that the eligible professional has ''more frequently'' than is required to qualify for or maintain board certification ''participated in a Maintenance of Certification Program for a year''. The Maintenance of Certification Program will determine what a physician must do to more frequently participate in a Maintenance of Certification Program and so certify that the eligible professional has met this requirement. While we do not believe that the ''more frequently'' requirement is applicable to the licensure requirement, given that one cannot be licensed ''more frequently'' than is required, the Maintenance of Certification Program has the discretion to determine which element(s) of a Maintenance of Certification Program must be completed more frequently. We believe that making this change will reduce burden on physicians and will increase participation while being consistent with the requirement to ''more frequently'' participate in a Maintenance of Certification Program.

• With respect to the Maintenance of Certification Program practice assessment, which is specifically delineated in section 1848(m)(7)(B)(ii) of the Act as being required more often than is necessary to qualify for or maintain board certification, we believe we need to be more specific regarding our interpretation of the phrase ''more frequently.'' Additionally, we are aware that some specialty boards have varying Maintenance of Certification Program requirements for physicians to maintain board certification, based on the date of original certification. Some, we believe, may not be required to participate in a Maintenance of Certification Program at all in order to maintain board certification. Accordingly, we recognize that ''more often'' may vary among physicians certified by the same specialty board. We interpret the statutory provisions as requiring participation in and successful completion of at least one Maintenance of Certification Program practice assessment per year. Therefore, as a basic requirement, the physician must participate and successfully complete at least one Maintenance of Certification Program practice assessment for each year the physician participates in the Maintenance of Certification Program Incentive, regardless of whether or how often the physician is required to participate in a Maintenance of Certification Program to maintain board certification.

We are also aware that ABMS boards are at various stages in implementing the practice assessment modules, and some may not have such assessment modules in place. However, inasmuch as we interpret the statute to require a Maintenance of Certification Program practice assessment at least once per program year as part of the Maintenance of Certification Program, eligible professionals who do not have available, through their boards or otherwise, a Maintenance of Certification Program practice assessment are not eligible for the 0.5 percent incentive.

We believe that the experience of care survey provides particularly valuable information and proposed that a qualified Maintenance of Certification Program practice assessment must include a survey of patient experience with care. The Secretary may request information on the survey of patient experience with care, under section 1848(m)(7)(B)(iii) of the Act. In view of the importance of this information, and the lack of readily available alternative sources, we proposed to require that Maintenance of Certification Programs submit information about the patient experience of care survey(s) used by physicians to fulfill the Maintenance of Certification Program practice assessment. We are not, at this time, requesting the results of the survey for the eligible professionals for whom information is being submitted by the Maintenance of Certification Program. We may, however, request such information for appropriate validation purposes and may propose to request such data for future years of the Maintenance of Certification Program Incentive.

Some Maintenance of Certification Programs underwent a self-nomination process in 2011 to enable their members to be eligible for this Physician Quality Reporting System Maintenance of Certification Program Incentive for 2011 Physician Quality Reporting System. We proposed (76 FR 42883) that a Maintenance of Certification Program that was approved after undergoing the self-nomination process in 2011 must submit a self-nomination statement for

each year the Maintenance of Certification Program intends to participate in the Physician Quality Reporting System Maintenance of Certification Program. In the self-nomination statement, we proposed that the previously approved program must provide us with updates to its program in its self-nomination statement. We proposed that this self-nomination statement be submitted to CMS via a web-based tool. We received no comments regarding the self-nomination process for those Maintenance of Certification Programs that underwent a self-nomination process in 2011. Therefore, we are finalizing the proposed requirements.

For Maintenance of Certification Programs new for 2012, we proposed (76 FR 42883) that Maintenance of Certification Programs wishing to enable their diplomates to be eligible for an additional Physician Quality Reporting System incentive payment for the 2012 Physician Quality Reporting System would need to go through a self-nomination process by January 31, 2012. We proposed that the board must include all of the following information in their self-nomination statement to us:

- Provide detailed information regarding the Maintenance of Certification Program with reference to the statutory requirements for such program;
- Indicate the organization sponsoring the Maintenance of Certification Program, and whether the Maintenance of Certification Program is sponsored by an ABMS board. If not an ABMS board, indicate whether and how the program is substantially equivalent to the ABMS Maintenance of Certification Program process;
- Indicate that the program is in existence as of January 1, 2012;
- Indicate that the program has at least 1 active participant;
- The frequency of a cycle of Maintenance of Certification Program for the specific Maintenance of Certification Program of the sponsoring organization; including what constitutes ''more frequently'' for the Maintenance of Certification Program itself and for the practice assessment for the specific Maintenance of Certification Program of the sponsoring organization;
- Confirmation from the board that the practice assessment will occur and be completed in the year the physician is participating in the Maintenance of Certification Program Incentive;
- What was, is, or will be the first year of availability of the Maintenance of Certification Program practice assessment for completion by an eligible professional;
- What data is collected under the patient experience of care survey and how this information would be provided to CMS;
- Describe how the Maintenance of Certification Program monitors that an eligible professional has implemented a quality improvement process for their practice; and
- Describe the methods, and data used under the Maintenance of Certification Program, and provide a list of all measures used in the Maintenance of Certification Program for 2011 and to be used for 2012, including the title and descriptions of each measure, the owner of the measure, whether the measure is NQF endorsed, and a link to a Web site containing the detailed specifications of the measures, or an electronic file containing the detailed specifications of the measures.

We proposed (76 FR 42883) that sponsoring organizations who desire to participate as a Maintenance of Certification Program must provide CMS the following information below in a CMS-specified file format by no later than the end of the first quarter of 2012:.

- The name, NPI and applicable TIN(s) of the eligible professional who would like to participate in this process;
- Attestation from the board that the information provided to CMS is accurate and complete.
- The board has signed documentation from the eligible professional that the eligible professional wishes to have the information released to us;
- Information from the patient experience of care survey;
- Information certifying that the eligible professional has participated in a Maintenance of Certification Program for a year, more frequently than is required to qualify for or maintain board certification status, including the year that the physician met the board certification requirements for the Maintenance of Certification Program, and the year the eligible professional participated in a Maintenance of Certification Program ''more frequently'' than is required to maintain or qualify for board certification; and
- Information certifying that the eligible professional has completed the Maintenance of Certification Program practice assessment at least one time each year the eligible professional participates in the Maintenance of Certification Program Incentive.

We proposed (76 FR 42883) that specialty boards that also desire to send Physician Quality Reporting System information to us on behalf of eligible professionals must meet the requirements for registry data submission and should follow the directions for self-nomination to become a qualified registry. Boards may also participate as registries for Physician Quality Reporting System data provided that they meet the registry requirements. As an alternative to requiring boards to either operate a qualified Physician Quality Reporting System registry or to self-nominate to submit Maintenance of Certification Program data to us on behalf of their members, we proposed to continue to allow the various boards to submit the Maintenance of Certification Program data to the ABMS and having ABMS submit the information on behalf of the various boards and their member eligible professionals to CMS. We received no comments on our proposed requirements for specialty boards that wish to send Physician Quality Reporting System information to us on behalf of eligible professionals and therefore, we are finalizing these requirements.

To the extent an eligible professional participates in multiple Maintenance of Certification Programs and meets the requirements under section 1848(m)(7) of the Act (Additional Incentive Payment) under multiple programs, we note that the eligible professional can qualify for only one additional 0.5 percent incentive per year.

We invited public comment on the requirements we proposed for earning a 0.5 percent incentive for participation in the Maintenance of Certification Program incentive. The following is a summary of the comments we received related to the Maintenance of Certification Program incentive.

Comment: Several commenters generally supported the Maintenance of Certification Program incentive and the requirements for earning such an incentive. One commenter asked whether or not CMS had a plan to allow physicians who are not Board-certified to participate in the Maintenance of Certification Program Incentive.

Response: We appreciate the commenters' support. Currently, we do not have a plan to allow physicians who are not Board-certified to participate in the Maintenance of Certification Program Incentive, because we defer to the various specialty boards to specify the particular actions a physician must complete to meet the ''more frequently'' requirement.

Comment: Another commenter asked that American Osteopathic Association and its Osteopathic Continuous Certification (OCC) program(s) be recognized as equivalent to the American Board of Medical Specialties (ABMS) Maintenance of Certification Programs for the purpose of qualifying

for a Maintenance of Certification Program incentive.

Response: We cannot approve an organization's certification program for participation in the Maintenance of Certification Program incentive unless the organization meets all of the requirements we are finalizing.

Comment: One commenter was opposed to having physicians report Maintenance of Certification Program details that they must also report to hospitals. The commenter suggested that we eliminate this duplicative reporting.

Response: Our proposal calls for Maintenance of Certification data to be submitted in one of two ways. First, the data can be submitted directly from the qualified Maintenance of Certification Program entity. Secondly, the data can be submitted by an ABMS Maintenance of Certification registry, if the ABMS chooses to proceed down this path. We do not believe that either of these mechanisms places additional burden on the provider, hospitals or specialties societies.

Comment: Some commenters stated that the requirements to earn a Maintenance of Certification Program incentive are generally too burdensome for both physicians and medical specialty boards.

Response: We appreciate the commenter's feedback. However, the general requirements for earning the Maintenance of Certification Program incentive are specified in section 1848(m)(7) of the Act. Therefore, physicians must meet all of the below requirements to be eligible for a Maintenance of Certification Program incentive.

Comment: Several commenters supported our proposal to reinterpret the definition of ''more frequently'' to apply to one of three parts, in addition to requiring a practice assessment, instead of applying to each of the four parts. Some of these commenters expressed support in giving the respective medical specialty boards more deference in applying the ''more frequently'' requirement for earning a Maintenance of Certification Program incentive.

Response: Based on the comments we received and for the reasons we explained previously, we are finalizing the ''more frequently'' requirement for the Maintenance of Certification Program incentive.

Comment: Some commenters supported our decision to refrain from requiring the reporting of patient experience of care survey data at this time.

Response: We appreciate the commenters' feedback and are not requiring the reporting of patient experience of care survey data at this time.

After considering the comments and for the reasons stated previously, we are finalizing our proposals regarding the Maintenance of Certification Program incentive. We are also finalizing the requirements for the 2013 and 2014 Maintenance of Certification Program additional incentive. With respect to dates specific to the Maintenance of Certification Program additional incentive, we are finalizing dates that correspond to the additional incentive year. Specifically, new Maintenance of Certification that wish to enable their diplomats to be eligible for the additional Physician Quality Reporting System 0.5 percent for 2013 and/or 2014 must go through the same nomination process by January 31, 2013 and January 31, 2014, respectively.

In addition, with respect to its self-nomination statement, a Maintenance of Certification Program wishing to enable its diplomats to earn a 2013 and 2014 Maintenance of Certification Program additional incentive must indicate that the program is in existence as of January 1, 2012 for the 2012 additional incentive, January 1, 2013 for the 2013 additional incentive, and January 1, 2014 for the 2014 additional incentive. With respect to the information required in the self-nomination statement, sponsoring organizations that desire to participate as a Maintenance of Certification Program must provide this information to CMS in a CMS-specified file format by no later than the end of the first quarter of 2013 and 2014 for the 2014 and 2014 Maintenance of Certification additional incentive.

h. Feedback Reports

Section 1848(m)(5)(H) of the Act requires the Secretary to provide timely feedback to eligible professionals on the performance of the eligible professional with respect to satisfactorily submitting data on quality measures. Since the inception of the program in 2007, the Physician Quality Reporting System has provided eligible professionals who have reported Physician Quality Reporting System data on quality measures feedback reports at the TIN/NPI level detailing participation in the Physician Quality Reporting System, including reporting rate and performance rate information. For 2008, we improved the format and content of feedback reports based on stakeholder input. We also developed an alternate report distribution method whereby each eligible professional can directly request and receive a feedback report. Starting in 2011, we provided an opportunity for eligible professionals to request their NPI-level feedback reports via the Communication Support Page at *https://www.qualitynet.org/portal/server.pt/community/communications_support_system/234.*

In accordance with Section 1848(m)(5)(H) of the Act, we will continue to provide feedback reports to individuals and group practices that attempt to report on at least one Physician Quality Reporting System quality measure. We proposed (76 FR 42884) to provide feedback reports for 2012 and beyond, on or about the time of issuance of the incentive payments, consistent with our current practice.

We received the following comment regarding this proposal.

Comment: One commenter questioned why annual feedback reports are provided around the time Physician Quality Reporting System incentive payments are distributed.

Response: We disseminate annual feedback reports at the same time incentive payments are made so that the provider has adequate information available to understand how the incentive payment was calculated. Therefore, we will continue to distribute annual feedback reports around the time Physician Quality Reporting System incentive payments are distributed.

Comment: One commenter stated that we should improve the accessibility of feedback reports, as eligible professionals in the past have had trouble accessing these feedback reports. Another commenter stated that annual feedback reports should be distributed before the issuance of incentive payments.

Response: We believe that providing annual feedback reports on or about the issuance of incentive payments is timely. However, we would like to increase accessibility, speed, and ease of distributing feedback reports to eligible professionals. Therefore, we are working with finding other ways, aside from accessing feedback reports through Carried/MACs or with the use of an IACS account. For example, in addition to being able to access feedback reports through this traditional method, eligible professionals may request 2010 Physician Quality Reporting System NPI-level feedback reports via the Communication Support Page. We believe that accessing feedback reports through the Communication Support Page is a faster method of receiving feedback reports. We welcome any suggestions on improving accessibility to Physician Quality Reporting System feedback reports.

For the reasons stated previously, for 2012 and beyond, we are finalizing our proposal to provide feedback reports to individuals and group practices that attempt to report on at least one Physician Quality Reporting System quality measure on or about the time of issuance of the incentive payments.

In addition, we believe it would be beneficial for eligible professionals to also receive interim feedback reports. Therefore, we proposed (76 FR 42884) to provide interim feedback reports, which would be simplified versions of the feedback reports we currently provide, to eligible professionals reporting individual measures and measures groups through the claims-based reporting mechanism for 2012 and beyond, and issue them in the summer of the respective program year. We believe interim feedback reports would be particularly valuable to eligible professionals reporting measures groups, because it would let an eligible professional know how many more cases he or she needs to report to satisfy the criteria for satisfactory reporting for claims-based reporting of measures groups.

We invited public comment on our proposal to provide interim feedback reports related to reporting via the claims-based reporting mechanism for 2012 and beyond. The following is a summary of comments we received.

Comment: Several commenters supported our proposal to provide interim feedback reports. However, some commenters suggested that we allow stakeholders to comment on the form and content of these interim feedback reports.

Response: We appreciate the commenters' support in our proposal to provide interim feedback reports and are finalizing our proposal to provide interim feedback reports for claims-based reporting for 2012 and beyond. However, as the form and content of these feedback reports are already being developed, we cannot make changes related to the form and content of these interim feedback reports for 2012. However, for interim feedback reports that will be developed for future program years, we expect to provide an opportunity for the public to provide suggestions regarding the form and content of these interim feedback reports.

Comment: Some commenters suggested that we provide interim feedback reports that provide reporting information via other reporting mechanisms aside from claims, such as registry and EHR.

Response: We appreciate the commenters' feedback. However, since we do not receive data from the registry and EHR reporting mechanisms until the following calendar year, it is not technically feasible for us to develop interim feedback reports that provide reporting performance related to registry and/or EHR-based reporting. However, as stated in previously in section VI.F.1.d, we are finalizing our proposal to require registries and EHR vendors to provide such feedback reports, if technically feasible.

After considering the issues raised in the comments we received and for the reasons stated previously, we are finalizing our proposal to provide interim feedback reports for eligible professionals reporting individual measures and measures groups through the claims-based reporting mechanism for 2012 and beyond. These reports will be a simplified version of annual feedback reports that we currently provide for such eligible professionals and will be based on claims for dates of service occurring on or after January 1 and processed by March 31 of the respective program year (that is, January 1, 2012 and processed by March 31, 2012 for the 2012 program year). We expect that we would be able to make these interim feedback reports available to eligible professionals in the summer of the respective program year (that is, summer 2012 for the 2012 program year).

i. Informal Review

Under 42 CFR 414.90(i), eligible professionals or group practices may seek an informal review of the determination that the eligible professional or group practice did not satisfactorily submit data on quality measures under the Physician Quality Reporting System.

To maintain program consistency until we have further experience with the informal review process that we implemented for the 2011 Physician Quality Reporting System, we proposed (76 FR 42884) to largely retain the same informal review process that was finalized in the 2011 MPFS final rule with comment period (75 FR 73549 through 73551) for 2012 and beyond. Specifically, we proposed to base the informal process on our current inquiry process whereby an eligible professional can contact the Quality Net Help Desk (Help Desk) (via phone or email) for general Physician Quality Reporting System and eRx Incentive Program information, information on Physician Quality Reporting System feedback report availability and access, and/or information on Physician Quality Reporting System Portal password issues.

For purposes of the informal process required under section 1848(m)(5)(E) of the Act, we proposed the following inquiry process:

- An eligible professional electing to utilize the informal process must request an informal review within 90 days of the release of his or her feedback report, irrespective of when an eligible professional actually accesses his/her feedback report.
- An eligible professional may request an informal review through use of a web-based tool, if technically feasible. We believe use of the web-based tool will provide a more efficient way to record informal review requests, as the web-based tool will guide the eligible professional through the creation of an informal review requests. For example, the web-based tool will prompt an eligible professional of any necessary information s/he must provide. If not technically feasible, we proposed that an eligible professional may request the informal review by notifying the Quality Net Help Desk via email at *qnetsupport@sdps.org.* In the request for an informal review, the eligible professional must summarize his or her concern(s) of the eligible professional and the reason(s) for requesting an informal review.
- We further proposed (76 FR 42884) that CMS would provide the eligible professional with a response to his or her request for an informal review within 90 days of receiving the original request. In 2011, we proposed to provide the eligible professional with a response to his or her request for an informal review within 60 days of receiving the original request. However, we anticipate that the volume of informal review requests will grow as participation in the Physician Quality Reporting System grows, particularly as we move towards the implementation of the 2015 payment adjustment. Furthermore, we believe that the time it takes for CMS to calculate data on Physician Quality Reporting System quality measures will be greater than in 2011, since we are proposing additional individual measures and measures groups. For these reasons, we proposed to amend 42 CFR 414.90(i)(2) to indicate that CMS will provide a written response within 90 days of the receipt of the original request for an informal review.
- As this process is informal and the statute does not require a formal appeals process, we will not include a hearing or evidence submission process, although the eligible professional may submit information to assist in the review.

• Based on our informal review, we will provide a written response. Where we find that the eligible professional did satisfactorily report, we proposed to provide the applicable incentive payment.

• Given that this is an informal review process and given the limitations on review under section 1848(m)(5)(E) of the Act, decisions based on the informal review will be final, and there will be no further review or appeal.

We invited public comment on the proposed informal review process for 2012 and beyond. The following is a summary of the comments regarding the informal review process.

Comment: Some commenters were opposed to our proposal to extend the time CMS must provide a response to the eligible professional's request for an informal review from 60 days to 90 days. One commenter acknowledged CMS anticipating a higher volume of informal review requests, but the commenter stated that 90 days was too long of a waiting period for eligible professionals to receive a response to their request for an informal review. Another commenter stated that extending the time CMS must provide a response does not provide eligible professionals with the opportunity to make a second request for a review within the 90 day window that eligible professionals are given to request an informal review.

Response: We appreciate the commenter's feedback. However, as we stated previously, we anticipate a higher volume of requests for informal review, particularly as we move towards the 2015 payment adjustment and continue to align with various CMS programs to encourage participation in the Physician Quality Reporting System. We believe that the time it takes for CMS to calculate data on Physician Quality Reporting System quality measures will be greater than in 2011, since we are proposing additional individual measures and measures groups. With respect to being able to request a second review, we note that all informal review decisions are final. Eligible professionals will not have the opportunity to request a second review. Therefore, for the reasons we noted, we are finalizing our proposal to extend the time CMS must provide a response to the eligible professional's request for an informal review from 60 days to 90 days.

Comment: One commenter urged us to create a hearing of evidentiary process to allow eligible professionals to submit additional evidence.

Response: As stated previously, we did not establish a hearing or evidentiary process because this review is informal. We understand that, in some instances, an eligible professional may need to provide additional information. Therefore, should we need additional information to process a request for an informal review, we will request this additional information. We note, however, that the need for additional information will not affect the deadline for CMS to provide a decision to the eligible professional.

Comment: One commenter was concerned with our proposal to use the Help Desk as the basis for our informal review process, because the commenter stated that practices have had difficulties obtaining reliable information from the Help Desk.

Response: We appreciate the commenter's feedback. However, the webbased tool is the finalized method under which we are accepting requests for informal review. The Help Desk, however, will perform informal review functions related to analysis of the informal review. We believe the informal review process, using the web-based tool in conjunction with the Help Desk, is the most efficient and most beneficial to the eligible professional. With respect to the commenter's concern that the Help Desk may provide inaccurate information, we will monitor the Help Desk for accuracy of the information provided.

Based on the comments received and for the reasons stated previously, for 2012 and beyond, we are finalizing the Physician Quality Reporting System informal review process, as proposed. Eligible professionals wishing to submit a request for an informal review are required to do so via a web-based tool, the Communication Support Page. Information on the Communication Support Page, including the link to the Page, will be available at *http://www.cms.gov/PQRS//*. Eligible professionals who have difficulty accessing the Communication Support Page, such as those eligible professionals who do not have internet access, may contact the Help Desk for assistance in submitting a request for an informal review. We also note that, with respect to informal reviews for the 2011 Physician Quality Reporting System, we stated (75 FR 73550) that eligible professionals wishing to submit a request for an informal review do so by submitting an email to the QualityNet Help Desk at *qnetsupport@sdps.org.* As we believe that submitting the informal review request via a web-based tool is a more efficient and secure method of receiving these informal review requests, we are also allowing use of the web-based tool to submit informal review requests for the 2011 Physician Quality Reporting System. We are finalizing our proposal to modify 42 CFR 414.90 to reflect these finalized proposals.

j. Future Payment Adjustments for the Physician Quality Reporting System

Beginning in 2015, a payment adjustment will apply under the Physician Quality Reporting System. Specifically, under section 1848(a)(8) of the Act, as added by section 3002(b) of the Affordable Care Act, with respect to covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professionals during the year shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. The applicable percent is—

• 98.5 percent for 2015; and

• 98.0 percent for 2016 and each subsequent year.

Under section 1848(a)(8)(C)(iii) of the Act provides that, for purposes of the payment adjustment, the ''quality reporting period'' with the respect to a year, is a period specified by the Secretary. In order to maintain consistency and program continuity, similar to the 12-month reporting period we are proposed for 2012, we proposed a 12-month reporting period for the 2015 payment adjustment. Specifically, in the proposed rule, we proposed (76 FR 42884–42885) that the reporting period for purposes of the 2015 payment adjustment would be the 2013 calendar year, that is, January 1, 2013 through December 31, 2013.

Comment: Several commenters opposed our proposal to establish CY 2013 as the reporting period for the 2015 payment adjustment, because they felt the report period for the 2015 payment adjustment should occur later in time. These commenters believed that the reporting period for the 2015 payment adjustment should mirror the reporting periods for the Physician Quality Reporting System incentives (*i.e.,* a CY 2012 reporting period for the 2012 incentive). Some commenters suggested CY 2014 or CY 2015 as the reporting period for the 2015 payment adjustment. One commenter urged us to align the reporting periods for Physician Quality Reporting System incentives as well as payment adjustments as closely as possible.

Response: We considered using a CY 2014 and CY 2015 reporting period for

the 2015 payment adjustment. However, it is not operationally feasible to create a full calendar year reporting period for the 2015 payment adjustment any later than CY 2013 and still avoid retroactive payments or the reprocessing of claims.

Section 1848(a)(8) of the Act requires that a payment adjustment be applied to covered professional services furnished by an eligible professional in in the particular payment adjustment year. Therefore, using 2015 as an example, we believe it is necessary to reduce the PFS amount concurrently for PFS allowed charges for covered professional services furnished in 2015. If we do not reduce the PFS amount concurrently with claims submissions in 2015, we would need to potentially recoup or provide added payments after the determination is made about whether the payment adjustment applies, or alternatively, hold claims until such a determination is made. In addition, we note that if such retroactive adjustments were made it may require a reconciliation of beneficiary co-payments. As a result, we need to determine whether eligible professionals have satisfactorily reported under the Physician Quality Reporting System based on a reporting period that occurs prior to 2015.

As for the suggestion that we use CY 2014 as the reporting period, we do not believe this would allow sufficient time for eligible professionals to report the Physician Quality reporting System measures, or allow us enough time to collect and analyze the data submitted by eligible professionals in order to avoid retroactive adjustments to payments in 2015, because we will not receive this data until months after the reporting period. Once we have completed our analysis, we also need time to make the necessary system changes to begin applying the payment adjustments to the appropriate individuals. All of this must occur prior to January 1, 2015, and so using a CY 2014 reporting period would not be feasible. We believe that the reporting period we proposed will allow a full calendar year for eligible professionals (which is consistent with the reporting periods finalized for the 2012 incentive) to meet the criteria for satisfactory reporting for purposes of the 2015 payment adjustment, while still providing us with enough time to collect and analyze the data submitted by eligible professionals for the 2015 payment adjustment without having to make retroactive payment adjustments in 2015. With regard to using a shorter reporting period (that is, less than 12 months), we may consider, in future notice and comment rulemaking, additional reporting periods that are less than 12 months for the 2015 payment adjustment, so that eligible professionals have additional opportunities to meet the requirements for the 2015 payment adjustment.

Therefore, for the reasons we've explained, we are finalizing our proposal to establish CY 2013 (that is, January 1, 2013 through December 31, 2013) as the reporting period for the 2015 payment adjustment. At this time, we are not aware of any viable alternatives that would allow us to address the issues we noted and still provide a full-year reporting period that falls after 2013. We will, however, continue to explore options for potentially using a reporting period closer to the time in which the payment adjustment is applied for future years of the payment adjustment.

Based on the reporting period we are finalizing in this final rule with comment period, if we determine that an eligible professional or group practice has not satisfactorily reported data on quality measures for the January 1, 2013 through December 31, 2013 reporting period for purposes of the 2015 payment adjustment, then the fee schedule amount for services furnished by the eligible professional or group practice during 2015 would be 98.5 percent of the fee schedule amount that would otherwise apply to such services. We intend to address the remaining requirements for the 2015 payment adjustment in future rulemaking.

2. Incentives and Payment Adjustments for Electronic Prescribing (eRx)—The Electronic Prescribing Incentive Program

a. Program Background and Statutory Authority

Electronic prescribing is the transmission using electronic media, of prescription or prescription-related information between the prescriber, dispenser, pharmacy benefit manager (PBM), or health plan, either directly or through an intermediary, including an electronic prescribing network. To encourage the use of electronic prescribing among eligible professionals, section 132 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1848(m) of the Act to establish the eRx Incentive Program. The eRx Incentive Program provides a combination of incentive payments and payment adjustments through 2014 to eligible professionals who are successful electronic prescribers. No eRx incentive payments or payment adjustments are authorized beyond 2014.

From 2009 through 2013, the Secretary is authorized to provide eligible professionals who are successful electronic prescribers an incentive payment equal to a percentage of the eligible professional's total estimated Medicare Part B PFS allowed charges (based on claims submitted not later than 2 months after the end of the reporting period) for all covered professional services furnished by the eligible professional during the respective reporting period. However, section 1848(m)(2)(D) of the Act, as added by section 4101(f)(2)(B) of Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) (ARRA), which also authorized the Medicare EHR Incentive Program, specifies that the eRx incentive does not apply to an eligible professional, if, for the EHR reporting period, the eligible professional earns an incentive payment under the Medicare EHR Incentive Program beginning in 2011.

The applicable electronic prescribing percent for incentive payments under the eRx Incentive Program are as follows:

- 2.0 percent for 2009.
- 2.0 percent for 2010.
- 1.0 percent for 2011.
- 1.0 percent for 2012.
- 0.5 percent for 2013.

In addition, for years 2012 through 2014, under section 1848(a)(5)(A) of the Act, a PFS payment adjustment applies to eligible professionals who are not successful electronic prescribers at an increasing rate through 2014. Specifically, if the eligible professional is not a successful electronic prescriber for the respective reporting period for the year, the PFS amount for covered professional services during the year shall be a percentage less than the PFS amount that would otherwise apply. The applicable electronic prescribing percent for payment adjustments under the eRx Incentive Program are as follows:

- 1.0 percent in 2012.
- 1.5 percent in 2013.
- 2.0 percent in 2014.

We believe the purpose of the eRx Incentive Program for 2012 and beyond is to continue to encourage significant expansion of electronic prescribing by authorizing a combination of financial incentives and payment adjustments. We proposed to modify the incentive and payment adjustment language in 42 CFR 414.92 to provide language more consistent with section 1848 of the Act (please note that in the proposed rule we inadvertently listed ''section 1848(k)'' instead of ''section 1848'').

We believe that the criteria used to determine who is a successful electronic prescriber for purposes of the eRx incentive are not required to be identical to the criteria used to determine the applicability of the eRx payment adjustment. In general, we believe that an incentive should be broadly available to encourage the widest possible adoption of electronic prescribing, even for low volume prescribers. On the other hand, we believe that a payment adjustment should be applied primarily to assure that those who have a large volume of prescribing do so electronically, without penalizing those for whom the adoption and use of an electronic prescribing system may be impractical given the low volume of prescribing. We also believe that eligible professionals who have met the requirements for receiving an incentive payment under the eRx Incentive Program for a particular year have sufficiently demonstrated their adoption and use of electronic prescribing technology and thus should not be subject to the payment adjustment in a future year.

Individual eligible professionals do not have to participate in the Physician Quality Reporting System in order to participate in the eRx Incentive Program (and vice versa). The provisions of the eRx Incentive Program are codified at 42 CFR 414.92.

In prior years, we have proposed and finalized the details of the eRx Incentive Program through an annual rulemaking process. Through this annual rulemaking process, we have previously established the criteria for avoiding the 2012 eRx payment adjustment in the 2011 PFS Final Rule with comment period (75 FR 73562 through 73565), as well as issued a final rule entitled ''Changes to the Electronic Prescribing (eRx) Incentive Program'' (76 FR 54953 through 54969), in which we proposed additional changes to the 2012 payment adjustment, as well as the electronic prescribing quality measure for certain reporting periods in 2011. We also established requirements for the 2013 eRx payment adjustment in the 2011 PFS Final Rule with comment period (75 FR 7356).

In this final rule with comment period, we are finalizing our comprehensive requirements for the 2012 and 2013 incentive payments, additional requirements for the 2013 payment adjustment, and requirements for the 2014 payment adjustment. We believe that finalizing criteria for the eRx Incentive Program for 2012 and beyond will provide eligible professionals with more time to familiarize themselves with the details of the eRx Incentive Program. We hope this will lead to increased, successful participation in the eRx Incentive Program. Details regarding requirements for the eRx Incentive Program for 2012 and 2013 incentive payments, additional requirements for the 2013 payment adjustment, and the requirements for the 2014 payment adjustment, including our rationale for finalizing such requirements, are described in the following section. We received comments that were not related to our specific proposals for the 2012 through 2014 eRx Incentive Program, and, while we appreciate the commenters' feedback, these comments are outside the scope of the issues addressed in this final rule with comment period and are not included.

b. Eligibility

For the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments, we proposed the following two ways eligible professionals may participate in the eRx Incentive Program: (1) as an individual eligible professional; or (2) as part of a group practice participating in the group practice reporting option (GPRO) for the eRx Incentive Program (eRx GPRO) (76 FR 42886). Professionals eligible to participate in the eRx Incentive Program are defined at 42 CFR 414.92(b) and more information is available on the eRx Incentive Program section of the CMS Web site at: *http://www.cms.gov/ERxIncentive/05_Eligible%20Professionals.asp#TopOfPage.*

(1) Individual Eligible Professionals

(A) Definition of Eligible Professional

As in the 2011 eRx Incentive Program, we proposed that, for individual eligible professionals participating in the eRx Incentive Program for purposes of the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments, the determination of whether an eligible professional is a successful electronic prescriber will be made at the individual professional level, based on the National Provider Identifier (NPI) number (76 FR 42886). As some individuals (identified by NPIs) may be associated with more than one practice or Tax Identification Number (TIN), for the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments, we proposed that the determination of whether an eligible professional is a successful electronic prescriber will continue to be made for each unique TIN/NPI combination. Then, as in previous years, incentive payments would then be made to the applicable holder of the TIN. We proposed continuing to use the TIN/NPI combination as the unit of analysis to maintain program continuity, as individual eligible professionals are already familiar with this level of analysis and payment. We invited public comment on our proposal to continue analyzing data using the TIN/NPI combination while providing payment to the applicable holder of the TIN. We received no comments on our proposal to continue analyzing data using the TIN/NPI combination while providing payment to the applicable holder of the TIN and are therefore, finalizing this proposal.

As in prior program years, we proposed that individual eligible professionals who wish to participate in the eRx Incentive Program for purposes of the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments may simply start participating (76 FR 42886). Individual eligible professionals are not required to register or notify CMS they intend to participate; rather, they may simply begin to report the eRx measure. We invited public comment on the proposed process for individual eligible professionals to participate in the eRx Incentive Program. We received no comments regarding our proposal, and therefore, we are finalizing our proposal that individual eligible professionals who wish to participate in the eRx Incentive Program for purposes of the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments may simply start participating.

(2) Group Practices

As required under section 1848(m)(3)(C) of the Act, we established a process under which eligible professionals in a group practice (as defined by the Secretary) would be treated as having met the requirements for submitting data on electronic prescribing quality measures for covered professional services for a reporting period (or, for purposes of the payment adjustment under section 1848(a)(5) of the Act, for a reporting period for a year) if, in lieu of reporting the electronic prescribing measure, the group practice reports measures determined appropriate by the Secretary, such as measures that target high-cost chronic conditions and preventive care, in a form and manner, and at a time specified by the Secretary. Specifically, we first established the eRx group practice reporting option (eRx GPRO) in 2010, which was further modified in the 2011 PFS Final Rule (75 FR 73502). In addition to determining whether an eligible professional is a successful electronic prescriber for incentive

payment and payment adjustment purposes based on separately analyzing whether the individual eligible professionals are successful electronic prescribers, we proposed to also make the determination that the group practice, as a whole, is a successful electronic prescriber in accordance with section 1848(m)(3)(C) of the Act for those group practices that wish to participate in the eRx GPRO.

(A) Definition of ''Group Practice''

Section 1848(m)(3)(C)(i) of the Act authorizes the Secretary to define ''group practice,'' which CMS defined by referencing our regulation at § 414.90 (b). For the 2011 eRx Incentive Program, under § 414.92(b), a group practice is—

(1) Defined at § 414.90(b), that is participating in the Physician Quality Reporting System; or

(2)(a) In a Medicare approved demonstration project that is deemed to be participating in the Physician Quality Reporting System group practice reporting option; and

(b) Has indicated its desire to participate in the electronic prescribing group practice option.

However, for purposes of determining whether a group practice is a successful electronic prescriber for CYs 2012 through 2014, we proposed to modify the definition of the ''group practice'' at 42 CFR 414.92(b) to be consistent with modifications we proposed for the definition of ''group practice'' at 42 CFR 414.90(b) for the 2012 Physician Quality Reporting System (76 FR 42886).

In particular, we proposed to modify the definition of group practice under the Physician Quality Reporting System definition at 42 CFR 414.90(b) by defining a group practice as a single TIN with at least 25 or more eligible professionals, as identified by their individual NPI, who have reassigned their Medicare billing rights to the TIN. Given that the definition of ''group practice'' at 42 CFR 414.92(b) follows the Physician Quality Reporting System definition, we proposed to apply the modification to the definition for group practice under the eRx Incentive Program.

Although we noted this proposed change would eliminate group practices comprised of 2 to 24 eligible professionals for the purpose of the eRx GPRO, we believed changing the definition of ''group practice'' would not pose a significant burden to these small group practices, because they could still participate as individual eligible professionals. For 2010, out of 107 group practices that self-nominated to participate in GPRO II for the Physician Quality Reporting System, 68 of these group practices qualified to participate in the eRx Incentive Program under GPRO II. However, during the opt-out period which ended on May 12, 2011, 6 of these 68 group practices dropped out of GPRO II participation, leaving only 62 group practices to participate in GPRO II for 2010. Due to the low participation of only 62 groups, we believed that participation in the eRx GPRO should be limited to only those group practices with 25 or more eligible professionals. We noted that participating under GPRO II may be more burdensome for very small group practices than participating as eligible professionals. For example, with respect to the payment adjustment, additional limitations may apply to eligible professionals as individuals that are not applied to group practices, which present an additional burden to the group practice.

We also proposed (76 FR 42866) to modify the language that references Medicare demonstrations to more broadly recognize other similar Medicare programs that group practices may be participating in so that such practices may be eligible to participate in the eRx Incentive Program. We received no comments related to our proposal to more broadly recognize Medicare programs other than the PQRS GPRO where group practices may be participating. Therefore, we are finalizing this modification at 42 CFR 414.92(b). We are also modifying 42 CFR 414.92 to make clear that all group practices must indicate their desire to participate in the eRx GPRO.

We invited public comment on our proposed definition of group practice and below is a summary of the comments we received and our responses.

Comment: One commenter was concerned with our proposal to change the definition of group practice under the eRx Incentive Program to groups comprised of 25 or more eligible professionals, consistent with our proposal to change the definition of group practice under the Physician Quality Reporting System. The commenter was concerned that this definition change would preclude smaller groups from participating in the eRx GPRO.

Response: As we stated previously, in 2011, we allowed groups of 2–24 individual eligible professionals to participate as a group practice under the eRx GPRO II. Unfortunately, the turnout for these smaller group practices electing to participate under the eRx GPRO II was low. Therefore, due to low participation last year in the eRx GPRO by groups comprised of 2–24 eligible professionals, we are finalizing our proposal to use the definition of group practice under the Physician Quality Reporting System, which excludes groups comprised of 2–24 eligible professionals from participating in the eRx GPRO. We note that these smaller group practices may continue to report the electronic prescribing measure for purposes of the 2012 and 2013 incentives and 2013 and 2014 payment adjustments as individual eligible professionals.

Based on the comments received and for the reasons stated above, we are finalizing our proposed definition of group practice at § 414.92(b) for purposes of participating under the eRx GPRO. However, we are making minor technical changes to the clause numbers under 42 CFR 414.92(b) to more accurately reflect this changed definition of group practice.

(B) Process To Participate in the eRx Incentive Program—eRx GPRO

We proposed (76 FR 42881) that if a group practice wishes to participate in the eRx Incentive Program under the eRx GPRO, the group practice must self-nominate to do so. To self-nominate, we proposed that the group practice follow the requirements for self-nomination under the Physician Quality Reporting System, as well as specifically indicate its intent to participate in the eRx Incentive Program as a group practice.

If a group practice self-nominates to participate in the eRx GPRO for a calendar year, then we proposed to consider that the group practice is participating in the eRx GPRO for purposes of both the incentive payment (with respect to any incentive payment reporting period that occurs during the calendar year) and the payment adjustment (with respect to any payment adjustment reporting period that occurs during the calendar year). For example, the 2013 payment adjustment reporting period occurs during calendar year 2012 (January 1, 2012 through June 30, 2012).

We invited public comment on the requirements for eligible professionals to participate as an eRx GPRO for purposes of the eRx Incentive Program. The following is a summary of the comments we received regarding this proposal.

Comment: Some commenters opposed our proposal to require a group practice wishing to participate as a group under the eRx GPRO to also participate in the Physician Quality Reporting System, since some practitioners, such as dermatologists, may not be able to participate in the Physician Quality Reporting System GPRO due to a lack of

measures that are applicable to their respective specialties.

Response: We appreciate the commenters' feedback. However, as in prior years and for operational reasons, we must require that all group practices wishing to participate as a group under the eRx GPRO also participate in the Physician Quality Reporting System. From an operational standpoint, group practices participating in the eRx GPRO must meet all the requirements of participating as a group practice under the Physician Quality Reporting System GPRO to ensure that the group practice is fully aware of requirements for participating as a group practice under the eRx GPRO. All GPRO educational sessions we hold focus on reporting under the GPRO for purposes of both programs. Furthermore, it is easier to keep track of which group practices are participating under the GPRO option for both the Physician Quality Reporting System and the eRx Incentive Program by requiring that group practices participating in the eRx GPRO also participate in the Physician Quality Reporting System GPRO. Please note, however, that this is not a requirement that group practices meet the requirements for satisfactory reporting under the Physician Quality Reporting System in order to participate in the eRx GPRO. We also note this does not preclude individuals within group practices from participating in the eRx Incentive Program as individuals.

Comment: We received one comment on the self-nomination process. The commenter felt the process is overly burdensome.

Response: In determining what should be included in the self-nomination process, we attempted to balance what we believed was necessary to determine a group practice's intent to participate in the eRx GPRO versus the burden to the group practice. For example, we believe it is necessary to require group practices to indicate their intent to participate in the eRx Incentive Program under the eRx GPRO in writing to keep track of who is participating under the eRx Incentive Program under the eRx GPRO so the eligible professionals associated under the respective group practice may be analyzed at the group level. We believe that the requirement to submit a self-nomination statement is not an unduly burdensome task for a group practice. With respect to the additional requirements we are finalizing, such as requiring that group practices wishing to participate in the eRx Incentive Program under the eRx GPRO attend scheduled training sessions, we believe that these requirements provide group practices with needed guidance on how to meet the requirements for becoming a successful electronic prescribers as group practices. This added guidance, in our opinion, will lead to a greater probability that group practices participating under the eRx GPRO will qualify to earn the 2012 and 2013 incentives as well as fulfill criteria for the 2013 and 2014 payment adjustments.

After considering the comments received and for the reasons stated in our responses, we are finalizing our proposal that, in order for a group practice to participate as a group under the eRx GPRO, the group practice must self-nominate for each calendar year the group wishes to participate in the eRx GPRO. If a group practice self-nominates to participate in the eRx GPRO for a calendar year, then we will consider that the group practice to be participating in the eRx GPRO as a group practice for purposes of both the incentive payment and the payment adjustment. Therefore, if an eligible professional is part of a group practice participating in the eRx GPRO for a respective program year, the eligible professional in the group practice is precluded from participating as an individual eligible e professional for purposes of both the 2012 and 2013 incentives and 2013 and 2014 payment adjustments. For example, the 2013 payment adjustment reporting period occurs during calendar year 2012 (January 1, 2012 through June 30, 2012). Therefore, any group practice participating in the eRx GPRO during calendar year 2012 would be considered to be participating in the eRx GPRO for both the 2012 incentive and 2013 payment adjustment.

Also, as we clarified in the proposed rule (76 FR 42887), a group practice that is deemed to be participating in the Physician Quality Reporting System, such as an ACO participating under the Medicare Shared Savings Program, will not be deemed participating as a group practice in the eRx Incentive Program. To participate in the eRx Incentive Program under the eRx GPRO, such group practices must self-nominate to do so. Instructions for submitting the self-nomination statement are the same as the instructions for submitting a self-nomination statement for the Physician Quality Reporting System. Each year, we expect to notify a group practice of the selection decision with respect to participation in the eRx GPRO during the first quarter of the year.

c. Reporting Periods

(1) Reporting Periods for the 2012 and 2013 eRx Incentives

Section 1848(m)(6)(C)(i)(II) of the Act defines ''reporting period'' under the eRx Incentive Program for years after 2008 to be the entire year. We also have authority under section 1848(m)(6)(C)(ii) of the Act to revise the reporting period if the Secretary determines such revision is appropriate, produces valid results on measures reported, and is consistent with the goals of maximizing scientific validity and reducing administrative burden. We proposed (76 FR 42887), the entire calendar year as the reporting period for purposes of the 2012 and 2013 incentive payment (January 1, 2012 through December 31, 2012 for the 2012 incentive and January 1, 2013 through December 31, 2013 for the 2013 incentive, respectively). Accordingly, we proposed to modify 42 CFR 414.92(d)(1).

We invited public comment on the proposed reporting periods for the 2012 and 2013 incentives. The following is a summary of the comment we received regarding these proposals.

Comment: One commenter supported our proposals to base the 2012 and 2013 incentives off of 12-month reporting periods.

Response: We appreciate the commenter's feedback and are finalizing our proposed reporting periods for the 2012 and 2013 incentives.

Based on the comment received and for the reasons stated above, we are finalizing the reporting period for the 2012 incentive as the 12-month period of January 1, 2012 through December 31, 2012, and reporting period for the 2013 incentive as the 12-month period of January 1, 2013 through December 31, 2013, and finalizing the changes to the regulation at § 414.92(d)(1).

(2) Reporting Periods for the 2013 and 2014 eRx Payment Adjustments

Under our authority under section 1848(m)(6)(C)(ii) of the Act, in the 2011 PFS final rule with comment period, we finalized two different reporting periods: A 6-month reporting period (between January 1, 2011 and June 30, 2011) for purposes of the 2012 payment adjustment for both individual eligible professionals and group practices participating in the eRx GPRO (75 FR 73562 through 73563) and a 12-month reporting period (between January 1, 2011 and December 31, 2011) for purposes of the 2013 payment adjustment for individual eligible professionals and group practices

participating in the eRx GPRO (75 FR 73565).

In addition to the 12-month reporting period finalized in the 2011 PFS final rule with comment period, in the proposed rule we proposed (76 FR 32887), for both individual eligible professionals and group practices participating in the eRx GPRO, an additional 6-month reporting period (between January 1, 2012 and June 30, 2012) for purposes of the 2013 payment adjustment.

For similar reasons, for the 2014 payment adjustment, we proposed a 12-month reporting period (between January 1, 2012 and December 31, 2 012) that would apply to individual eligible professionals and a 6-month reporting period (between January 1, 2013 and June 30, 2013) that would apply to both individual eligible professionals and group practices, so that two different reporting periods would provide eligible professionals with two opportunities to be successful electronic prescribers.

We invited public comment on the proposed reporting periods for the 2013 and 2014 payment adjustments. The following is a summary of the comments we received regarding these proposals.

Comment: Several commenters supported our proposed reporting periods for the 2013 and 2014 payment adjustment, including our proposal to provide multiple reporting periods. A few commenters opposed, however, our proposal to provide multiple reporting periods for the 2013 and 2014 payment adjustments, stating that having multiple reporting periods leads to greater program complexity. Rather, a few commenters suggested that we should use a single, 12-month reporting period that would provide us with 12 months of data.

Response: We appreciate the commenter's feedback. However, we believe that, in this instance, our interest in providing eligible professionals and group practices with additional opportunities to become successful electronic prescribers outweighs our interest in streamlining the program and collecting 12 months of data. Furthermore, we note that eligible professionals are not required to qualify for the 2013 and 2014 payment adjustments under multiple reporting periods. Eligible professionals may choose under which respective reporting period the eligible professionals plan to satisfy the requirements for the 2013 and 2014 payment adjustments. We note that the main purpose of having eligible professionals report on the electronic prescribing measure is to ensure electronic prescribing systems are being utilized, not to collect data. Therefore, we are finalizing the proposed reporting periods for the 2013 and 2014 payment adjustments.

Comment: Several commenters were opposed to our proposed reporting periods for the 2013 and 2014 payment adjustments and suggested that we instead finalize reporting periods for the 2013 and 2014 payment adjustments that occur later in time. For example, some commenters believed that the 2013 and 2014 payment adjustments should be based on data reported in 2013 and 2014, respectively. Another commenter suggested a 9-month reporting period (that is, January 1, 2012 through September 1, 2012) for the 2013 payment adjustment.

Response: We appreciate the commenters' feedback. However, as we stated in the 2011 PFS Final Rule (75 FR 73562), under section 1848(a)(5)(D) of the Act, we have the discretion to define the ''reporting period'' for purposes of the payment adjustment with respect to a year. We interpreted the payment adjustment provision under section 1848(a)(5) of the Act as having the 2012 payment adjustment applied to reduce the PFS amount concurrently with claims submissions in 2012. Accordingly, we believe that it is necessary to apply the 2013 and 2014 payment adjustment concurrently with claim submissions in 2013 and 2014, respectively.

With respect to the suggested 9-month reporting period, for operational reasons, we cannot finalize a reporting period that ends later than June 30, 2012 for the 2013 payment adjustment and June 30, 2013 for the 2014 payment adjustment. The process required to perform a full analysis of eligible professionals' claims data can take more than five months to complete. This is due to numerous factors, including the allowance of a one month run-out for claims processing (for example, through July 29, 2012, for claims with dates of service of January 1, 2012, through June 30, 2012). Additionally, the time required to perform the data analyses to determine non-successful electronic prescribers, and to update the systems to make the appropriate reductions to Physician Fee Schedule payments for claims submitted on or after January 1, 2012 and January 1, 2013 respectively can take up to four months to complete. Taking into account these operational issues, we believe that finalizing a reporting period ending on June 30, 2012 and June 30, 2013 for the 2013 and 2014 respective payment adjustments will allow us to avoid having to recoup overpayments.

After considering the comments received and for the reasons explained in our responses, we are finalizing the 6-month reporting periods for the 2013 and 2014 payment adjustments. Specifically, in addition to the 12-month reporting period finalized in the 2011 PFS final rule with comment period, we are finalizing an additional 6-month reporting period (that is, January 1, 2012 through June 30, 2012) for purposes of the 2013 payment adjustment. For the 2014 payment adjustment, we are finalizing a 6-month reporting period (between January 1, 2013 and June 30, 2013) for both individual eligible professionals and group practices participating in the eRx GPRO. We also are finalizing a 12-month reporting period (between January 1, 2012 and December 31, 2012) for individual eligible professionals for the 2014 payment adjustment. As for group practices, we note that there was some ambiguity in the proposed rule (76 FR 42985), with regard to a 12-month reporting period for group practices participating in the eRx GPRO for the 2014 payment adjustment. Although we proposed criteria for being a successful electronic prescriber for group practices reporting from January 1, 2012 through December 31, 2012, for the 2014 payment adjustment (76 FR 42985 through 42986), we only proposed that the 12-month reporting period for the 2014 payment adjustment (that is, January 1, 2012 through December 31, 2012) would apply to individual eligible professionals (76 FR 42887). Additionally, at 42 CFR 414.92(f)(1), we proposed regulatory changes that would provide for this 12-month reporting period (76 FR 42946). Since, as discussed in section VI.F.1.e.(6). of this final rule with comment period, we are finalizing the proposed criteria for being a successful electronic prescriber pertaining to a 12-month period for group practices for purposes of the 2014 payment adjustment, we are also finalizing the 12-month reporting period (that is, January 1, 2012 through December 31, 2012) for group practices participating under the eRx GPRO for the 2014 payment adjustment. We believe this will afford group practices additional options for reporting for purposes of the 2014 payment adjustment.

Therefore, we are finalizing the proposed changes to the regulation at 42 CFR 414.92(f)(1).

d. Standard for Determining Successful Electronic Prescribers

Section 1848(m)(3)(B) of the Act governs the requirements for being a ''successful electronic prescriber,'' for

purposes of the incentive payment under section 1848(m)(2) of the Act and the payment adjustment under section 1848(a)(5) of the Act. The Secretary is authorized to use one of two possible criteria for determining whether an eligible professional is a successful electronic prescriber. One criterion, under section 1848(m)(3)(B)(ii) of the Act, is based on the eligible professional's reporting, in at least 50 percent of the reportable cases, on any electronic prescribing quality measures that have been established under the Physician Quality Reporting System, and are applicable to services furnished by the eligible professional for the reporting period. However, for years after 2009, section 1848(m)(3)(D) of the Act permits the Secretary in consultation with stakeholders and experts to revise the criteria for submitting data on electronic prescribing quality measures under section 1848(m)(3)(B)(ii) of the Act.

The second criterion, under section 1848(m)(3)(B)(iii) of the Act, is based on the electronic submission by the eligible professional of a sufficient number (as determined by the Secretary) of prescriptions under Part D during the reporting period. If the Secretary decides to use this standard, then, in accordance with section 1848(m)(3)(B)(iv) of the Act, the Secretary is authorized to use Part D data to assess whether a sufficient number of prescriptions have been submitted by eligible professionals. However, under section 1848(m)(3)(B)(i) of the Act, if the Secretary decides the standard based on a sufficient number of electronic Part D prescriptions applies for a particular reporting period, then the standard based on the reporting on electronic prescribing quality measures does not apply.

We considered use of the second criterion for determining successful prescribing under the eRx Incentive Program. While we recognize the benefits of using Part D data as the standard for determining successful electronic prescribers, we believe use of Part D prescriptions for analysis may be premature. For example, there is uncertainty as to the accuracies of reporting electronic prescribing activities using Part D data. For example, if an electronic prescription is converted to a facsimile when reaching the pharmacy on Part D data, the transmission is still reported as a pure, electronic prescribing event. Furthermore, use of Part D data would require a complete overhaul of the current requirements for the eRx Incentive Program. For instance, if we choose to shift to the use of Part D data, the program would have to adopt a new form of measurement, a new form of analysis other than use of an eligible professionals' TIN/NPI (TIN data is not available in Part D data sets), and new criteria for eligible professionals and eRx GPROs to become successful electronic prescribers. Therefore, we did not propose to use the second criterion.

For the reasons stated previously, we proposed (76 FR 42888) to continue to require eligible professionals to report on the electronic prescribing quality measure used in 2011 to determine whether an eligible professional is a successful electronic prescriber for the remainder of the eRx Incentive Program. We proposed, however, to modify the electronic prescribing quality measure's specifications and use modified reporting criteria based on the authority provided under section 1848(m)(3)(D) of the Act (76 FR 42888). We invited public comment on the continued use of reporting the electronic prescribing quality measure for purposes of the ''successful electronic prescriber'' determination under the program. We received no comments regarding our proposal to continue use of the electronic prescribing quality measure standard and therefore, we are finalizing our proposal to use the electronic prescribing quality measure standard for purposes of determining whether an eligible professional is a successful electronic prescriber. Our proposals and final decisions with regard to the criteria for being a successful electronic prescriber under this standard for the 2012 and 2013 eRx Incentives and the 2013 and 2014 eRx payment adjustments are discussed in the following sections VI.F.2.g.(2)., VI.F.2.g.(3)., and VI.F.2.h.(2). of this final rule with comment period.

(1) Reporting the Electronic Prescribing Quality Measure

The electronic prescribing quality measure, similar to the Physician Quality Reporting System measures, has two basic elements, which include: (1) A denominator that defines the patient population on which the eligible professional's performance is being measured; and (2) a reporting numerator, which identifies whether or not a clinical quality action was performed. The final details of the electronic prescribing measure specified later in this section apply to the following eRx Incentive Program years: The 2012 eRx incentive payment; the 2013 eRx incentive payment; the 2013 eRx payment adjustment; and the 2014 eRx payment adjustment.

Under section 1848(k)(2)(C)(i) of the Act, the electronic prescribing quality measure, which was initially introduced under the Physician Quality Reporting System, shall be a measure selected by the Secretary that has been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. Currently, that entity is the National Quality Forum (NQF). The electronic prescribing measure we proposed to retain, NQF Measure #0486: Adoption of Medication e-Prescribing, was endorsed by the NQF in 2011. However, pursuant to the changes finalized in the 2011 ''Changes to the Electronic Prescribing (eRx) Incentive Program'' final rule, we modified the description statement of the NQF-endorsed electronic prescribing measure to allow for use of Certified EHR Technology to report the electronic prescribing quality measure (76 FR 54954–54956). This modification has not yet been reviewed by the NQF. In light of this, we are not aware of any other NQF-endorsed measure related to electronic prescribing by eligible professionals that would be appropriate for use in the eRx Incentive Program. Therefore, we believe that the use of this eRx measure falls within the exception under section 1848(k)(2)(C)(ii) of the Act.

(2) The Denominator for the Electronic Prescribing Measure

The denominator for the electronic prescribing quality measure consists of specific billing codes for covered professional services.

As initially authorized under section 1848(k)(2)(A)(ii) of the Act, and further established through rulemaking and under section 1848(m)(2)(B)(i) of the Act, we may modify the codes making up the denominator of the electronic prescribing measure. For 2011, we expanded the scope of the denominator codes for 2010 to covered professional services outside the professional office and outpatient setting, such as professional services furnished in skilled nursing facilities or the home care setting (75 FR 73555). For purposes of reporting periods during CYs 2012 and 2013 (for the 2012 and 2013 incentives and the 2013 and 2014 payment adjustments), we proposed (76 FR 42888) to retain these CPT and HCPCS codes in the denominator of the electronic prescribing measure, because we believe that these codes represent the types of services for which prescriptions are likely to be generated. Therefore, if we were to measure an eligible professional's performance on the electronic prescribing measure, we would want to do so only for patients who saw the professional for such services. Although in prior years we

only permitted eligible professionals to report the electronic prescribing measure's numerator in connection with a service in the measure's denominator, and proposed to continue this requirement for purposes of the 2012 and 2013 incentives, in contrast, for the 2013 and 2014 payment adjustments, we proposed to depart from this requirement, as discussed in section VI.F.2.i. of this final rule with comment period.

We invited public and only received the following comment on our proposal to retain the denominator codes contained in the 2011 electronic prescribing measure:

Comment: One commenter requested that codes 90804, 90806, 96151, and 96152, which reflect psychotherapy services, be removed from the denominator of the electronic prescribing measure, because the commenter believed prescriptions should not be generated for these types of services.

Response: We appreciate the commenter's feedback, but we disagree. We believe these codes represent the types of services for which prescriptions may be generated and therefore, are appropriate to include in the denominator of the electronic prescribing measure. We point out, however, that by finalizing these denominator codes, we are not attempting to promote or discourage the generation of prescriptions for these psychotherapy services.

Based on the comment received and for the reasons explained in our responses, we are finalizing our proposal to retain the denominator codes contained in the 2011 electronic prescribing measure. Specifically, we are finalizing for the 2012 and 2013 eRx program years the following denominator CPT and HCPCS codes in the denominator of the electronic prescribing measure: 90801, 90802, 90804, 90805, 90806, 90807, 90808, 90809, 90862, 92002, 92004, 92012, 92014, 96150, 96151, 96152, 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99315, 99316, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, G0101, G0108, and G0109 (75 FR 73555).

(3) The Reporting Numerator for the Electronic Prescribing Measure

Currently, the electronic prescribing measure's numerator consists of a single code, G8553, which indicates that the prescription was generated and transmitted via a qualified electronic prescribing system (and below, we discuss in greater detail what constitutes a ''qualified system''). For purposes of reporting the electronic prescribing quality measure for the 2012 and 2013 incentives and the 2013 and 2014 payment adjustment, we proposed (76 FR 42888–42889) that an eligible professional or group practice participating in the eRx GPRO can report the code associated with the measure's numerator whenever a prescription is generated and transmitted electronically. We invited public comment on the proposed numerator for the electronic prescribing measure for CYs 2012 through 2013 eRx Incentive Program, but, we did not receive any comments related to the proposed electronic prescribing measure's numerator G-code for CYs 2012 and 2013. Therefore, for CYs 2012 and 2013 of the eRx Incentive Program, we are finalizing G–8553 for electronic prescribing measure's numerator.

We intend to post the final electronic prescribing measure specifications on the ''eRx Measure'' page of the eRx Incentive Program section of the CMS Web site at *http://www.cms.gov/ERXIncentive* by no later than—

- December 31, 2011 for the reporting periods that occur during calendar year 2012.
- December 31, 2012 for the reporting periods that occur during calendar year 2013.

In the event that additional changes are needed to the measure specifications for years after 2012, we will do so via notice and comment rulemaking prior to posting the final measure specifications for that year.

e. Required Functionalities and Part D Electronic Prescribing Standards

As discussed in greater detail below, for purposes of the 2012 and 2013 incentive and 2013 and 2014 payment adjustment, we proposed (76 FR 42889) that when the eligible professional or group practice reports the measure's numerator G-code, the eligible professional or group practice must have and regularly use a ''qualified'' electronic prescribing system, which we further proposed to define as either a system with the four functionalities previously identified in the electronic prescribing measure specifications, or Certified EHR Technology, as defined at 42 CFR 495.4 and 45 CFR 170.102. We also made proposals with regard to the Part D electronic prescribing standards for the electronic prescribing measures. Our proposed technological requirements of the electronic prescribing quality measure are discussed below.

(1) ''Qualified'' Electronic Prescribing System

We are aware that there are significant numbers of eligible professionals who are interested in participating in the eRx Incentive Program but currently do not have an electronic prescribing system or Certified EHR Technology. Generally, the electronic prescribing measure does not require the use of any particular system or transmission network; only that the system be a ''qualified'' system. If the professional does not have general access to an electronic prescribing system or Certified EHR Technology in the practice setting, the eligible professional will not be able to report the electronic prescribing measure. In addition to not being eligible for an incentive payment, an eligible professional who does not report the electronic prescribing measure for 2012 or 2013 will be subject to the 2013 or 2014 eRx payment adjustment, unless an exception applies.

We proposed (76 FR 4289) to continue to recognize as a ''qualified'' electronic prescribing system for purposes of the electronic prescribing quality measure any system that can perform the four functionalities that were identified and required under the program in 2010 and 2011 (76 FR 42889). We invited public comment on our proposal that the definition of a ''qualified electronic prescribing system,'' include systems that have these four functionalities. We did not receive any comments regarding our proposal to retain the same functionalities. Therefore, for years 2012 through 2014 of the eRx Incentive Program, we are finalizing our decision to recognize as a ''qualified'' electronic prescribing system, a system that can do the following:

- Generate a complete active medication list incorporating electronic data received from applicable pharmacies and PBMs, if available.
- Enable eligible professionals to select medications, print prescriptions, electronically transmit prescriptions, as well as provide notifications (that is, signals to warn the prescriber of possible undesirable or unsafe situations including potentially inappropriate dose or route of administration of a drug, drug-drug interactions, allergy concerns, or warnings and cautions). This functionality must be enabled.
- Provide information related to lower cost, therapeutically appropriate alternatives (if any). The ability of an electronic prescribing system to receive tiered formulary information, if

available, would again suffice for this requirement for reporting the electronic prescribing measure during the reporting periods occurring in CYs 2012 and 2013 until this function is more widely available in the marketplace.

• Provide information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan (if available).

For reporting periods that occur in CYs 2012 and 2013, we also proposed to expand the definition of a ''qualified'' electronic prescribing system to include Certified EHR Technology, as defined at 42 CFR 495.4 and 45 CFR 170.102, because we believe the technological requirements for electronic prescribing under the EHR Incentive Program are similar to the technological requirements for the eRx Incentive Program. We believe expanding the definition of a ''qualified'' electronic prescribing system in this way will align the requirements of the eRx and the Medicare EHR Incentive Program and potentially reduce unnecessary investment in multiple technologies for purposes of meeting the requirements for each program. This proposal was consistent with changes we finalized for certain reporting periods in CY 2011 for the 2011 eRx incentive and the 2013 eRx payment adjustment in the September 6, 2011 final rule entitled ''Medicare Program; Changes to the Electronic Prescribing (eRx) Incentive Program'' (76 FR 54953, 54956).

We invited public comment on the proposed requirements of a ''qualified'' electronic prescribing system for purposes of reporting the electronic prescribing measure. The following is a summary of the comments we received regarding these proposals.

Comment: Several commenters supported our proposal to retain our modification of the electronic prescribing measure to allow for use of Certified EHR Technology. Commenters supported our efforts to align the eRx Incentive Program and EHR Incentive Program in this manner. Commenters also believed that allowing for use of Certified EHR Technology reduces burden on eligible professionals.

Response: We appreciate the commenters' supportive feedback and are finalizing our proposal to expand the definition of a ''qualified'' electronic prescribing system to include Certified EHR Technology for the reasons we and commenters noted.

Therefore, in summary, for reporting periods that occur during CYs 2012 and 2013 of the eRx Incentive Program, we are finalizing our proposal that a ''qualified'' electronic prescribing system for the electronic prescribing quality measure is one that either meets the four functionalities noted, or is Certified EHR Technology, as defined at 42 CFR 495.4 and 45 CFR 170.102 (regardless of whether the Certified EHR Technology has all four functionalities noted).

(2) Part D Electronic Prescribing Standards

Section 1848(m)(3)(B)(v) of the Act specifies that to the extent practicable, in determining whether an eligible professional is a successful electronic prescriber, ''the Secretary shall ensure that eligible professionals utilize electronic prescribing systems in compliance with standards established for such systems pursuant to the Part D Electronic Prescribing Program under section 1860D–4(e) of the Act''. The Part D standards for electronic prescribing systems establish which electronic standards Part D sponsors, providers, and dispensers must use when they electronically transmit prescriptions and certain prescription related information for Part D covered drugs that are prescribed for Part D eligible individuals.

To be a qualified electronic prescribing system under the eRx Incentive Program, electronic systems must convey the information listed previously using the standards currently in effect for the Part D electronic prescribing program. The latest Part D electronic prescribing standards, and those that had previously been adopted, can be found on the CMS Web site at *http://www.cms.gov/eprescribing.*

To ensure that eligible professionals utilize electronic prescribing systems that meet these requirements, the electronic prescribing measure requires that those functionalities required for a ''qualified'' electronic prescribing system are equivalent to the adopted Part D electronic prescribing standards. We proposed (76 FR 42889 and 42890) to modify the Part D electronic prescribing standards required for a ''qualified'' electronic prescribing system under the eRx Incentive Program to have these standards consistent with current, CMS Part D electronic prescribing standards.

The Part D electronic prescribing standards currently in place that are relevant to the four functionalities described previously are as follows:

• Generate medication list—Use the National Council for Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8 Release 1 or 10.6, October 2005 (hereinafter ''NCPDP SCRIPT 8.1 or 10.6'') Medication History Standard. Use of NCPDP SCRIPT 10.6 is a new option for use in the eRx Incentive Program.

• Transmit prescriptions electronically—Use the NCPDP SCRIPT 8.1or 10.6 for the transactions listed at § 423.160(b)(2).

• Provide information on lower cost alternatives—Use the NCPDP Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (hereinafter ''NCPDP Formulary and Benefits 1.0'').

• Provide information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan use:

++ NCPDP Formulary and Benefits 1.0 for communicating formulary and benefits information between prescribers and plans.

++ Accredited Standards Committee (ASC) X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010A1, October 2002, Washington Publishing Company, 004010X092A1 for communicating eligibility information between the plan and prescribers.

++ NCPDP Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 for communicating eligibility information between the plan and dispensers.

We did not receive any comments regarding our proposals related to part D electronic prescribing standards and therefore, we are finalizing our proposal that, for purposes of the 2012 and 2013 eRx Incentive Program, ''qualified'' electronic prescribing systems must meet all of the part D electronic prescribing standards specified.

Above, we specified the current Part D electronic prescribing standards that are relevant to the four functionalities. Should these Part D electronic prescribing standards subsequently change, we note that the eligible professional's electronic prescribing system must, at all times during the respective reporting period, comply with the current Part D electronic prescribing standards. For example, on October 24, 2011, CMS proposed to update some of the previously stated Part D electronic prescribing standards to the four functionalities (76 FR 65916). Specifically, CMS proposed to update

Accredited Standards Committee (ASC) X12N 270/271–Health Care Eligibility Benefit Inquiry and Response, Version 4010 to Version 5010. If CMS finalizes its proposal, an eligible professional's electronic prescribing system must comply with the Version 5010 update by the effective date that would be specified in the final rule.

There are Part D electronic prescribing standards that are in effect for functionalities that are not commonly utilized at this time. One example is Rx Fill Notification, which is discussed in the Part D electronic prescribing final rule (73 FR 18926). For purposes of the eRx Incentive Program for CYs 2012 through 2014, we again are not requiring that an electronic prescribing system contain all functionalities for which there are available Part D electronic prescribing standards since many of these functionalities are not commonly available. For those ''qualified'' electronic prescribing systems that have the four *functionalities previously described,* such systems must use the adopted Part D electronic prescribing standards listed previously for electronic messaging only.

There are other aspects of the functionalities for a ''qualified'' system that are not dependent on electronic messaging and are part of the software of the electronic prescribing system, for which Part D standards for electronic prescribing do not pertain and are not required for purposes of the eRx Incentive Program. For example, the requirements in the second functionality that require the system to allow professionals to select medications, print prescriptions, and conduct alerts are functions included in the particular software, for which Part D standards for electronic messaging do not apply.

As stated previously, in this final rule with comment period, we are finalizing our proposal to expand the definition of a ''qualified'' electronic prescribing system under the electronic prescribing quality measure to also recognize Certified EHR Technology. Among other requirements, Certified EHR Technology must be able to electronically generate and transmit prescriptions and prescription-related information in accordance with certain standards, some of which have been adopted for purposes of electronic prescribing under Part D. Similar to the electronic prescribing systems that have the four functionalities previously noted, Certified EHR Technology also must be able to check for drug-drug interactions and check whether drugs are in a formulary or a preferred drug list, although the certification criteria do not specify any standards for the performance of those functions. We believe that it is acceptable that not all of the Part D eRx standards are required for Certified EHR Technology in light of our desire to better align the requirements of the eRx and the Medicare EHR Incentive Programs, and potentially reduce unnecessary investment in multiple technologies for purposes of meeting the requirements for each program. Furthermore, to the extent that an eligible professional uses Certified EHR Technology to electronically prescribe under Part D, he or she would still be required to comply with the applicable Part D standards to do so.

f. Reporting Mechanisms for the 2012 and 2013 Reporting Periods

For purposes of the January 1, 2011 through December 31, 2011 reporting period for the 2011 incentive payment and 2013 payment adjustment, an eligible professional (and eRx GPRO, for purposes of the 2011 incentive) may report on the electronic prescribing measure to meet the criteria for being a successful electronic prescriber via three reporting mechanisms—claims, qualified registry, and qualified EHR product. However, for purposes of the 2012 payment adjustment, due to operational limitations, only the claims-based reporting mechanism was available for purposes of reporting on the electronic prescribing measure for the 2012 payment adjustment (75 FR 73563).

For reporting periods that occur during CY 2012 and 2013, to provide eligible professionals and groups practices with multiple mechanisms to report on the electronic prescribing measure for purposes of reporting the electronic prescribing measure for the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments, we proposed (76 FR 42890) the following three reporting mechanisms—claims, qualified registry, and qualified EHR (including both direct EHR-based reporting and EHR data submission vendors). However, as in the past, we indicated we would not combine data on the electronic prescribing measure submitted via multiple reporting mechanisms. Combining data received via multiple reporting mechanisms would add significant complexity to our analytics and potentially delay incentive payments. Therefore, we proposed that an eligible professional or eRx GPRO would need to meet the relevant reporting criteria for the incentive or payment adjustment using a single reporting mechanism.

For reporting periods that occur during CYs 2012 and 2013, we also proposed that a group practice that wishes to participate in the eRx Incentive Program as an eRx GPRO for a particular calendar year would have to indicate which reporting mechanism the group practice intends to use to report the electronic prescribing measure. That is, the group practice would need to indicate at the time it self-nominates which reporting mechanism (claims, qualified registry, qualified direct EHR-based reporting, or qualified EHR data submission vendor) the group practice intends to use for purposes of participating in the eRx GPRO.

The following is a summary of the comments we received regarding these proposals.

Comment: One commenter supported our proposal to allow multiple reporting mechanisms to report the electronic prescribing measure for purposes of the payment adjustment, particularly for those group practices that are transitioning to the use of EHR systems.

Response: We appreciate the commenter's feedback. We are finalizing the claims, registry, and EHR-based reporting mechanisms for the12-month reporting periods that apply to the 2012 and 2013 incentives and 2014 payment adjustment. However, because the EHR and/or registry would no longer need to search for the codes in the electronic prescribing measure's denominator for purposes of the 6-month reporting periods that apply to the 2013 and 2014 payment adjustments, CMS would need to be able to release new file specifications to reflect this change in time to reliably test the submission of the results from EHRs and registries prior to the actual data submission occurring in July. We will not be able to release the new file specifications in time to conduct this additional testing, which raises the chances of an eligible professional failing to successfully report through no fault of their own. Therefore, we are not finalizing the registry and EHR-based reporting mechanisms for the 6-month reporting periods pertaining to the 2013 and 2014 payment adjustments. In addition, we note that if we had allowed use of registry and EHR-based reporting for the 6-month reporting periods for the 2013 and 2014 payment adjustments, this would require registry and EHR vendors to submit electronic prescribing data for an additional instance during 2012 and 2013 (that is, in addition to the data submission for the 12-month reporting period). Since providing an additional submission instance of electronic prescribing data has not been a function of qualified registries and EHRs in past

program years, CMS would need to vet vendors to ensure their systems allow for interim submissions. At this time, it is not operationally feasible to vet these vendors to ensure their systems allow for a submission instance.

We do not believe that the lack of registry and EHR-based reporting mechanisms for the 6-month reporting periods for the 2013 and 2014 payment adjustments would substantially prevent eligible professionals and group practices from meeting the criteria for being successful electronic prescribers, because eligible professionals may still report on the electronic prescribing measure during these reporting periods via claims and via all three reporting mechanisms (claims, registry, and EHR) for the 12-month 2014 payment adjustment reporting period. We note that, according to the 2009 Reporting Experience available on our Web site at *www.cms.gov/eRxincentive/,* the claims-based reporting mechanism was the most widely used reporting mechanism in 2009. Therefore, it follows that we anticipate that most eligible professionals and group practices participating in the eRx Incentive Program for the 2013 and 2014 payment adjustment would do so via the claims-based reporting mechanism.

Comment: One commenter urged us to allow group practices participating in the eRx GPRO to change their method of reporting during the reporting period.

Response: We appreciate the commenter's feedback. However, because it would be a substantial operational burden to analyze group practice reporting via multiple reporting mechanisms, we must require that group practices choose only one method of reporting during the reporting period. Regardless, we note that all three reporting mechanisms—claims, registry, and EHR—are available for reporting under the eRx GPRO.

After considering the comments received and for the reasons stated in our responses, we are finalizing the following reporting mechanisms for the 12-month reporting periods for the 2012 and 2013 incentives, and the 2014 payment adjustment: claims, registry, and EHR. The requirements for each reporting mechanism with respect to the 2012 and 2013 incentives and 2013 and 2014 payment adjustments are described below. In this final rule, we also are finalizing the claims-based reporting mechanism for the 6-month reporting periods pertaining to the 2013 and 2014 payment adjustments; however, as we explained previously, we are not finalizing registry or EHR-based reporting for these 6-month reporting periods. We are therefore modifying 42 CFR 414.92 to reflect that only the claims-based reporting mechanism may be used for purposes of the 6-month 2013 and 2014 payment adjustment reporting periods.

(1) Claims-Based Reporting

For purposes of reporting the electronic prescribing quality measure for the 2012 and 2013 incentives and the 2013 and 2014 payment adjustments, we proposed (75 FR 42890 and 42891) to again retain the claims-based reporting mechanism that has been used since the implementation of the eRx Incentive Program in 2009. We did not propose any prerequisites, such as registration, to begin reporting on the electronic prescribing quality measure via claims. Retaining the claims-based mechanism allows eligible professionals and group practices to begin to report on the electronic prescribing quality measure without the added cost of submitting data to a registry or purchasing an EHR system (if the eligible professional is using a standalone eRx system) as eligible professionals already report PFS charges via claims.

The following is a summary of the only comment we received regarding this proposal.

Comment: One commenter urged us to continue to offer the claims-based reporting mechanism until the registry and EHR-based reporting mechanisms are widely used.

Response: We agree and are finalizing the claims-based reporting mechanism.

We are finalizing the claims-based reporting mechanism for purposes of reporting the electronic prescribing quality measure for the 2012 and 2013 incentives and the 2013 and 2014 payment adjustments. Accordingly, we are modifying 42 CFR 414.92 to reflect our decision to finalize this proposal.

In the proposed rule, we also proposed that if an eligible professional or group practice chooses the claims-based reporting mechanism, the eligible professional or group practice must directly submit data on the electronic prescribing quality measure (76 FR 42890). For eligible professionals and group practices participating in the eRx GPRO using the claims-based reporting mechanism for purposes of reporting the electronic prescribing measure during a 12-month incentive or payment adjustment reporting period, we proposed that all claims for services must be processed by us no later than two months after the respective reporting period, for the claim to be included in our data analysis. (For example, for an eligible professional using the 12-month, 2014 payment adjustment reporting period, all claims for services between January 1, 2012 and December 31, 2012 must be processed no later than February 22, 2013 to be included in our data analysis.) For eligible professionals and group practices using the claims-based reporting mechanism for purposes of reporting the electronic prescribing measure during a 6-month payment adjustment reporting period, we proposed that all claims for services must be processed by us by no later than one month after the respective reporting period, for the claim to be included in our data analysis. (For example, for an eligible professional using the 6-month, 2013 payment adjustment reporting period, all claims for services between January 1, 2012 and June 30, 2012 must be processed no later than July 27, 2012, for the claims to be included in our data analysis.) We invited but did not receive any public comment regarding the processing of claims. Therefore, for the reasons explained, we are finalizing these requirements. We believe that these requirements for using the claims-based reporting mechanism will allow sufficient time for eligible professionals to report the electronic prescribing measure, allow us to collect and analyze the data submitted by eligible professionals, and avoid retroactive adjustments of payments.

(2) Registry-Based Reporting

For purposes of reporting for the 2012 and 2013 incentives and the 2013 and 2014 payment adjustments, we proposed (76 FR 42891) to continue the registry-based reporting mechanism first introduced under the 2010 eRx Incentive Program. We believed this would provide an opportunity for individual eligible professionals and group practices who choose to participate in the Physician Quality Reporting System via registry to use the same reporting mechanism for reporting the electronic prescribing measure, and this would provide eligible professionals and group practices with another alternative reporting mechanism. In addition, unlike claims-based reporting, although there may be a cost associated with submitting data to a registry, reporting of the electronic prescribing measure to CMS is done entirely by the registry.

We also proposed that only registries qualified to submit quality measure results and numerator and denominator data on quality measures on behalf of eligible professionals for the Physician Quality Reporting System for the applicable calendar year would be qualified to submit measure results and numerator and denominator data on the

electronic prescribing measure on behalf of eligible professionals for the eRx Incentive Program.

Some registries that self-nominate to become a qualified registry for the Physician Quality Reporting System may not choose to self-nominate to become a qualified registry for purposes for the eRx Incentive Program. We proposed that registries that want to qualify would need to submit measure results and numerator and denominator data on the electronic prescribing measure for reporting periods that occur during CYs 2012 and 2013 at the time that they submit their self-nomination letter for the 2012 and 2013 Physician Quality Reporting System, respectively. The self-nomination process and requirements for registries for the Physician Quality Reporting System, which also will apply to the registries for the eRx Incentive Program, are discussed in the Physician Quality Reporting System section VI.F.1.(d).(2). of this final rule with comment period. We will post a final list of qualified registries for the eRx Incentive Program for CYs 2012 and 2013 on the eRx Incentive Program section of the CMS Web site at *http://www.cms.gov/ERXIncentive* when we post the final list of qualified registries for the Physician Quality Reporting System for 2012 and 2013 respectively on the Physician Quality Reporting System section of the CMS Web site.

Since we proposed a 12-month reporting period for purposes of the 2012 and 2013 incentive and 6 and 12-month reporting periods for purposes of the 2013 and 2014 payment adjustments (as described in the section previously), we further proposed that qualified registries would need to submit the electronic prescribing measure for the eRx Incentive Program to us in two separate transmissions, based on the proposed reporting periods for the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments. Specifically, we proposed that qualified registries would need to submit 2012 and 2013 data on the electronic prescribing measure in two separate submissions:

- Following the end of the respective 6-month payment adjustment reporting period (between July 1, 2012 and August 19, 2012, for purposes of the 2013 eRx payment adjustment, and between July 1, 2013 and August 19, 2013, for purposes of the 2014 eRx payment adjustment); and
- Following the end of the 12-month reporting period for the 2012 and 2013 incentives and 2014 payment adjustment.

We invited public comment but received no comments on our proposed requirements for registry-based reporting for purposes of reporting for the 2012 and 2013 incentives, as well as for reporting during the 6-month and 12-month reporting periods for the 2013 and 2014 payment adjustments. We are modifying 42 CFR 414.92 to finalize the requirements for registry-based reporting for purpose of the 12-month reporting periods for the 2012 and 2013 incentives, and the 2014 payment adjustment. As stated previously, due to the operational issues associated with ensuring that qualified registries are able to allow for an additional submission instance, we are not finalizing registry-based reporting for the 6-month reporting periods for the 2013 and 2014 payment adjustments, and therefore, are not finalizing the corresponding registry requirements that we proposed. Therefore, qualified registries must submit the electronic prescribing quality measure for the eRx Incentive Program to us in one transmission, for the 12-month reporting periods applicable for the 2012 and 2013 incentive payments and the 2013 and 2014 payment adjustments. Specifically, qualified registries must submit 2012 and 2013 data on the electronic prescribing quality measure following the end of the respective 12-month reporting period for the 2012 and 2013 incentives and the 2014 payment adjustment.

(3) EHR-Based Reporting

For purposes of reporting for the 2012 and 2013 incentives and the 2014 payment adjustment, we proposed (76 FR 42891–42892) to retain the EHR-based reporting mechanism to encourage the use of EHR technology as well as provide eligible professionals and group practices with a third reporting option. We proposed this reporting mechanism to provide an opportunity for eligible professionals and group practices who choose to participate in the Physician Quality Reporting System via EHR, as well as eligible professionals who participate in the Medicaid or Medicare EHR Incentive Program, to use the same reporting mechanism for reporting the electronic prescribing measure under the eRx Incentive Program.

We proposed that EHR technology and EHR data submission vendors (as described by the Physician Quality Reporting System) ''qualified'' to submit extracted Medicare clinical quality data to us for the Physician Quality Reporting System would be able to be used by an eligible professional or group practice to submit data on the electronic prescribing measure for the 2012 and 2013 incentives and 2014 payment adjustment. The proposed self-nomination process and requirements for direct EHR-based reporting products and EHR data submission vendors for the Physician Quality Reporting System as discussed previously the proposed rule (76 FR 42846) would apply to the EHR products and EHR data submission vendors for the eRx Incentive Program. We hoped this third reporting option for eligible professionals and group practices would encourage the use of EHR technology.

We also proposed that direct EHR-based reporting vendors and EHR data submission vendors must indicate their desire to have one or more of their EHR products approved for use in the eRx Incentive Program for the reporting periods that occur in CYs 2012 and 2013 at the same time they self-nominate for the respective 2012 and 2013 Physician Quality Reporting System. We further noted that a list of approved EHR technology, their vendors (including the technology's version that is approved) for the eRx Incentive Program would be posted on the eRx Incentive Program section of the CMS Web site at *http://www.cms.gov/ERXIncentive* when we posted the list of approved EHR technology for the Physician Quality Reporting System.

We also proposed that eligible professionals using their approved EHR systems must submit the electronic prescribing measure for the eRx Incentive Program to us in two separate submissions—

- Following the end of the respective 6-month payment adjustment reporting period (between July 1, 2012 and August 19, 2012, for purposes of the 2013 eRx payment adjustment, and between July 1, 2013 and August 19, 2013, for purposes of the 2014 eRx payment adjustment); and
- Following the end of the 12-month reporting period for the 2012 and 2013 incentives and 2014 payment adjustment.

Similarly, we proposed that EHR data submission vendors must submit the electronic prescribing measure to on behalf of eligible professionals to us in two separate submissions:

- Following the end of the respective 6-month payment adjustment reporting period (between July 1, 2012 and August 19, 2012, for purposes of the 2013 eRx payment adjustment, and between July 1, 2013 and August 19, 2013, for purposes of the 2014 eRx payment adjustment); and
- Following the end of the 12-month reporting period for the 2012 and 2013

incentives and 2014 payment adjustment.

We invited public comment but received no comments on our proposed requirements for EHR-based reporting for purposes of reporting for the 2012 and 2013 incentives and the 2013 and 2014 payment adjustments. As noted previously, however, we are not finalizing EHR-based reporting for the 6-month reporting periods for the 2013 and 2014 payment adjustments. Therefore, in this final rule with comment period, we are only finalizing the requirements discussed previously for reporting the electronic prescribing measure via the EHR-based reporting mechanism for the 12-month reporting period for the 2012 and 2013 incentives and the 2014 payment adjustment. We are modifying 42 CFR 414.92 to reflect these final requirements for EHR-based reporting.

g. The 2012 and 2013 eRx Incentives

42 CFR 414.92(d) governs the requirements for individual eligible professionals to qualify to receive an incentive payment. We proposed (76 FR 42892) to modify 42 CFR 414.92(d) to add the words ''being a,'' so that the provision reads:

In order to be considered a successful electronic prescriber and qualify to earn an electronic prescribing incentive payment (subject to paragraph (c)(3) of this section), an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for being a successful electronic prescriber under section 1848(m)(3)(B) of the Act and as specified by CMS during the reporting period specified in paragraph (d)(1) of this section and using one of the reporting mechanisms specified in paragraph (d)(2) of this section. Although an eligible professional may attempt to qualify for the electronic prescribing incentive payment using more than one reporting mechanism (as specified in paragraph (d)(2) of this section), the eligible professional will receive only one electronic prescribing incentive payment per TIN/NPI combination for a program year.

We invited but did not receive any public comment on our proposal to make the technical change to 42 CFR 414.92(d). Therefore, since we believe this change provides more clarity to the provision, we are finalizing this proposed change.

(1) Applicability of 2012 and 2013 eRx Incentives for Eligible Professionals and Group Practices

Section 1848(m)(2)(B) of the Act imposes a limitation on the applicability of the eRx incentive payment. The Secretary is authorized to choose 1 of 2 possible criteria for determining whether or not the limitation applies to an eligible professional (or group practice)—

- Whether Medicare Part B allowed charges for covered professional services furnished by the eligible professional (or group practice) for the codes to which the electronic prescribing quality measure applies are less than 10 percent of the total Medicare Part B PFS allowed charges for all such covered professional services furnished by the eligible professional during the reporting period; OR
- Whether the eligible professional submits (both electronically and non-electronically) a sufficient number (as determined by the Secretary) of prescriptions under Part D (which can, again, be assessed using Part D drug claims data). If the Secretary decides to use this criterion, the criterion based on the reporting on electronic prescribing measures would no longer apply.

Based on our proposal to make the determination of whether an eligible professional or group practice is a ''successful electronic prescriber'' based on submission of the electronic prescribing measure (the first criterion), we proposed (76 FR 42892) to apply the criterion under section 1848(m)(2)(B)(i) of the Act for the limitation for both the 2012 and 2013 incentives. We invited but received no public comment on our proposal. Therefore, the 2012 and/or 2013 incentive is not applicable if the Medicare Part B allowed charges for covered professional services furnished by the eligible professional (or group practice) for the codes to which the electronic prescribing quality measure applies are less than 10 percent of the total Medicare Part B PFS allowed charges for all covered professional services furnished by the eligible professional or group practice during the reporting period.

For purposes of the 2012 and 2013 incentives, this analysis would be performed during the first quarters of 2013 and 2014 respectively by dividing the eligible professional's or participating group practice's total 2012 and 2013 respective Medicare Part B PFS allowed charges for all such covered professional services submitted for the measure's denominator codes by the eligible professional's or group practices' total Medicare Part B PFS allowed charges for all covered professional services. If the result is 10 percent or more, then the statutory limitation will not apply and a successful electronic prescriber would qualify to earn the electronic prescribing incentive payment. If the result is less than 10 percent, then the statutory limitation will apply, and the eligible professional or group practice will not earn an electronic prescribing incentive payment even if he or she meets the reporting criteria for being a successful electronic prescriber. Although an individual eligible professional or group practice may decide to conduct his or her own assessment of how likely this statutory limitation is expected to apply to him or her before deciding whether or not to report the electronic prescribing measure, an individual eligible professional or group practice may report the electronic prescribing measure without regard to the statutory limitation for the incentive payment.

(2) Reporting Criteria for Being a Successful Electronic for the 2012 and 2013 eRx Incentives—Individual Eligible Professionals

Section 1848(m)(3)(D) of the Act authorizes the Secretary to revise the criteria for submitting data on the electronic prescribing measure under section 1848(m)(3)(B)(ii) of the Act, which requires the measure to be reported in at least 50 percent of the cases in which the measure is reportable.

For the 2012 and 2013 incentives, to maintain program consistency from year to year, we proposed (76 FR 42892) to make the determination of whether an individual eligible professional is a successful electronic prescriber for purposes of the incentive based on a count of the number of times (minimum threshold of 25) an eligible professional reports that at least one prescription created during the denominator-eligible encounter is generated using a qualified electronic prescribing system, which would include Certified EHR Technology (that is, reports the G8553 code when the eligible professional bills for one of the services included in the measure's denominator). We believe this criterion adequately addresses the goal of the eRx Incentive Program, specifically to promote the use of electronic prescribing systems.

We invited public comment on the proposed criteria for successful electronic prescriber and the following is a summary of the comments we received.

Comment: One commenter supported our proposed criteria for being a successful electronic prescriber for purposes of the 2012 and 2013 incentives, further stating that reporting the electronic prescribing measure for 25 unique visits is a reasonable and attainable threshold.

Response: We appreciate the commenter's feedback and are finalizing our proposal to base the determination of whether or not an eligible professional is a successful electronic

prescriber for the 2012 and 2013 incentives by reporting on the electronic prescribing measure for at least 25 unique visits.

Comment: A few commenters suggested that we reduce the number of times an eligible professional is required to report the electronic prescribing measure for purposes of the 2012 and 2013 incentives to 10 unique visits, similar to the reporting requirements for the 2013 and 2014 payment adjustments.

Response: We appreciate the commenters' feedback. However, we proposed this reporting criterion for the 2012 and 2013 incentives because the criterion parallels the criterion established for the 2011 incentive. We believe that it is in the eligible professional's best interest to provide uniform year-to-year reporting requirements for purposes of earning an incentive. In addition, we note that whereas the 10 count criteria for reporting the electronic prescribing measure for a payment adjustment applies to a 6-month reporting period, this 25 count criteria for earning an incentive applies to a 12-month reporting period. Since the requirement to report 25 times is based on a longer reporting period, we believe it is reasonable to require a higher reporting threshold for purposes of the 2012 and 2013 incentives, than what was required for the 2012 payment adjustment (which was based on a shorter, 6-month reporting period).

Comment: Several commenters encouraged us to align the reporting requirements for the 2012 and 2013 incentives with the reporting requirements for the 2013 and 2014 payment adjustments by allowing the reporting of the electronic prescribing measure's numerator for non-denominator-eligible visits.

Response: We appreciate the commenters' feedback. However, as we stated previously, we do not believe that the reporting criteria for becoming a successful electronic prescriber for the incentives and payment adjustments need to be identical. Rather, we believe that, although the incentives and payment adjustments were both implemented to encourage the use of electronic prescribing, the criteria to become a successful electronic prescriber for purposes of the 2012 and 2013 incentives should be more stringent.

After considering the comments received and for the reasons stated in our responses, for the 2012 and 2013 incentives, we are finalizing the criteria for being a successful electronic prescriber as proposed for individual eligible professionals . A summary of the finalized criteria for being a successful electronic prescriber for purposes of the 2012 and 2013 incentives are described in the following Tables 73 and 74.

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TABLE 72: CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2012 INCENTIVE– INDIVIDUAL ELIGIBLE PROFESSIONALS

Reporting Period	Reporting Mechanism	Criteria for Being a Successful Electronic Prescriber
Jan 1, 2012 – Dec 31, 2012	Claims	Report the electronic prescribing measure's numerator for at least 25 unique denominator-eligible visits
Jan 1, 2012 – Dec 31, 2012	Registry	Report the electronic prescribing measure's numerator for at least 25 unique denominator-eligible visits
Jan 1, 2012 – Dec 31, 2012	EHR (Direct EHR-based reporting & EHR Data Submission Vendor)	Report the electronic prescribing measure's numerator for at least 25 unique denominator-eligible visits

TABLE 73: CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2013 INCENTIVE– INDIVIDUAL ELIGIBLE PROFESSIONALS

Reporting Period	Reporting Mechanism	Criteria for Being a Successful Electronic Prescriber
Jan 1, 2013 – Dec 31, 2013	Claims	Report the electronic prescribing measure's numerator for at least 25 unique denominator-eligible visits
Jan 1, 2013 – Dec 31, 2013	Registry	Report the electronic prescribing measure's numerator for at least 25 unique denominator-eligible visits
Jan 1, 2013 – Dec 31, 2013	EHR (Direct EHR-based reporting & EHR Data Submission Vendor)	Report the electronic prescribing measure's numerator for at least 25 unique denominator-eligible visits

(3) Criteria for Being a Successful Electronic Prescriber 2012 and 2013 eRx Incentives—Group Practices

Under section 1848(m)(3)(B) of the Act, in order to qualify for the incentive payment, an eligible professional or group practice must be a ''successful electronic prescriber.'' To simplify the reporting criteria for group practices using the eRx GPRO used in prior years, we proposed (76 FR 42893) that, for the 2012 and 2013 incentive payments, to be a successful prescriber, a group practice using the eRx GPRO must report the electronic prescribing measure's numerator for at least 625 unique visits (for group practices comprised of 25–99 eligible professionals) or 2,500 unique visits (for group practices comprised of 100 or more eligible professionals) during the applicable reporting period. To obtain these reporting criteria, we multiplied the smallest group practice size for each respective threshold (that is, 25 for the first threshold and 100 for the second threshold) by the number of unique visits (25) an individual eligible professional must report on the electronic prescribing measure in order to qualify for an incentive payment. Although this may be a higher reporting threshold for group practices using the eRx GPRO comprised of 25–50 eligible professionals and group practices using the eRx GPRO comprised of 101–199 eligible professionals than in 2011, we believe it is still quite feasible for these group practices to meet the respective reporting threshold as this would be the reporting threshold should the members of the group practice choose to participate in the eRx Incentive Program as individual eligible professionals.

We invited but received no public comments on the proposed criteria for determining successful electronic prescribers for group practices reporting under the eRx GPRO reporting option for purposes of earning the 2012 and 2013 incentives. Therefore, we are finalizing the criteria as proposed. The

criteria for being successful electronic prescribers for group practices using the eRx GPRO reporting option for purposes of the 2012and 2013 incentive are summarized in the following Tables 75 and 76.

TABLE 74: CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2012 INCENTIVE– GROUP PRACTICES USING THE ERX GPRO REPORTING OPTION

Group Practice Size	Reporting Period	Reporting Mechanism	Criteria for Being a Successful Electronic Prescriber
25-99 eligible professionals	Jan 1, 2012 – Dec 31, 2012	Claims	Report the electronic prescribing measure's numerator for at least 625 unique denominator-eligible visits
25-99 eligible professionals	Jan 1, 2012 – Dec 31, 2012	Registry	Report the electronic prescribing measure's numerator for at least 625 unique denominator-eligible visits
25-99 eligible professionals	Jan 1, 2012 – Dec 31, 2012	EHR (Direct EHR-based reporting & EHR Data Submission Vendor)	Report the electronic prescribing measure's numerator for at least 625 unique denominator-eligible visits
100+ eligible professionals	Jan 1, 2012 – Dec 31, 2012	Claims	Report the electronic prescribing measure's numerator for at least 2,500 unique denominator-eligible visits
100+ eligible professionals	Jan 1, 2012 – Dec 31, 2012	Registry	Report the electronic prescribing measure's numerator for at least 2,500 unique denominator-eligible visits
100+ eligible professionals	Jan1, 2012 – Dec 31, 2012	EHR (Direct EHR-based reporting & EHR Data Submission Vendor)	Report the electronic prescribing measure's numerator for at least 2,500 unique denominator-eligible visits

TABLE 75: CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2013 INCENTIVE– GROUP PRACTICES USING THE ERX GPRO REPORTING OPTION

Group Practice Size	Reporting Period	Reporting Mechanism	Criteria for Being a Successful Electronic Prescriber
25-99 eligible professionals	Jan 1, 2013 – Dec 31, 2013	Claims	Report the electronic prescribing measure's numerator for at least 625 unique denominator-eligible visits
25-99 eligible professionals	Jan 1, 2013 – Dec 31, 2013	Registry	Report the electronic prescribing measure's numerator for at least 625 unique denominator-eligible visits
25-99 eligible professionals	Jan 1, 2013 – Dec 31, 2013	EHR (Direct EHR-based reporting & EHR Data Submission Vendor)	Report the electronic prescribing measure's numerator for at least 625 unique denominator-eligible visits
100+ eligible professionals	Jan 1, 2013 – Dec 31, 2013	Claims	Report the electronic prescribing measure's numerator for at least 2,500 unique denominator-eligible visits
100+ eligible professionals	Jan 1, 2013 – Dec 31, 2013	Registry	Report the electronic prescribing measure's numerator for at least 2,500 unique denominator-eligible visits
100+ eligible professionals	Jan 1, 2013 – Dec 31, 2013	EHR (Direct EHR-based reporting & EHR Data Submission Vendor)	Report the electronic prescribing measure's numerator for at least 2,500 unique denominator-eligible visits

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(4) No Double Payments

We are prohibited from making double payments under section 1848(m)(3)(C)(iii) of the Act, which requires that payments to a group practice shall be in lieu of the payments that would otherwise be made under the eRx Incentive Program to eligible professionals individually in the group practice for being a successful electronic prescriber. Accordingly, we proposed (76 FR 42893) to make incentive payments to group practices based on the determination that the group practice, as a whole, is a successful electronic prescriber for the respective program year. An individual eligible professional who is affiliated with a group practice participating in the eRx GPRO reporting option that meets the requirements of being a successful electronic prescriber under a group practice would not be eligible to earn a separate eRx incentive payment on the basis of the individual eligible professional meeting the criteria for successful electronic reporter at the individual level.

We invited but received no public comment on our proposal to prohibit double payments and are therefore finalizing this proposal. We also proposed to make a technical change to 42 CFR 414.92(g)(5)(ii) to modify ''another'' to ''a'' to clarify the provision. However, we inadvertently listed the wrong provision. The provision that we intended to modify was 42 CFR 414.92(e)(2)(ii). Since we believe this technical change will not substantively affect the regulation and believe this technical change will clarify this provision, we are making a technical change to modify ''another'' to ''a'' under 42 CFR 414.92(e)(2)(ii).

h. The 2013 and 2014 Electronic Prescribing Payment Adjustments

As previously stated, for 2012, 2013, and 2014, if the eligible professional is not a successful electronic prescriber for the reporting period for the year, the PFS amount for covered professional services furnished by such professionals during the year shall be less than the PFS amount that would otherwise apply by—

- 1.0 percent for 2012;
- 1.5 percent for 2013; and
- 2.0 percent for 2014.

We proposed (76 FR 42893) to modify 42 CFR 414.92 to provide further explanation of the requirements for individual eligible professionals and group practices for the 2013 and 2014 payment adjustment, as described later in this section. Paragraph 42 CFR 414.92(f) was designated to address ''public reporting of an eligible professional's or group practice's Electronic Prescribing Incentive Program data.'' However, we are redesignating this paragraph as 42 CFR 414.92(g). In its place, we are redesignating paragraph (f) so that 414.92(f) addresses the requirements for the 2013 and 2014 payment adjustments.

(1) Limitations to the 2013 and 2014 eRx Payment Adjustments—Individual Eligible Professionals

Whereas we believe that an incentive should be broadly available to encourage the widest possible adoption of electronic prescribing, even for low volume prescribers, we believe that a payment adjustment should be applied primarily to assure that those who have a large volume of prescribing do so electronically, without penalizing those for whom the adoption and use of an electronic prescribing system may be impractical given the low volume of prescribing. We proposed (76 FR 42893 through 42899) limitations on the applicability of the 2013 and 2014 payment adjustments. Specifically, we proposed that the 2013 and 2014 payment adjustments would not apply if:

- An eligible professional is not an MD, DO, podiatrist, nurse practitioner, or physician assistant as of June 30, 2012, for purposes of the 2013 payment adjustment and June 30, 2013, for purposes of the 2014 payment adjustment. Since these eligible professionals do not generally prescribe, we have excluded these eligible professionals from the eRx Incentive Program.

For purposes of determining whether an eligible professional is an MD, DO, podiatrist, nurse practitioner, or physician assistant we would use National Plan and Provider Enumeration System (NPPES) data. It is an eligible professional's responsibility to ensure that his or her primary taxonomy code in NPPES is accurate. However, in 2011, we also established a G-code, (G8644) that eligible professionals can use to report to us that they do not have prescribing privileges. We proposed to retain the reporting of this G-code for purposes of the 2013 and 2014 payment adjustments. For purposes of the 2013 payment adjustment, we proposed that eligible professionals who report this G-code must do so on a claim with dates of services during the 6-month reporting period (January 1, 2012 and June 30, 2012). For purposes of the 2014 payment adjustment, we proposed that eligible professionals who report this G-code must do so on a claim with dates of services during the 6-month reporting period (January 1, 2013 and June 30, 2013) so that we are able to distinguish whether a professional is reporting this G-code for the 2013 payment adjustment or the 2014 payment adjustment.

- The eligible professional's Medicare Part B allowed charges for covered professional services to which the electronic prescribing quality measure applies are less than 10 percent of the total Medicare Part B PFS allowed charges for all covered professional services furnished by the eligible professional during the respective payment adjustment reporting period. This is a required limitation under section 1848(m)(2)(B) of the Act. This calculation will be performed by dividing the eligible professional's total 2011 Medicare Part B PFS allowed charges for all such covered professional services submitted for the measure's denominator codes by the eligible professional's total Medicare Part B PFS allowed charges for all covered professional services (as assessed at the TIN/NPI level). If the result is 10 percent or more, then the statutory limitation will not apply. If the result is less than 10 percent, then the statutory limitation will apply. For the 12-month incentive and payment adjustment reporting periods, this calculation is expected to take place in the first quarter of the year following the reporting period (for example, in the first quarter of 2013 for the 12-month reporting period for the 2012 incentive). For the 6-month payment adjustment reporting period, this calculation is expected to take place within the calendar year for the respective 6-month reporting period (for example, within 2012 for the 6-month reporting period for the 2013 payment adjustment).

- An eligible professional does not have at least 100 cases (that is, claims for patient services) containing an encounter code that falls within the denominator of the electronic prescribing measure for dates of service during: the 6-month reporting period (January 1, 2012 through June 30, 2012) for the 2013 payment adjustment or the 6-month reporting period (January 1, 2013 through June 30, 2013) for the 2014 payment adjustment. If an eligible professional has less than 100 denominator-eligible instances in a 6-month period, this will be an indicator to us that the professional likely has a small Medicare patient population.

We invited but received no public comment on our proposed limitations to the 2013 and 2014 eRx payment adjustments for individual eligible professionals. Therefore, we are finalizing all of the above limitations to the 2013 and 2014 eRx payment adjustments for individual eligible professionals as proposed, as set forth at 42 CFR 414.92.

(2) Requirements for the 2013 and 2014 eRx Payment Adjustments—Individual Eligible Professionals

Section 1848(a)(5) of the Act requires a payment adjustment to be applied with respect to covered professional services furnished by an eligible professional in 2013 and 2014, if the eligible professional is not a successful electronic prescriber, as set forth in section 1848(m)(3)(B) of the Act, for the reporting period for the year. Section 1848(m)(3)(D) of the Act authorizes the Secretary to revise the criteria for submitting data on the electronic prescribing quality measure. In the 2011 PFS Final Rule with comment period, we established the same reporting criteria for being a successful electronic prescriber for purposes of the 2011 incentive and the 2013 payment adjustment, based on a 12-month reporting period in 2011 (75 FR 73565). In order to create another opportunity for an eligible professional to become a successful electronic prescriber for purposes of the 2013 payment adjustment, we proposed (76 FR 42894) that, based on the proposed 6-month reporting period, an eligible professional would be a successful electronic prescriber if he/she reports the electronic prescribing measure's numerator, that is, at least 1 prescription for Medicare Part B PFS patients was created during an encounter was generated and transmitted electronically using a qualified electronic prescribing system at least 10 times during the 6-month payment adjustment reporting period (that is, January 1, 2012 through June 30, 2012). Unlike the reporting criteria for the incentive payments where the numerator must be reported in connection with a denominator-eligible visit, for purposes of the 2013 and 2014 payment adjustments, we proposed that an eligible professional would be able to report the measure's numerator for any Medicare Part B PFS service provided during the reporting period, regardless of whether the code for such service appears in the denominator, because we recognize that eligible professionals may generate prescriptions during encounters that are not necessarily included in the measure's denominator.

We also sought to provide more than one opportunity for eligible professionals to avoid the 2014 payment adjustment by becoming a successful electronic prescriber. Therefore, consistent with the final criteria for successful electronic prescribing for purposes of the 2013 payment adjustment, we proposed (76 FR 42894 and 42895) the following criteria for an

eligible professional to be a successful electronic prescriber for purposes of the 2014 payment adjustment: (1) An eligible professional meets the criteria for the 2013 incentive, that is, reports that at least one prescription for a Medicare Part B PFS patient created during an encounter was generated and transmitted electronically using a qualified electronic prescribing system for at least 25 denominator-eligible encounters during the 12-month payment adjustment reporting period (that is, January 1, 2012 through December 31, 2012), or (2) An eligible professional reports the electronic prescribing measure's numerator (that is, that at least 1 prescription for a Medicare Part B PFS patient created during an encounter was generated and transmitted electronically using a qualified electronic prescribing system) at least 10 times during the 6-month payment adjustment reporting period (that is, January 1, 2013 through June 30, 2013).

As with the 2012 and 2013 incentive payments, we proposed that the determination of whether an eligible professional is subject to the payment adjustment would be made at the individual professional level, based on the NPI and for each unique TIN/NPI combination.

We proposed the previous criteria for being a successful electronic prescriber for purposes of the 2013 and 2014 payment adjustments because, aside from not requiring the reporting of the electronic prescribing measure's numerator for denominator-eligible encounters (which only applies to the 6-month, 2013 and 2014 payment adjustment reporting periods), they are consistent with the criteria for being a successful electronic prescriber for purposes of the 2012 and 2013 payment adjustments that were finalized in the CY 2011 PFS final rule with comment period (75 FR 73562 through 73565).

We invited public comment on the proposed criteria for being a successful electronic prescriber for the 2013 and 2014 payment adjustments for individual eligible professionals. The following is a summary of the comments received regarding these proposals.

Comment: Some commenters supported our proposal to simplify the payment adjustment reporting criteria by proposing criteria for the 2013 and 2014 payment adjustments (to report on the electronic prescribing measure's numerator for at least 10 unique visits during the respective 6-month reporting periods for the 2013 and 2014 payment adjustments) that are parallel to criteria established for the 2011 payment adjustment, aside from not requiring the reporting of the electronic prescribing measure's numerator for denominator-eligible encounters.

Response: We appreciate the commenters' support. For the 2013 and 2014 payment adjustments, we are finalizing the proposed reporting criteria for being a successful electronic prescriber for individual eligible professionals. Note that, for the 6-month reporting periods alone for 2013 and 2014 payment adjustments, eligible professionals are not required to report on an electronic prescribing event tied to a denominator-eligible encounter. Rather, eligible professionals may report on an electronic prescribing event for any unique visit.

Comment: Several commenters supported our proposal to allow reporting of the electronic prescribing measure for visits not associated with the electronic prescribing measure's denominator for purposes of the 2013 and 2014 payment adjustments.

Response: We appreciate the commenters' support of our proposal and are finalizing our proposal to allow for reporting of the electronic prescribing measure for visits not associated with the electronic prescribing measure's denominator for purposes of the 2013 and 2014 payment adjustments.

Comment: One commenter stated that the criteria we proposed for individual eligible professionals to become successful electronic prescribers for purposes of the 2013 and 2014 payment adjustment is too low. The commenter stated that, similar to the criteria required for achieving meaningful use under the EHR Incentive Program, we should require eligible professionals to report on at least 40 percent of all electronic prescriptions. At a minimum, the commenter believed the eligible professionals should use the 2012 and 2013 incentive criteria for purposes of the 2013 and 2014 payment adjustment.

Response: We appreciate the commenters' feedback. However, we proposed these criteria for being a successful electronic prescriber for the 2013 and 2014 payment adjustments because we believe these criteria achieve our goal of encouraging eligible professionals to utilize electronic prescribing systems. Furthermore, as we noted, we previously finalized criteria for being a successful electronic prescriber for the 2013 payment adjustment that are identical to the criteria finalized for the 2011 incentive. Likewise, we proposed and are finalizing criteria for becoming a successful electronic prescriber for the 2014 payment adjustment that are identical to the criteria we finalized for the 2012 incentive.

After considering the comments received and for the reasons stated above, we are finalizing the proposed criteria for individual eligible professionals to be successful electronic prescribers for purposes of the 2013 and 2014 payment adjustments. Specifically, for purposes of the 2013 payment adjustment, an individual eligible professional is a successful electronic prescriber if an eligible professional reports the electronic prescribing measure's numerator at least 10 times during the 6-month 2013 payment adjustment reporting period (that is, January 1, 2012 through June 30, 2012, regardless of whether the encounter is associated with at least one denominator code of the electronic prescribing measure). For purposes of the 2014 payment adjustment, an eligible professional is a successful electronic prescriber if: (1) An eligible professional reports that at least one prescription for Medicare Part B PFS patients created during an encounter was generated and transmitted electronically using a qualified electronic prescribing system for at least 25 denominator-eligible visits during the 12-month payment adjustment reporting period (that is, January 1, 2012 through December 31, 2012) (note that this is the same criteria for the 2013 incentive); or (2) an eligible professional reports the electronic prescribing measure's numerator at least 10 times during the 6-month payment adjustment reporting period (that is, January 1, 2013 through June 30, 2013). Tables 77 and 78 reflect the final criteria we are adopting in this final rule with comment period for being a successful electronic prescriber for an individual eligible professional for purposes of the 2013 and 2014 payment adjustments, respectively.

TABLE 76: CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2013 ERX PAYMENT ADJUSTMENT FOR THE 6-MONTH REPORTING PERIOD – INDIVIDUAL ELIGIBLE PROFESSIONALS*

Reporting Period	Reporting Mechanism	Reporting Criteria
12-month (Jan 1, 2011-Dec 31, 2011)*	Claims*	Reports on the 2011 electronic prescribing measure's numerator code at least 25 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2011 eRx incentive)*
12-month (Jan 1, 2011-Dec 31, 2011)*	Registry*	Reports on the 2011 electronic prescribing measure's numerator code at least 25 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2011 eRx incentive)*
12-month (Jan 1, 2011-Dec 31, 2011)*	EHR*	Reports on the 2011 electronic prescribing measure's numerator code at least 25 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2011 eRx incentive)*
6-month (Jan 1, 2012-Jun 30, 2012)	Claims	Report the electronic prescribing measure's numerator code at least 10 times (regardless of whether the encounter is associated with at least 1 of the denominator codes)

* Established in the CY 2011 PFS final rule with comment period.

TABLE 77. CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2014 ERX PAYMENT ADJUSTMENT – INDIVIDUAL ELIGIBLE PROFESSIONALS

Reporting Period	Reporting Mechanism	Reporting Criteria
12-month (Jan 1, 2012 - Dec 31, 2012)	Claims	Report the electronic prescribing measure's numerator code at least 25 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2013 eRx incentive)
12-month (Jan 1, 2012 - Dec 31, 2012)	Registry	Report the electronic prescribing measure's numerator code at least 25 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2013 eRx incentive)
12-month (Jan 1, 2012 - Dec 31, 2012)	EHR (Direct EHR-based reporting & EHR Data Submission Vendor)	Report the electronic prescribing measure's numerator code at least 25 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2013 eRx incentive)
6-month (Jan 1, 2013 - Jun 30, 2013)	Claims	Report the electronic prescribing measure's numerator code at least 10 times (regardless of whether the encounter is associated with at least 1 of the denominator codes)

(3) Requirements for the 2013 and 2014 eRx Payment Adjustments—Group Practices

Under section 1848(m)(3)(C) of the Act, we are also required to establish and have in place a process under which eligible professionals in a group practice shall be treated as a successful electronic prescriber for purposes of the payment adjustment. For purposes of the 2013 and 2014 payment adjustments, we proposed (76 FR 42895) that if a group practice chooses to participate in the eRx GPRO during CYs 2012 and 2013, respectively, then the group practice would be evaluated for applicability of the 2013 and 2014 payment adjustment as a group practice.

We proposed (76 FR 42895) an eRx GPRO would be a successful electronic prescriber for purposes of the 2013 payment adjustment if, during the 6-month reporting period (January 1, 2012 through June 30, 2012), a group practice reports the electronic prescribing measure's numerator (that is, that at least 1 prescription for Medicare Part B PFS patients created during an encounter was generated and transmitted electronically using a qualified electronic prescribing system) at least 625 times (for group practices comprised of 25 to 99 eligible professionals) or 2,500 times (for group practices comprised of 100+ eligible professionals).

Similarly, for the 2014 payment adjustment, we proposed (76 FR 42895) the following: A group practice would be a successful electronic prescriber if the group practice meets the 2012 criteria for being a successful electronic prescriber for purposes of the 2012 incentive payment. In other words, the group practice would need to report the electronic prescribing measure's numerator for at least 625 (for group practices comprised of 25 to 99 eligible professionals) or 2,500 (for group practices comprised of 100 or more eligible professionals) times for encounters associated with at least 1 of the denominator code that occurs between January 1, 2012 and December 31, 2012. In addition, we proposed that a group practice would also be a successful electronic prescriber for purposes of the 2014 payment adjustment if, during the 6-month reporting period (January 1, 2013 through June 30, 2013), a group practice reports the electronic prescribing measure's numerator (that is, that at least 1 prescription for Medicare Part B PFS patients created during an encounter was generated and transmitted electronically using a qualified electronic prescribing system) at least 625 times (for group practices with 25 to 99 eligible professionals) or 2,500 times (for group practices with 100+ eligible professionals).

We invited but received no public comments on the proposed criteria for being a successful electronic prescriber for group practices under the eRx GPROs for the 2013 and 2014 electronic prescribing payment adjustments. Therefore, we are finalizing our proposed criteria for the 2013 and 2014 payment adjustment as proposed. 79 and 80 summarize the criteria for being a successful electronic prescriber for a group practice for purposes of the 2013 and 2014 payment adjustments, respectively.

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TABLE 78: CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2013 ERX PAYMENT ADJUSTMENT FOR THE 6-MONTH REPORTING PERIOD – GROUP PRACTICES

Group Practice Size	Reporting Period	Reporting Mechanism	Reporting Criteria
25-99 Eligible Professionals	6-month (Jan 1, 2012 - Jun 30, 2012)	Claims	Report the electronic prescribing measure's numerator code at least 625 times
100+ Eligible Professionals	6-month (Jan 1, 2012 – Jun 30, 2012)	Claims	Report the electronic prescribing measure's numerator code at least 2,500 times

TABLE 79. CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2014 ERX PAYMENT ADJUSTMENT – GROUP PRACTICES USING THE ERX GPRO REPORTING OPTION

Group Practice Size	Reporting Period	Reporting Mechanism	Criteria
25-99 Eligible Professionals	12-month (Jan 1, 2012 – Dec 31, 2012)	Claims	Report the electronic prescribing measure's numerator for at least 625 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2012 eRx incentive)
25-99 Eligible Professionals	12-month (Jan 1, 2012 – Dec 31, 2012)	Registry	Report the electronic prescribing measure's numerator for at least 625 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2012 eRx incentive)
25-99 Eligible Professionals	12-month (Jan 1, 2012 – Dec 31, 2012)	EHR (Direct EHR-based reporting & EHR Data Submission Vendor)	Report the electronic prescribing measure's numerator for at least 625 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2012 eRx incentive)
100+ Eligible Professionals	12-month (Jan 1, 2012 – Dec 31, 2012)	Claims	Report the electronic prescribing measure's numerator for at least 2,500 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2012 incentive)
100+ Eligible Professionals	12-month (Jan 1, 2012 – Dec 31, 2012)	Registry	Report the electronic prescribing measure's numerator for at least 2,500 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2012 incentive)
100+ Eligible Professionals	12-month (Jan 1, 2012 – Dec 31, 2012)	EHR (Direct EHR-based reporting & EHR Data Submission Vendor)	Report the electronic prescribing measure's numerator for at least 2,500 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2012 incentive)
25-99 Eligible Professionals	6-month (Jan 1, 2013 - Jun 30, 2013)	Claims	Report the electronic prescribing measure's numerator code at least 625 times

Group Practice Size	Reporting Period	Reporting Mechanism	Criteria
100+ Eligible Professionals	6-month (Jan 1, 2013 - Jun 30, 2013)	Claims	Report the electronic prescribing measure's numerator code at least 2,500 times

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In addition, in accordance with the limitation under section 1848(m)(2)(B)(i) of the Act, the 2013 or 2014 payment adjustment does not apply to a group practice in which less than 10 percent of the group practice's estimated total allowed charges for the respective 6-month or 12-month payment adjustment reporting period are comprised of services which appear in the denominator of the 2012 or 2013 electronic prescribing measure. To be consistent with how this limitation is applied to group practices for purposes of the incentive, we proposed to determine whether this limitation applies to a group practice for the payment adjustment at the TIN level. Because we received no public comment on this proposal, we are finalizing this proposal as proposed.

(4) Significant Hardship Exemptions

Section 1848(a)(5)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment, if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship.

(A) Significant Hardship Exemptions

In the CY 2011 PFS final rule with comment period (75 FR 73564 through 75 FR 73565), we finalized two circumstances under which an eligible professional or eRx GPRO can request consideration for a significant hardship exemption for the 2012 eRx payment adjustment:

- The eligible professional or group practice practices in a rural area with limited high speed internet access.
- The eligible professional or group practice practices in an area with limited available pharmacies for electronic prescribing.

For the 2013 and 2014 payment adjustments, we proposed (76 FR 42896) to retain these two significant hardship exemption categories.

After publication of the CY 2011 PFS Final Rule with comment period, we received numerous requests to expand the categories under the significant hardship exemption for the payment adjustment. Some stakeholders recommended specific circumstances of significant hardship for our consideration (for example, eligible professionals who have prescribing privileges but do not prescribe under their NPI, eligible professionals who prescribe a high volume of narcotics, and eligible professionals who electronically prescribe but typically do not do so for any of the services included in the electronic prescribing measure's denominator), while others strongly suggested we consider increasing the number of specific hardship exemption categories. We believe that many of the circumstances raised by stakeholders may pose a significant hardship and limit eligible professionals and group practices in their ability to meet the requirements for being successful electronic prescribers either because of the nature of their practice or because of the limitations of the electronic prescribing measure itself, and as a result, such professionals might be unfairly penalized. Therefore, in the final rule entitled ''Medicare Program; Changes to the Electronic Prescribing (eRx) Incentive Program'' that was published in the September 6, 2011 **Federal Register**, (76 FR 54963), we expanded the categories under the significant hardship exemption for the 2012 payment adjustment. Because we believe the reasons why we expanded the categories under the significant hardship exemption for the 2012 payment adjustment also apply to the 2013 and 2014 payment adjustments, we proposed (76 FR 42896) to retain the following significant hardship exemptions for the 2013 and 2014 payment adjustments:

- Inability to electronically prescribe due to local, state, or Federal law or regulation
- Eligible professionals who prescribe fewer than 100 prescriptions during a 6-month, payment adjustment reporting period

(i) Inability to Electronically Prescribe Due to Local, State, or Federal Law or Regulation

We proposed (76 FR 42896–42897) that, to the extent that local, State, or Federal law or regulation limits or prevents an eligible professional or group practice that otherwise has general prescribing authority from electronically prescribing (for example, eligible professionals who prescribe a large volume of narcotics, which may not be electronically prescribed in some states, or eligible professionals who practice in a State that prohibits or limits the transmission of electronic prescriptions via a third party network such as Surescripts), the eligible professional or group practice would be able to request consideration for an exemption from application of the 2013 and/or 2014 payment adjustments, which would be reviewed on a case-by-case basis. We believe eligible professionals in this situation face a significant hardship with regard to the requirements for being successful electronic prescribers because while they may meet the 10 percent threshold for applicability of the payment adjustment, or the 100 denominator-eligible cases limit in a 6-month payment adjustment reporting period, they may not have sufficient opportunities to meet the requirements for being a successful electronic prescriber because Federal, State, or local law or regulation limit the number of opportunities that an eligible professional or group practice has to electronically prescribe.

(ii) Eligible Professionals Who Prescribe Fewer Than 100 Prescriptions During a 6-Month, Payment Adjustment Reporting Period

We proposed (76 FR 42897) that an eligible professional who has prescribing privileges, but prescribes fewer than 100 prescriptions during a 6-month, payment adjustment reporting period (for example, a nurse practitioner who may not write prescriptions under his or her own NPI, a physician who decides to let his Drug Enforcement Administration registration expire during the reporting period without renewing it, or, for purposes of the 2013 payment adjustment, an eligible professional who prescribed fewer than 100 prescriptions between January 1, 2012 and June 30, 2012 regardless of whether the prescriptions were electronically prescribed or not), yet

still meets the 10 percent threshold for applicability of the payment adjustment, would be able to request consideration for a significant hardship exemption from application of the 2013 and/or 2014 payment adjustment, which would be reviewed on a case-by-case basis. We believe that it is a significant hardship for eligible professionals who have prescribing privileges, but infrequently prescribe, to become successful electronic prescribers because the nature of their practice may limit the number of opportunities an eligible professional or group practice to prescribe, much less electronically prescribe.

We invited public comments on our proposal to modify 42 CFR 414.92 to include the significant hardship exemption categories we proposed for the 2013 and 2014 payment adjustments. The following is a summary of the comments we received.

Comment: Several commenters supported our proposed significant hardship exemption categories. Some commenters sought clarification on who may apply for significant hardship exemptions.

Response: We appreciate the commenters' feedback and are finalizing the proposed significant hardship exemption categories for the 2013 and 2014 payment adjustments. We have provided examples of who may potentially qualify for an exemption under each finalized significant hardship exemption category. However, we note that the examples provided are not exhaustive. Any eligible professional who believes he or she qualifies for an exemption under any of the significant hardship exemption categories may request consideration for an exemption.

Comment: Some commenters supported our specific proposal to adopt the significant hardship exemption category for eligible professionals who are unable to electronically prescribe due to local, State, or Federal law or regulation for the 2013 and 2014 payment adjustments.

Response: We appreciate the commenters' support. Based on the comments received and for the reasons explained in our responses, we are finalizing this significant hardship exemption category.

Comment: One commenter asked whether the significant hardship exemption category for eligible professionals who are unable to electronically prescribe due to local, State, or Federal law or regulation applies to physicians who cannot submit electronic prescriptions of controlled substances because their vendor software is not yet compliant with Federal and/or state requirement.

Response: We appreciate the commenter's question. Such a scenario may or may not fall under this particular significant hardship exemption category. As we indicated, this significant hardship exemption is aimed at addressing instances where an eligible professional would find it a significant hardship to submit a substantial portion of their prescriptions electronically because local, State, or Federal law or regulation limits or prevents an eligible professional or group practice that otherwise has general prescribing authority from electronically prescribing. Our analysis, however, is fact-specific, so we would need to look at the particular law, the details about why the professional's vendor software is in ''non-compliance'', and the professional's particular circumstances to determine whether a significant hardship exists and an exemption can be granted under this category. For example, we understand that the Drug Enforcement Agency (DEA) has proposed (75 FR 16236) but not yet finalized requirements for the transmission of electronic prescriptions of controlled substances, and that system vendors are awaiting these finalizing requirements so that its electronic prescribing systems may allow for the transmission of electronic prescriptions of controlled substances in a manner that is compliant with current Federal law. However, whether or not we would grant a exemption under this significant hardship exemption category would depend on the amount of controlled substances an eligible professional prescribes relative to other prescriptions. We also note that this significant hardship exemption category is not intended for eligible professionals to refrain from updating their respective electronic prescribing systems in order to qualify for and exemption under this significant hardship exemption category.

Comment: Some commenters specifically supported the proposed significant hardship exemption category for eligible professionals who prescribe fewer than 100 prescriptions during a 6-month, payment adjustment reporting period.

Response: We appreciate the commenters' support and are finalizing this significant hardship exemption category for purposes of the 2013 and 2014 payment adjustment.

Comment: One commenter suggested that we ensure that all physicians who cannot or do not write prescriptions be sufficiently accounted for in our proposed significant hardship exemption categories.

Response: We respectfully disagree. We believe the significant hardship exemptions, as well as the limitations we are finalizing for the 2013 and 2014 payment adjustments, adequately encompass the scenarios in which it would be a significant hardship to comply with the criteria for being successful electronic prescribers for the 2013 and/or 2014 payment adjustments.

Comment: Some commenters recommended additional significant hardship exemption categories to the 2013 and 2014 payment adjustments. Specifically, commenters requested the following be added as significant hardship exemption categories for the 2013 and 2014 payment adjustments: (1) Eligible professionals who are eligible for Social Security benefits or nearing retirement; (2) eligible professionals who work solely within skilled nursing facilities or hospital settings; (3) eligible professionals who attempted to report the electronic prescribing measure for purposes of the 2013 and 2014 payment adjustments but encountered problems when reporting the electronic prescribing measure; (4) eligible professionals who elect not to purchase an electronic prescribing system; and (5) eligible professionals whose patients prefer paper prescriptions.

Response: We appreciate the commenters' feedback but respectfully disagree. With respect to eligible professionals who are over 60, eligible for social security benefits, or nearing retirement; eligible professionals who work solely in skilled nursing homes or hospital settings; eligible professionals who experienced system problems when attempting to report the electronic prescribing measure; eligible professionals simply electing not to purchase an electronic prescribing system; or eligible professionals whose patients prefer paper prescriptions, most of these scenarios were raised by commenters during the comment period and addressed in the CY 2011 PFS final rule, as well as the 2011 ''Medicare Program; Changes to the Electronic Prescribing (eRx) Incentive Program'' final rule. As we stated in the CY 2011 PFS final rule (75 FR 73564) and the 2011 eRx final rule (76 FR 54962), we believe these instances do not constitute significant hardships in the manner that these significant hardship exemption categories that we are finalizing do. We believe that encouraging the use of electronic prescribing outweighs the cost of purchasing an electronic prescribing system, because we believe use of these systems will readily provide patient prescription history

leading to better management of patient prescriptions and greater patient safety and care.

Specifically, with respect to eligible professionals who are over 60, eligible for social security benefits, or nearing retirement, we believe that these eligible professionals still have the ability to use electronic prescribing systems. With respect to eligible professionals who practice off-site, such as those practicing in nursing homes, we note that although these eligible professionals may not readily have an electronic prescribing system available, these eligible professionals still have the ability to provide an electronic prescription. With respect to system errors, in general, we understand that problems may occur with regard to successful reporting of the eRx measure. However, we do not believe that such errors constitute a significant hardship under section 1848(a)(5)(B) of the Act. Rather, these are reporting errors that may have prevented an eligible professional from successfully reporting the eRx measure.

Comment: Commenters requested the following as additional significant hardship exemption categories for the 2013 and 2014 payment adjustments: Eligible professionals who plan to adopt EHR technology for purposes of participating in the EHR Incentive Program.

Response: With respect to providing a significant hardship exemption for eligible professionals planning to adopt Certified EHR Technology to participate in the EHR Incentive Program, we note that we finalized such a significant hardship exemption category for the 2012 payment adjustment because the certification and listing of certified EHR technologies (certified Complete EHRs and certified EHR Modules) on the ONC Certified HIT Products List (CHPL) did not begin until September 2010 (76 FR 54957). As such, eligible professionals may have delayed purchasing an EHR system. This is no longer the case. The list of Certified EHR Technology has been available for over a year, and the EHR Incentive Program has been implemented. Therefore, we believe that this significant hardship exemption category is no longer applicable to the 2013 and 2014 payment adjustments.

Comment: Commenters requested the following additional significant hardship exemption categories for the 2013 and 2014 payment adjustments: Eligible professionals who report the electronic prescribing measure at least 10 times during CYs 2012 and 2013 for the 2013 and 2014 respective payment adjustments, but did not do so during the first 6-months of 2012 and 2013.

Response: We disagree with commenters suggestion for this significant exemption hardship category, because it would be contrary to the reporting periods we are finalizing for the 2013 and 2014 payment adjustments.

Based on the comments received and for the reasons stated in our responses, we are finalizing the following significant hardship exemption categories for the 2013 and 2014 payment adjustments, which will be reflected under 42 CFR 414.92:

- The eligible professional or group practice practices in a rural area with limited high speed internet access.
- The eligible professional or group practice practices in an area with limited available pharmacies for electronic prescribing.
- Inability to electronically prescribe due to local, state, or Federal law or regulation.
- Eligible professionals who prescribe fewer than 100 prescriptions during a 6-month, payment adjustment reporting period.

(B) Process for Submitting Significant Hardship Exemptions—Individual Eligible Professionals and Group Practices

To request a significant hardship exemption for any of the proposed categories, we proposed (76 FR 42897) that an eligible professional provide to us by the end of the 2013 and/or 2014 payment adjustment reporting periods (that is June 30, 2012 for the 2013 payment adjustment and June 30, 2013 for the 2014 payment adjustment), the following:

- The name of the practice and other identifying information (for example: TIN, NPI, mailing address, and email address of all affected eligible professionals.
- The significant hardship exemption category(ies) that apply.
- A justification statement describing how compliance with the requirement for being a successful electronic prescriber for the respective 2013 and/or 2014 payment adjustment during the reporting period would result in a significant hardship to the eligible professional. And that the justification statement be specific as to the category under which the eligible professional or group practice is submitting its request and include an explanation how the exemption applies.
- An attestation of the accuracy of the information provided.

We also proposed that eligible professionals or group practices would be required, upon request, to provide additional supporting documentation if there is insufficient information to justify the request or make the determination whether a significant hardship exists.

We also proposed that eligible professionals or group practices would be able to submit significant hardship exemption requests using the web-based tool or interface (that we are also using for requests for exemptions due to significant hardships for the 2012 payment adjustment). We proposed that the following two hardships also be reportable by G-code on claims in addition to using the web-based tool or interface:

- The eligible professional or group practice practices in a rural area with limited high speed internet access (report G-code G9642).
- The eligible professional or group practice practices in an area with limited available pharmacies for electronic prescribing (report G-code G8643).

We also proposed that once we have completed our review of the eligible professional's or group practice's request and made a decision, we will notify the eligible professional or group practice of our decision and all such decisions would be final. Eligible professionals or group practices will not have the opportunity to request reconsiderations of their requests for significant hardship exemption. We invited public comment on the proposed process for individual eligible professionals and group practices for submitting these requests for significant hardship exemptions to us (including comments on the type of information we proposed eligible professionals must submit, the proposed options for how the information could be submitted, and the proposed timeframes for submission). The following is a summary of the comments received related to our proposed process for submitting requests for significant hardship exemptions.

Comment: Some commenters support the use of a web-based tool whereby eligible professionals and group practices may submit requests for significant hardship exemptions.

Response: We appreciate the commenter's feedback and are finalizing our proposal to allow for use of a web-based tool to submit requests for significant hardship exemption requests. Eligible professionals wishing to request a significant hardship exemption to the 2013 and 2014 payment adjustments may do so through the Communications Support Page, available at *https://www.qualitynet.org/portal/server.pt/community/communications_support_system/234.*

Comment: One commenter urged us to allow for the submission of significant hardship requests via other methods aside from a web-based tool, such as via telephone, because eligible professionals requesting significant hardship exemptions may not have access to the internet.

Response: We appreciate the commenter's feedback. However, we believe that the web-based tool provides the most efficient method of submitting a significant hardship request. In limited instances where eligible professionals may not be able to submit a significant hardship request via the web-based tool due to lack of internet access, eligible professionals may call the QualityNet Help Desk for assistance on requesting a hardship.

Comment: One commenter suggested that, although eligible professionals need only request one significant hardship exemption, eligible professionals may apply for more than one significant hardship exemption request if more than one category applies.

Response: If an eligible professional believes that more than one significant hardship exemption category applies to his/her practice, s/he must request a significant hardship exemption under at least one significant hardship exemption category. However, the eligible professional may indicate that more than one significant hardship exemption category applies to his or her practice in the eligible professional's justification statement.

Comment: A few commenters suggested that we extend the deadline to submit significant hardship exemptions for purposes of the 2013 and 2014 payment adjustment, noting that we provided an extended deadline to submit significant hardship exemption requests for purposes of the 2012 payment adjustment.

Response: We did finalize an extended deadline of November 1, 2011 to submit requests for significant hardship exemptions for the 2012 payment adjustment (76 FR 54964). We note, however, that the extension of the deadline for submitting requests for significant hardship exemptions for the 2012 payment adjustment was a unique situation, as new significant hardship exemption categories were finalized after the publication of the 2011 PFS Final Rule. However, we also noted that, due to the deadline extension, we may have to reprocess claims in instances where significant hardship requests were not reviewed in time. We believe that the deadlines we proposed for submitting requests for significant hardship exemptions for the 2013 and 2014 payment adjustments (that is, June 30, 2012 and June 30, 2013 respectively) provide eligible professionals with ample time to submit requests for significant hardship exemptions. Therefore, we are finalizing our proposed deadlines for submitting requests for significant hardship exemptions from the 2013 and 2014 payment adjustments. We note that, although we are making every attempt to do so, there is a possibility we may not have the Communications Support Page available for submitting requests for significant hardship exemptions by January 1, 2012. We do not expect that such a delay would adversely affect eligible professionals because, although eligible professionals may need time to prepare and develop its request (and that time remains unchanged), the time needed to actually submit the request through the Web page should not take a substantial amount of time (that is, we would not expect that it would take an eligible professional 6 months to do a single web-based submission). We recognize, however, that eligible professionals may not want to be limited with regard to the particular day(s) it submits its request before the deadline. Therefore, in the event there is a delay in making the Communication Support Page available for submitting requests for significant hardship exemptions, we may extend the deadline for submitting requests for significant hardship exemptions for the 2013 payment adjustment.

Based on the comments received and for the reasons stated previously, we are finalizing the following process for submitting a request for a significant hardship exemption under the significant hardship exemption categories we are finalizing for the 2013 and 2014 payment adjustments.

Eligible professionals and group practices may report the following G-codes for the following significant hardship exemption categories on claims for services rendered during the respective 2013 and 2014 6-month reporting periods.

- The eligible professional or group practice practices in a rural area with limited high speed internet access (report G-code G9642).
- The eligible professional or group practice practices in an area with limited available pharmacies for electronic prescribing (report G-code G8643).

Eligible professionals may submit requests for a significant hardship exemption category with respect to any of the finalized significant hardship exemption categories via a web-based tool, the Communication Support Page, which is available at *https://www.qualitynet.org/portal/server.pt/community/communications_support_system/234.* More information on this web-based tool is available on our Web site at *http://www.cms.gov/ERXincentive/.* To request a significant hardship exemption via the web-based tool for any of the categories we are finalizing, including a request under the two significant hardship exemptions categories that are also reportable via G-code, an eligible professional must provide to us by June 30, 2012 for the 2013 payment adjustment and June 30, 2013 for the 2014 payment adjustment, the following—

- The name of the practice and other identifying information (for example: TIN, individual NPI, mailing address, and email address of all affected eligible professionals;
- The significant hardship exemption category(ies) that apply;
- A justification statement describing how compliance with the requirement for being a successful electronic prescriber for the respective 2013 and/or 2014 payment adjustment during the reporting period would result in a significant hardship to the eligible professional; and
- An attestation of the accuracy of the information provided—

++ The justification statement should be specific to the category under which the eligible professional or group practice is submitting its request and must explain how the exemption applies to the professional. For example, if the eligible professional is requesting a significant hardship exemption due to Federal, State, or local law or regulation, he or she must cite the applicable law and how the law restricts the eligible professional's ability to electronically prescribe. We will review the information submitted by each eligible professional on a case-by-case basis. In addition, an eligible professional or group practice must, upon request, provide additional supporting documentation if there is insufficient information (such as, but not limited to, a TIN or NPI that we cannot match to the Medicare claims, a certification number for the Certified EHR Technology that does not appear on the list of Certified EHR Technology, or an incomplete justification for the significant hardship exemption request) to justify the request or make the determination of whether a significant hardship exists.

G. Physician Compare Web Site

1. Background and Statutory Authority

Section 10331(a)(1) of the Affordable Care Act (42 U.S.C. 1395w–5 note) requires that, by no later than January 1, 2011, we develop a Physician Compare Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act as well as information on other eligible professionals who participate in the Physician Quality Reporting System under section 1848 of the Act (42 U.S.C. 1395w–4). Public reporting of performance results on standardized quality measures currently exists on *http://www.medicare.gov* for the following:

- Hospitals (Hospital Compare).
- Dialysis facilities (Dialysis Facility Compare).
- Nursing homes (Nursing Home Compare).
- Home health facilities (Home Health Compare).

As an initial step towards providing information on the quality of care for services furnished by physicians and other professionals to Medicare beneficiaries, we have enhanced the existing Physician and Other Health Care Professionals directory at *http://www.medicare.gov* to develop a similar Compare Web site specific to physicians and other professionals. In accordance with section 10331 of the Affordable Care Act, we launched the first phase of the Physician Compare Internet Web site on December 30, 2010. This initial phase included the posting of the names of eligible professionals that satisfactorily submitted quality data for the 2009 Physician Quality Reporting System.

2. Final Plans

Section 10331(a)(2) of the Affordable Care Act also requires that, no later than January 1, 2013, and with respect to reporting periods that begin no earlier than January 1, 2012, we implement a plan for making information on physician performance publicly available through the Physician Compare Web site. To the extent that scientifically sound measures are developed and are available, we are required to include, to the extent practicable, the following types of measures for public reporting:

- Measures collected under the Physician Quality Reporting System.
- An assessment of patient health outcomes and functional status of patients.
- An assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use.
- An assessment of efficiency.
- An assessment of patient experience and patient, caregiver, and family engagement.
- An assessment of the safety, effectiveness, and timeliness of care.
- Other information as determined appropriate by the Secretary.

As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan, we must include, to the extent practicable, the following:

- Processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary.
- Processes for physicians and eligible professionals whose information is being publically reported to have a reasonable opportunity, as determined by the Secretary, to review their results before posting to Physician Compare.
- Processes to ensure the data published on Physician Compare provides a robust and accurate portrayal of a physician's performance.
- Data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent applicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance.
- Processes to ensure appropriate attribution of care when multiple and other providers are involved in the care of the patient.
- Processes to ensure timely statistical performance feedback is provided to physicians concerning the data published on Physician Compare.
- Implementation of computer and data infrastructure and systems used to support valid, reliable, and accurate reporting activities.

Section 10331(d) of the Affordable Care Act requires us to consider input from multi-stakeholder groups in selecting quality measures for Physician Compare. In developing the plan for making information on physician performance publicly available through the Physician Compare Web site, section 10331(e) of the Affordable Care Act requires the Secretary, as the Secretary deems appropriate, to consider the plan to transition to value-based purchasing for physicians and other practitioners that was developed under section 131(d) of the Medicare Improvements for Patients and Providers Act of 2008.

We are required, under section 10331(f) of the Affordable Care Act, to submit a report to the Congress by January 1, 2015 on the Physician Compare Web site developed, and include information on the efforts and plans to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice. Section 10331(g) of the Affordable Care Act provides that any time before that date, we may continue to expand the information made available on Physician Compare.

We believe section 10331 of the Affordable Care Act supports our overarching goals to foster transparency and public reporting by providing consumers with quality of care information to make informed decisions about their health care, while encouraging clinicians to improve on the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, we intend to utilize the Physician Compare Web site to publicly report physician performance results.

For purposes of implementing a plan to publicly report physician performance, we plan to use data reported under the existing Physician Quality Reporting System as an initial step for making public physician ''measure performance'' information on Physician Compare. By ''measure performance,'' we mean the percent of times that a particular clinical quality action was reported as being performed, or a particular outcome was attained, for the applicable persons to whom a measure applies as described in the denominator for the measure.

The Physician Quality Reporting System is a readily available source of measures performance data. First implemented in 2007, the program has grown to include over 200 measures (see tables 47 through 72 in section VI.F.1.f. of this final rule with comment period for a list of the measures available for reporting in 2012). The measures used in the Physician Quality Reporting System cover a wide range of health conditions and topics and include measures applicable to most physician specialties and other clinicians. Work is underway to ensure consistency of quality measures reported under the Physician Quality Reporting System and the EHR Incentive Program.

The first phase of the plan to make information on physicians and other eligible professionals who participate in the Physician Quality Reporting System publically available was completed through the launch of the Physician Compare Web site and the posting of the names of those eligible professionals who satisfactorily participated in the Physician Quality Reporting System.

During the second phase of the plan, occurring in 2011 through 2012, we will continue to work towards the development and improvement of the Web site. Our plans for Physician Compare Web site development during this second phase include monthly data refreshes and a semiannual Web site release to incorporate updates and improvements to the Web site. Updates will include the addition of the names of eligible professionals who are successful electronic prescribers, as required by section 1848(m)(5)(G) of the Act, as well as the names of those eligible professionals who participate in the EHR Incentive Program, as required by section 1848(o)(3)(D) of the Act. Additional enhancements planned include the addition of links to specialty board Web sites that can provide more information on an eligible professional's board certification status and improved Web site functionality and layout.

Moving towards the reporting of physician performance information, we proposed to take an initial step by making public the performance rates of the quality measures that group practices submit under the 2012 Physician Quality Reporting System group practice reporting option (GPRO) (76 FR 42899). We also proposed to publicly report the performance rates of the quality measures that the group practices participating in the Physician Group Practice demonstration report on the Physician Compare Web site as early as 2013 for performance information collected in CY 2012. We would make public the measure performance for each of the measures included in the 2012 Physician Quality Reporting System GPRO. Since the quality measures in GPRO are reported for the group as a whole, the information on measure performance would also apply to the group as a whole, rather than to individual physicians within a group.

Public reporting of the group practices' 2012 measure performance results at the group practice level would begin public reporting at the earliest time specified by the statute. We believe the design of the GPRO (see section VI.F.b.2. of this final rule with comment pe) facilitates making public groups' performance results. All groups participating in the GPRO would be reporting on the same set of clinical quality measures, which allows for comparison of the results across groups.

To eliminate the risk of calculating performance rates based on a small denominator, we proposed to set a minimum patient sample size threshold (76 FR 42899). A minimum threshold of 25 patients would have to be met in order for the group practice's measure performance rate to be reported on the Physician Compare Web site. If the threshold of 25 patients is not met for a particular measure, the group's performance rate for that measure would be suppressed and not publicly reported. In determining the minimum patient sample size, we took into consideration the minimum patient sample size used by other Compare Web sites that publicly report measure performance data. We wanted to ensure that we used a number large enough to accurately reflect measure performance, but not so large that it would limit the number of groups for which measure performance could be reported. In taking into consideration the minimum patient sample size used by other Compare Web sites that publicly report measure performance data, we also considered a minimum patient sample size of 10 patients, 20 patients and 30 patients. As we are proposing to report measure performance at a group level and a majority of the other Compare Web sites use minimum sample sizes of between 20 and 30 patients, we concluded that a minimum patient sample size of 25 would meet our criteria (76 FR 42899).

We also proposed that group practices participating in the 2012 Physician Quality Reporting System GPRO would agree in advance to have their reporting performance results publicly reported as part of their self-nomination to participate in the 2012 Physician Quality Reporting System GPRO. Finally, we proposed to modify the GPRO web interface for 2012 to calculate the numerator, denominator, and measure performance rate for each measure from the data that the group practices use to populate the tool and provide each group practice this information at the time of data submission. This feature would allow the group practice the opportunity to review their measure performance results before they are made public in accordance with section 10331(b) of the Affordable Care Act. For groups reporting using GPRO information that is made public in 2013, we did not propose to post information with respect to the measure performance of individual physicians or eligible professionals associated with the group. However, we proposed to identify the individual eligible professionals who were associated with the group during the reporting period.

We believe a staged approach to public reporting of physician information allows for the use of information currently available while we develop the infrastructure necessary to support the collection of additional types of measures and public reporting of individual physicians' quality measure performance results. Implementation of subsequent phases of the plan will need to be developed and addressed in future notice and comment rulemaking, as needed. We invited comments regarding our proposals to: (1) To publicly report group practices' measure performance results in 2013 based on group practices' 2012 Physician Quality Reporting System performance results under GPRO; and (2) utilize a minimum patient sample size of 25 for reporting and displaying measure performance on the Physician Compare Web site.

We received several comments from the public on the CY 2012 PFS proposed rule related to the Physician Compare Web site. General comments about the Physician Compare Web site are addressed as follows.

Comment: CMS received positive feedback supporting our staged approach to developing the Physician Compare Web site, including improvements planned for our second phase development and public reporting of physician information and performance.

Response: We appreciate the commenters' positive feedback. We believe a staged approach to the Web site development and public reporting of physician information and performance will allow us to use the information currently available while we continue to work towards improvement of the Web site and develop the infrastructure necessary to support the collection of additional types of information and measures.

Comment: CMS received several comments expressing concerns over the accuracy of the physician information currently being displayed on the Physician Compare Web site. Specifically, the comments mentioned inaccuracies around basic physician information, specialties, licensure, and practice location/affiliation. Commenters urged CMS to validate the accuracy of successful participation in the various CMS quality measure reporting programs.

Response: We appreciate the commenters' feedback. We are committed to including accurate and up-to-date provider information on the Physician Compare Web site and continue to work towards the necessary steps to make improvements. We look forward to engaging the provider community toward that end. The provider information used to populate the Physician Compare Web site comes from the Provider Enrollment, Chain, and Ownership System (PECOS) and an

external data source. In order for a physician or other health care professional's information to appear on the Physician Compare Web site, their enrollment record in PECOS must be current and in ''approved'' status, a valid physical location or address must be identified and the provider must have a valid State license and NPI. There is a 45–60 day lag for new enrollment, updates, and changes to take place in PECOS. Currently, physicians and eligible professionals can find instructions on how to update and correct their information on the Physician Compare Web site under the ''Note to Provider'' section located on the ''About the Data'' page. In general, most updates or corrections to provider information can be made through PECOS, either via Internet-based PECOS or a paper process. Corrections can also be requested through the Web site's feedback tool function.

Comment: CMS also received several comments expressing concern around the eventual reporting of measures performance on the Physician Compare Web site. These comments included general concerns about the accuracy of the data to be reported, as well as specific concerns regarding the lack of measures available to assess safety, effectiveness and timeliness of care, and continuity and coordination of care. Several comments stated that CMS must ensure that measure performance data is properly attributed to the correct provider or practice and that data is risk adjusted.

Response: We appreciate the commenters' feedback. As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan to include performance data on Physician Compare, we must include, to the extent practicable, processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary, as well as processes to ensure appropriate attribution of care when multiple and other providers are involved in the care of the patient. We are committed to working towards reported measures that are accurate and complete.

Comment: Several commenters urged CMS to provide a specific mechanism whereby providers can report and correct data errors. Many commenters suggested that a 30-day timeframe to correct errors should be implemented by CMS.

Response: We appreciate the commenters' feedback. Through regular data refreshes, CMS is working toward more accurate and up-to-date information on Physician Compare. We intend to conduct monthly refreshes and semi-annual updates as technically feasible. We look forward to engaging with providers and stakeholders to further address these concerns.

Comment: CMS received comments urging CMS to develop appropriate disclaimer language to note potential issues with accuracy and to avoid any misinterpretation of data. Many of the comments requested that CMS work with the provider community to develop disclaimers and one comment suggested the use of a ''splash page'' whereby Web site users would have to read the disclaimer and ''accept'' before seeing the data.

Response: We appreciate the commenters' feedback. We look forward to the opportunity to work with providers and external stakeholders and discuss options for presenting performance information in a way that is accurate and understood by consumers. CMS will take the idea of creating a disclaimer ''splash page'' into consideration. Currently, the Physician Compare Web site has disclaimer language to explain that the Physician Quality Reporting System is a voluntary program. The disclaimer includes some of the numerous reasons why physicians or other healthcare professionals, who are committed to providing high quality care to their patients, may have chosen not to report quality information under the Physician Quality Reporting System.

Comment: One commenter expressed concern over whether a psychiatrist's performance can ever be accurately reflected on Physician Compare because many of the measure categories prescribed by the Affordable Care Act (*i.e.,* patient health outcomes and functional status, continuity and coordination of care and care transitions, patient experience and patient, caregiver, and family engagement, etc.) fail to account for environmental factors affecting patient outcomes.

Response: We appreciate the commenter's feedback. CMS is committed to working with providers and external stakeholders toward the aim of presenting accurate performance data on Physician Compare, and the various specialties represented therein. CMS recognizes that measures around patient outcomes, patient experience, etc. are inherently dependent on patient factors and this is not unique to psychiatry. As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan to include performance data on Physician Compare, we must include, to the extent practicable, processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary. As such, CMS will need to account for patient factors affecting patient outcomes through risk-adjustment, exclusions, and/or appropriate disclaimer language to explain how patient factors beyond the control of the physician or other eligible professional can affect patient outcomes.

Comment: One commenter urged CMS to assure that the physician information provided to the public on the Physician Compare Web site is based on quality data and not cost and claims data.

Response: We appreciate the commenters' feedback. As we proposed in the proposed rule (76 FR 42899) and are finalizing below, CMS will only publicly report group practices' measure performance results in 2013 based on group practices' 2012 Physician Quality Reporting System performance results under GPRO at this time. We did not propose to make cost and claims data public.

Comment: One commenter stated that implementation of the Physician Compare Web site is intertwined with Section 3003 of the Affordable Care Act, which requires Medicare to confidentially report both quality and cost data to individual physicians and groups. The commenter expressed concerns over the public reporting of ''confidential'' data and urged CMS to clarify what, if any, ''confidential'' information it plans to make available to the public.

Response: We appreciate the commenters' feedback. The Physician Compare Web site is mandated by section 10331 of the Affordable Care Act, which authorizes CMS to publicly report information on physician performance. Section 3003 of the Affordable Care Act amends a separate program, the Physician Feedback Program. While these two sections both address quality data, section 10331 does not classify the quality data as ''confidential.'' In this final rule, we are finalizing our proposal to publicly report group practices' measure performance results in 2013 based on group practices' 2012 Physician Quality Reporting System performance results under GPRO. Section 10331 of the Affordable Care Act also requires CMS to include, to the extent practicable, measures collected under the Physician Quality Reporting System. Based on established CMS data security procedures and as otherwise required by law, all patient data will be confidential

and protected. Therefore, on the Physician Compare Web site, patient data will be aggregated and no patient identifiers will be made public.

Comment: One commenter urged CMS to develop public reporting formats that are consistent with established public reporting formats (that is, Consumer Union).

Response: We appreciate the commenters' feedback. We will take into consideration the idea of using a data report format for Physician Compare consistent with established formats, as feasible. We look forward to engaging providers, stakeholders, and consumers in further considering this issue.

Comment: One commenter expressed that they would like to review how CMS intends to integrate data from other payers.

Response: We appreciate the commenters' feedback. In this final rule, we are finalizing our proposal to only publicly report group practices' measure performance results in 2013 based on group practices' 2012 Physician Quality Reporting System performance results under GPRO. The Physician Quality Reporting System only utilizes Medicare Part B data. Implementation of subsequent plans for reporting quality data, including any plan to utilize data from other payers, will need to be developed and addressed in future notice and comment rulemaking, as needed.

Comment: We received comments suggesting that National Committee for Quality Assurance recognition information and participation information in other established, medical society-driven educational and voluntary quality of care initiatives be included on the Physician Compare Web site.

Response: We appreciate the commenter's feedback. We will take into consideration incorporating recognition and participation in other established, medical society-driven educational and voluntary quality of care initiatives information on Physician Compare. Currently, the Physician Compare Web site includes on the names of those physicians and other eligible professionals who satisfactorily report data under the Physician Quality Reporting System, as well as the names of those professionals who are successful electronic prescribers under the Electronic Prescribing (eRx) Incentive Program. Section 1848(o)(3)(D) of the HITECH Act requires the Secretary to list in an easily understandable format the names, business addresses, and business phone numbers of the Medicare EPs and, as determined appropriate by the Secretary, of group practices receiving incentive payments for being meaningful EHR users under the Medicare FFS program on our Internet Web site. As such, we plan to add information for Medicare eligible professionals who received incentive payments for being meaningful EHR users under the Medicare FFS program in 2012.

Comment: CMS received a number of comments expressing concern over how hospital related data will be incorporated on the Physician Compare Web site. Specifically, commenters were concerned about reporting performance for physicians who treat hospital inpatients and the lack of performance measures within the Physician Quality Reporting System appropriate for the hospital setting. Commenters urged CMS to make hospital affiliation information available on Physician Compare.

Response: We appreciate the commenters' feedback. We agree that illustrating hospital and physician integration and alignment is important. We will take into consideration the potential option of incorporating hospital affiliation information on Physician Compare.

Comment: CMS received comments requesting us to clarify how the group practice data displayed on Physician Compare will reflect the performance of eligible professionals who are employed in hospitals and health systems, how physician-to-group attribution will be managed and how both provider-level and group-level will reside on the same Web site.

Response: We appreciate the commenter's feedback. In this final rule, we are finalizing our proposal to publicly report group practices' measure performance results in 2013 based on group practices' 2012 Physician Quality Reporting System performance results under GPRO as an initial step towards public reporting of physician performance. We believe that reporting at the group practice level will reflect the performance of the group practice or health system as a whole. We believe reporting at the group level encourages the group's shared responsibility for patient health outcomes and care coordination. While we intend to identify those eligible professionals who have assigned their Medicare Part B billing rights to the group practice's tax identification number, performance rates will not be displayed on the individual eligible professionals' profile on Physician Compare in 2013. Implementation of subsequent plans for reporting physician performance will need to be developed and addressed in future notice and comment rulemaking, as needed.

Comment: CMS received several comments urging CMS to ensure that the Physician Compare Web site is user-friendly and that the public can understand the data being reporting. Specifically, commenters stressed the importance of provider input on the design and content of the Web site and that CMS implement a public education program to help users understand the data and use information properly.

Response: We appreciate the commenters' feedback. We will consider engaging providers and external stakeholders, as well as consumers, to provide input into the design and content of Physician Compare.

Comment: We received several comments about the data review period and appeal process for performance measures reported on the Physician Compare Web site. Specifically, one commenter urged CMS to clarify the review process for group practices and one requested that group practices should have the opportunity to review comparative benchmark data, before data is publicly reported. Other commenters urged CMS to provide physicians with an opportunity to review their data and allow physicians to request corrections to the data. Commenters recommended at least a 60-day to 6-month time period be provided for physicians to review the data before it is made public on Physician Compare.

Response: We appreciate the commenters' feedback. Section 10331(b) of the Affordable Care Act requires CMS to establish processes for physicians and eligible professionals whose information is being publically reported to have a reasonable opportunity, as determined by the Secretary, to review their results before posting to Physician Compare. In this final rule, we are finalizing our proposal to publicly report group practices' measure performance results in 2013 based on group practices' 2012 Physician Quality Reporting System performance results under GPRO as an initial step towards public reporting of physician performance. We are also finalizing our proposal to modify the group practice data collection tool or ''GPRO Web Interface''. The GPRO web interface will calculate and display the denominator, numerator and measure performance rate for each measure from the data that the group practice uses to populate the GPRO web interface. This feature will allow the group practice to review its measure performance prior to posting on the Physician Compare Web site. Group practices participating in GPRO currently receive comparative benchmark data in their feedback

reports and they will continue to receive comparative benchmark data. CMS will take into consideration the suggested time period for reviewing data and will address in future rulemaking.

Comment: Commenters expressed concern that the specialty list on Physician Compare is inaccurate or incomplete.

Response: We appreciate the commenters' feedback. We are committed to including accurate and complete information for all specialties on the Physician Compare web site. We look forward to engaging the provider community toward that end.

Comment: CMS received comments supporting the inclusion of physician board certification information on Physician Compare. Commenters stressed the importance of distinguishing between credible certification bodies and other organizations, as well as including accurate information that is not reliant on self-reported data. Commenters support a link from the Physician Compare site to other Web sites with board certification information until a data sharing agreement that would allow board certification information directly on the Physician Compare Web site can be finalized.

Response: We appreciate the commenters' feedback and support. We agree that board certification is valuable information for consumers and therefore, we are exploring the possibility of, and our options for, including board certification information on the Physician Compare web site (*e.g.,* through links to other Web sites; through data sharing, which would allow the information to be integrated with the Physician Compare Web site and displayed directly on the provider's profile page).

Comment: One commenter advocated that CMS customize the Physician Compare Web site content to educate users on the growing specialty of hospital medicine. The commenter suggested a link to the Hospital Compare Web site for those physicians in the hospital medicine specialty as quality in this specialty is tied to hospital quality.

Response: We appreciate the commenters' feedback. We are committed to working with providers and external stakeholders so that beneficiaries have the information necessary to be informed users of the Physician Compare web site. We will consider linking from Physician Compare to Hospital Compare as appropriate.

Comment: CMS received one comment supporting the reporting of group level performance on Physician Compare. The commenter believes that group practices will have a sufficient volume of patients to facilitate comparisons and it would be easier for groups to report on a core set of measures.

Response: We appreciate the commenters' feedback and support. As we indicated, in this final rule we are finalizing our proposal to publicly report Physician Compare group practices' measure performance results in 2013 based on group practices' 2012 Physician Quality Reporting System performance results under GPRO.

Comment: Multiple commenters expressed concern about the feasibility of reporting individual level performance on Physician Compare. Specifically, commenters mentioned inadequate sample size to make valid comparisons across eligible professionals, problems with attribution and the risk for patient de-selection by providers seeking to improve their measure performance.

Response: We appreciate the commenters' feedback. In this final rule with comment period, we are only taking the initial step of reporting physician performance data by publicly reporting group practices' measure performance results in 2013 based on group practices' 2012 Physician Quality Reporting System performance results under GPRO. We believe that additional time is needed to develop the infrastructure necessary to support the collection of additional types of measures and public reporting of individual physicians' quality measure performance results.

Comment: CMS received multiple comments urging CMS to take the necessary steps to enable reporting reliable comparative information at the individual provider level as soon as possible.

Response: We appreciate the commenters' feedback. As stated previously, we believe that additional time is needed to develop the infrastructure necessary to support the collection of additional types of measures and public reporting of individual physicians' quality measure performance results. We will continue to assess the feasibility of individual level reporting. The implementation of subsequent plans for reporting physician performance will need to be developed and addressed in future notice and comment rulemaking, as needed.

Comment: CMS received one comment urging CMS to populate Physician Compare with a core set of measures that are meaningful to patients. The commenter stated that the core set should include cross-cutting measures applicable to any physician as well as measures that apply to specific subsets of physicians. It was emphasized that patient experience, care coordination, functional status and other outcome measures should be the basis for the initial set of core measures.

Response: We appreciate the commenters' feedback. With regard to our final decision to publicly report group practices' measure performance results in 2013 based on group practices' 2012 Physician Quality Reporting System performance results under GPRO, all groups participating in GPRO would be reporting on the same set of clinical quality measures. The implementation of subsequent plans for reporting physician performance will need to be developed and addressed in future notice and comment rulemaking, as needed.

Comment: One commenter supported our proposal to use a minimum sample size of 25 patients for a measure to be reported on Physician Compare. Another commenter expressed concern over the minimum sample size of 25 patients. The commenter stated that 25 patients within a group practice for any specific measure is not an adequate representation of the practice's performance and is too small to enable consumers to see meaningful differences in provider performance.

Response: We appreciate the commenters' feedback. A majority of the other Compare Web sites use minimum sample sizes of between 20 and 30 patients and we concluded that a minimum patient sample size of 25 would meet our need for a number large enough to reflect measure performance, but not so large as to limit the number of groups for which measure performance can be reported.

Upon consideration of the comments and for the reasons we previously explained, we are finalizing our proposal to publicly report group practices' measure performance results in 2013 based on group practices' 2012 Physician Quality Reporting System performance results under GPRO. We are finalizing our proposal to use a minimum sample size of 25 patients for reporting and displaying measure performance on the Physician Compare Web site. Group practices participating in 2012 Physician Quality Reporting System GPRO must agree in advance to have their reporting performance results publicly reported as part of their self-nomination to participate in the 2012 Physician Quality Reporting System GPRO. We are also finalizing our proposal to modify the GPRO web

interface for 2012 to calculate the numerator, denominator and measure performance rate for each measure from the data that the group practices use to populate the web interface. This modification will allow the group practice the opportunity to preview their measure performance results before they are made public in 2013. In addition, as we discussed in the Medicare Shared Savings Program (MSSP) final rule, which displayed at the **Federal Register** on October 20, 2011, *http://www.ofr.gov/OFRUpload/OFRData/2011-27461_PI.pdf,* because Accountable Care Organizations (ACO) will be considered to be group practices under the Physician Quality Reporting System GPRO under the Shared Savings Program, we believe ACO performance on the quality measures reported using the GPRO web interface should be reported on Physician Compare in the same way that we are reporting on the performance of other group practices that participate in the Physician Quality Reporting System GPRO. Therefore, performance data on quality measures reported on by ACOs on behalf of its eligible professionals in group practices using the GPRO web interface will also be reported on the Physician Compare Web site in the same way as for the group practices that report under the Physician Quality Reporting System as discussed in this section.

H. Medicare EHR Incentive Program for Eligible Professionals for the 2012 Payment Year

1. Background

We proposed (76 FR 42899) changes to the method by which eligible professionals (EPs) would report clinical quality measures (CQMs) for the 2012 payment year for the Medicare EHR Incentive Program. Specifically, we proposed (76 FR 42900) that eligible professionals may satisfy the meaningful use objective to report CQMs to CMS by reporting them through: (1) Attestation; or (2)participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot. We received some comments that were not related to our proposals for the Medicare EHR Incentive Program for payment year 2012. While we appreciate the commenters' feedback, these comments are outside the scope of the issues addressed in this final rule.

2. Attestation

We proposed (76 FR 42900) that for the 2012 payment year, EPs may continue to report CQM results as calculated by Certified EHR Technology by attestation, as for the 2011 payment year.

Comment: Several commenters supported our proposal to continue reporting CQM results as calculated by Certified EHR Technology by attestation for the 2012 payment year.

Response: We appreciate the commenters' support and are finalizing our proposal to allow EPs to continue to report CQM results as calculated by Certified EHR Technology by attestation for the 2012 payment year.

Comment: One commenter was disappointed in our proposal to continue attestation due to our inability to receive electronically the information necessary for CQM reporting based solely on the use of PQRI 2009 Registry XML Specification content exchange standards as is required for Certified EHR Technology. The commenter urged us to rectify this situation.

Response: We appreciate the commenters' feedback. We are working to have the capability to receive CQM data reported electronically via Certified EHR Techology for the 2013 payment year. However, we note that attestation is only one method by which EPs may report the CQMs. In fact, EPs may submit CQM data through participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot that is described in the following section.

Based on the comments received and for the reasons stated in our responses, we are finalizing our proposal to allow EPs to continue to report CQM results as calculated by Certified EHR Technology by attestation for the 2012 payment year as proposed. We are revising 42 CFR 495.8(a)(2)(ii) as proposed.

3. The Physician Quality Reporting System-Medicare EHR Incentive Pilot

In addition to attestation, we proposed (76 FR 42900) to establish a Pilot mechanism through which EPs participating in the Medicare EHR Incentive Program may report CQM information electronically using Certified EHR Technology for the 2012 payment year.

We proposed to modify 42 CFR 495.8(a)(2) by adding a new paragraph to allow for the reporting of CQMs for the Medicare EHR Incentive Program via the Physician Quality Reporting System-Medicare EHR Incentive Pilot. Section 1848(o)(2)(B)(ii) of the Act provides authority for the Secretary to accept information on CQMs electronically on a Pilot basis. We proposed that EPs may participate in the Pilot on a voluntary basis, and that those EPs who choose not to participate may instead continue to attest to the results of the CQMs as calculated by Certified EHR Technology, consistent with the CQM reporting method for the 2011 payment year. However, we encourage participation in the Pilot based on our desire to adequately pilot electronic submission of CQMs and to move to a system of reporting where EPs can satisfy both the CQM reporting requirements for the EHR Incentive Program and the reporting requirements for the Physician Quality Reporting System EHR-based reporting mechanism with a single submission to their respective EHR systems, who will then provide calculated results to CMS in the form and manner specified for each respective program. To participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot, we proposed that EPs would be required to electronically report the CQMs using Certified EHR Technology via one of two options that are based on the existing reporting platforms of the Physician Quality Reporting System. As described later in this section, one option would be based on the infrastructure used for the Physician Quality Reporting System EHR data submission vendor reporting mechanism as described in section VI.F.1.d.3.B of this final rule with comment period. The second option would be based on the infrastructure used for the Physician Quality Reporting System EHR reporting mechanism as described in section VI.F.1.d.3.A of this final rule with comment period. EPs who seek to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot must also participate in the Physician Quality Reporting System itself, because the Pilot will rely on the infrastructure used for the Physician Quality Reporting System.

To move towards the integration of reporting on quality measures under the Physician Quality Reporting System with the reporting requirements of the Medicare EHR Incentive Program, as required by section 1848(m)(7) of the Act (''Integration of Physician Quality Reporting and EHR Reporting''), we proposed that participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot would require EPs to submit information on the same CQMs that were adopted for EPs for the Medicare EHR Incentive Program and included in Tables 6 and 7 of the July 28, 2010 final rule (75 FR 44398 through 44410). We proposed that EPs participating in this Pilot must submit information on the three core measures included in Table 7, up to

three of the alternate core measures included in Table 7 insofar as the denominator for one or more of the core measures is zero, and three additional measures from the measures included in Table 6, as is otherwise required by the final rule to successfully demonstrate meaningful use (75 FR 44409 through 44411). EPs who elect to participate in this Physician Quality Reporting System-Medicare EHR Incentive Pilot would still be required to report information on the CQMs as required under the Stage 1 criteria established for the Medicare EHR Incentive Program regardless of which option they select as described later in this section. As the reporting of CQMs is only one of the 15 core meaningful use objectives for EPs for the Medicare EHR Incentive Program, an EP who elects to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot would still be required to meet and attest to the remaining 14 core objectives and required menu set objectives using the attestation module on the CMS Web site for the program. Consequently, participation in this Pilot only applies to the method of reporting for meeting the meaningful use CQM objective in the EHR Incentive Program (42 CFR 495.6(d)(10)).

To participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot, we proposed EPs would be required to electronically report the CQMs by choosing one of the options described later in this section. By submitting the required information through the Pilot, we proposed that an EP could submit data on the same sample of beneficiaries to his/her EHR system to meet the core objective for reporting CQMs for the Medicare EHR Incentive Program for the 2012 payment year and the requirements for satisfactory reporting under the Physician Quality Reporting System. After attesting to all other meaningful use objectives, the EP's attestation file would be placed in a holding status with respect to the CQM objective only, until the EP reports the CQMs via one of the Physician Quality Reporting System-Medicare EHR Incentive Pilot options. Thus, the EP would not know if he/she successfully met the requirements for the Medicare EHR Incentive Program with respect to the CQM objective until the CQMs are received at the end of the submission period for measures for the Physician Quality Reporting System (we expect this would be 2 months after the close of the reporting period, which is the CY 2012, and no later than February 28, 2013). As explained later in this section, any EP participating in this Pilot would be required to report CQMs based on a full calendar year, regardless of the EP's year of participation in the Medicare EHR Incentive Program.

We also proposed (76 FR 42901) that an EP who selects one of the Pilot options and subsequently determines that completion of the Pilot is unfeasible may go back into the Medicare EHR Incentive Program attestation module on the CMS Web site and complete attestation for the CQMs assuming it is within the reporting timeframes established under the EHR Incentive Program. Although it is possible that an EP may find completion of the Pilot unfeasible, we note that participating in the Pilot provides the following advantage to EPs: participation in this Physician Quality Reporting System-Medicare EHR Incentive Pilot would allow for the receipt of EHR Incentive Program and Physician Quality Reporting System incentives, provided an EP meets the provisions described later in this section. We noted that although the EHR Incentive Program requires EPs to use Certified EHR Technology, for purposes of participating in the Physician Quality Reporting System-Medicare EHR Incentive Pilot, an EP's Certified EHR Technology must also conform to the qualifications for an EHR under the Physician Quality Reporting System.

Comment: Several commenters supported our proposal to establish the Physician Quality Reporting System-Medicare EHR Incentive Pilot. These commenters lauded our efforts to align the Physician Quality Reporting System and EHR Incentive Program.

Response: We appreciate the commenters' feedback and are finalizing our proposal to allow EPs to report CQMs for the EHR Incentive Program through the Physician Quality Reporting System-Medicare EHR Incentive Pilot for the 2012 payment year.

Comment: Although one commenter supported our proposal to establish the Physician Quality Reporting System-Medicare EHR Incentive Pilot, the commenter urged that we defer implementation of the Physician Quality Reporting System-Medicare EHR Incentive Pilot for an additional year.

Response: We appreciate the commenters' feedback. However, we note that participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot is voluntary. An EP may continue to use attestation as a method of reporting CQMs for the 2012 payment year to satisfy this meaningful use objective under the EHR Incentive Program. In fact, an EP may report the CQMs by attestation even if the EP also chooses to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot.

Comment: Some commenters opposed our proposal to require a CQM reporting period of 1 calendar year regardless of the EP's year of participation in the Medicare EHR Incentive Program.

Response: We appreciate the commenters' feedback. While the EHR Incentive Program only requires a 90-day EHR reporting period for EPs for their first payment year, EPs participating in the Physician Quality Reporting System-Medicare EHR Incentive Pilot must report clinical quality measures based on a full calendar year of data for two main reasons. First, as described in section VI.F.1, the Physician Quality Reporting System has established a 12-month reporting period with respect to the EHR reporting mechanism. Since the Physician Quality Reporting System-Medicare EHR Incentive Pilot is intended to allow reporting under both the Physician Quality Reporting System and the EHR Incentive Program, it is essential that, for purposes of participating in this Pilot, the reporting periods be identical. Second, unlike Certified EHR Technology that submits data submitted by EPs at any point throughout the year, qualified direct EHRs and EHR data submission vendors are only required to submit data to CMS once, following the end of the 12-month calendar year reporting period.

Comment: Some commenters opposed our proposal that the Physician Quality Reporting System-Medicare EHR Incentive Pilot would only collect data about Medicare patients.

Response: We appreciate the commenters' feedback. However, as described in section VI.F.1, the Physician Quality Reporting System only collects data related to Medicare patients. Since the Physician Quality Reporting System-Medicare EHR Incentive Pilot is intended to allow reporting under both the Physician Quality Reporting System and EHR Incentive Program, the type of data collected must only be from Medicare patients.

Comment: One commenter stated that the Physician Quality Reporting System-Medicare EHR Incentive Pilot is unlikely to attract volunteers, unless EHR vendors encourage participation in this Pilot.

Response: We appreciate the commenter's feedback. We encourage EPs to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot. We believe that the Physician Quality Reporting System-

Medicare EHR Incentive Pilot provides a way for EPs to submit data on a single sample set of beneficiaries to satisfy the requirements for two programs: the Physician Quality Reporting System and the EHR Incentive Program.

Comment: Several commenters did not believe that EPs would be willing to have their EHR Incentive Program incentive payments delayed in order to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot. These commenters urged us to find a solution to provide timely payments.

Response: We appreciate the commenters' feedback. Once the data from an EP participating in the Physician Quality Reporting System-Medicare EHR Incentive Pilot is received and CMS determines that the EP has successfully reported the CQMs under the Pilot, the EP would receive his/her incentive payment under the EHR Incentive Program if the EP has successfully demonstrated meaningful use. We also note that if, for some reason, an EP finds that he or she cannot successfully participate in the Pilot, the EP may also report on CQMs through attestation within the established timeframes of the EHR Incentive Program.

Please note that if an EP chooses to report CQMs through attestation and also participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot, for purposes of receiving an EHR Incentive Program incentive, an EP's attestation file would not need to be placed in a holding status for the CQM objective. However, as stated previously, the analysis of data for purposes of the Physician Quality Reporting System incentive will not be made until after the submission period for measures for the Physician Quality Reporting System.

Based on the comments received and for the reasons stated in our responses, we are finalizing our proposal to allow EPs to report CQMs for the EHR Incentive Program through the Physician Quality Reporting System-Medicare EHR Incentive Pilot for the 2012 payment year as proposed.

a. EHR Data Submission Vendor-Based Reporting Option

As discussed further in the Physician Quality Reporting System section VI.F.1(d).(3).(b). of this final rule with comment period, we proposed (76 FR 42901) that EPs participating in the Physician Quality Reporting System may choose to report the Physician Quality Reporting System measures to CMS via a Physician Quality Reporting System qualified EHR data submission vendor. For purposes of the Physician Quality Reporting System, a Physician Quality Reporting System qualified EHR data submission vendor will receive data from an EP's EHR and subsequently reformat and transmit the data in aggregate form on behalf of the EP to CMS. We noted that we expect to post a list of the 2012 Physician Quality Reporting System EHR data submission vendors that are qualified to submit data from an EP's Certified EHR Technology to CMS on the EP's behalf on the Physician Quality Reporting System section of the CMS Web site (*http://www.cms.gov/pqrs*) by summer 2012.

Under this option, the Physician Quality Reporting System qualified EHR data submission vendor would calculate the CQMs from the EP's Certified EHR Technology and then submit the calculated results to CMS on the EP's behalf via a secure portal for purposes of this Pilot. We explained that under this option, the calculated results would be different from what is required by the July 28, 2010 final rule in that the data would be: (1) Limited to Medicare patients rather than all patients; and (2) based on a CQM reporting period of 1 calendar year regardless of the EP's year of participation in the Medicare EHR Incentive Program.

The following is a summary of the comments we received on the proposed EHR data submission vendor-based reporting option under the Physician Quality Reporting System-Medicare EHR Incentive Pilot.

Comment: Some commenters supported the proposed EHR data submission vendor-based reporting option of the Physician Quality Reporting System-Medicare EHR Incentive Pilot.

Response: We appreciate the commenters' feedback and are finalizing the EHR data submission vendor-based reporting option under the Physician Quality Reporting System-Medicare EHR Incentive Pilot as proposed.

Comment: Some commenters believed that, in order to earn a Physician Quality Reporting System incentive through participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot, an EP's data submission vendor was required to submit *patient-level* data from which we would calculate CQM results using a uniform calculation process. One commenter asked why providing aggregate-level data would not suffice for meeting the CQM reporting objective through participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot.

Response: We appreciate the commenters' feedback. We note that incentives for either the Physician Quality Reporting System or the Medicare EHR Incentive Program, are earned under each respective program. For purposes of the Pilot, a qualified EHR data submission vendor would submit individual-level data as well as the calculated results of the CQMs to us. While the submission of calculated results is required for an eligible professional using this EHR data submission vendorbased reporting option to qualify for an incentive under the EHR Incentive Program, the Physician Quality Reporting System, as described previously in section VI.F.1 of this final rule, receives individual-level data from claims and EHR-based reporting to analyze whether an eligible professional has met the requirements for satisfactory reporting under the Physician Quality Reporting System. Therefore, in order for us to be able to calculate measure data for purposes of earning a Physician Quality Reporting System incentive, we are requiring CQM data elements to be submitted by an EP's qualified EHR data submission vendor at an individual level. Further, the Physician Quality Reporting System requires this individual-level data to be submitted in the QRDA format. We believe it is useful to utilize a standard (such as CDA of which QRDA is a subset) where one exists in our quality reporting initiatives.

Based on the comments received and for the reasons stated in our responses, we are finalizing the EHR data submission vendor-based reporting option for the Physician Quality Reporting System-Medicare EHR Incentive Pilot as proposed.

b. Direct EHR-Based Reporting Option

As discussed further in the Physician Quality Reporting System section VI.F.1.(d).(3).(a). of this final rule with comment period, we proposed (76 FR 42901) that EPs participating in the Physician Quality Reporting System via the direct EHR-based reporting mechanism can choose to report the Physician Quality Reporting System measures to CMS directly from the EP's EHR. Therefore, under this direct EHR-based reporting option, we proposed (76 FR 42901) that an EP participating in the Physician Quality Reporting System-Medicare EHR Incentive Pilot would submit CQM data directly from his or her Certified EHR Technology to CMS via a secure portal using the infrastructure of the Physician Quality Reporting System EHR reporting mechanism. We proposed that in order to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot under this option, the

EP's Certified EHR Technology must also be a 2012 Physician Quality Reporting System qualified EHR. We expect to post a list of the 2012 Physician Quality Reporting System qualified EHRs on the Physician Quality Reporting System section of the CMS Web site prior to January 1, 2012. Due to this Physician Quality Reporting System-Medicare EHR Incentive Pilot, we proposed to have an additional vetting process for EHR vendors wishing to participate in the Pilot. We expect to post a list of these additional 2012 qualified EHR vendors, if applicable, and their products in the summer of 2012.

Under this direct EHR-based reporting option, the data would be different from what is required by the July 28, 2010 final rule in that it would be: (1) limited to Medicare patients rather than all patients; (2) patient-level data from which we may calculate CQM results using a uniform calculation process, rather than aggregate results calculated by the EP's Certified EHR Technology; and (3) based on a CQM reporting period of 1 calendar year regardless of the EP's year of participation in the Medicare EHR Incentive Program.

In addition, we proposed (76 FR 42901) that if an EP successfully submits all required CQM data from Certified EHR Technology, which also must be a Physician Quality Reporting System qualified EHR product, directly to CMS, then the EP would also meet the criteria for satisfactory reporting under the 2012 Physician Quality Reporting System, which would also qualify the EP for an incentive under the 2012 Physician Quality Reporting System.

The following is a summary of the comments we received related to the direct EHR-based reporting option under the Physician Quality Reporting System-Medicare EHR Incentive Pilot.

Comment: Several commenters supported the proposed direct EHR-based reporting option of the Physician Quality Reporting System-Medicare EHR Incentive Pilot.

Response: We appreciate the commenters' feedback and are finalizing the direct EHR-based reporting option under the Physician Quality Reporting System-Medicare EHR Incentive Pilot.

Comment: Several commenters urged CMS to align the Physician Quality Reporting System qualification requirements for EHRs with the certification requirements for Certified EHR Technology so that a single EHR system could serve reporting requirements for both programs.

Response: We appreciate the comementers' feedback. We are working to align the EHR system requirements for the Physician Quality Reporting System and the EHR Incentive Program. However, for purposes of participating in the Physician Quality Reporting System-Medicare EHR Incentive Pilot under the direct EHR-based reporting option, Certified EHR Technology must also meet the qualification requirements stated under section VI.F.1.d.3 of this final rule with comment period. There are currently distinct differences between Certified EHR Technology and EHR systems that are qualified under the Physician Quality Reporting System. For example, as required by ONC's regulations (see 45 CFR part 170), Certified EHR Technology must include certain functionalities, such as the ability to create a summary of care record for transitions of care, the ability to calculate and submit clinical quality measures specified for the EHR Incentive Program, and must also have certain structured data elements that use specific language (for example, SNOMED, LOINC). On the other hand, an EHR that is ''qualified'' under the Physician Quality Reporting System is one that can capture all Physician Quality Reporting System measures, extract the data elements needed to calculate the measures, place the data elements in a QRDA format, and successfully transmit that data into the CMS portal. Therefore, it is necessary that an EHR system be qualified so as to ensure the system has the capability to report on Physician Quality Reporting System measures.

We note that there are EHR systems that are both ''qualified'' to report Physician Quality Reporting System quality measures and classified as Certified EHR Technology for purposes of reporting under the EHR Incentive Program. A list of EHR products that are both ''qualified'' and Certified EHR Technology will be made available on the Physician Quality Reporting System Web site, available at *https://www.cms.gov/PQRS/*.

Based on the comments received and for the reasons stated in our responses, we are finalizing the EHR-based reporting option under the Physician Quality Reporting System-Medicare EHR Incentive Pilot as proposed.

The Medicare EHR Incentive Program clinical quality measures, including the core and alternate core measures, and the 38 additional measures, are found in the Physician Quality Reporting System's Table 48 of this final rule with comment period.

4. Method for EPs to Indicate Election To Participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot for Payment Year 2012

We proposed (76 FR 42902) that EPs who wish to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot would be able to indicate within the EHR Incentive Program attestation module their intent to fulfill the meaningful use objective of reporting CQMs by participating in the Physician Quality Reporting System-Medicare EHR Incentive Pilot. The EHR Incentive Program attestation module is available on the CMS Web site at *https://www.cms.gov/EHRIncentivePrograms/32_Attestation.asp#TopOfPage*. The following is a summary of the comments we received that were related to this proposal.

Comment: Several commenters sought further clarification on how EPs may participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot.

Response: We appreciate the commenters' feedback. We will provide additional guidance on the process for participating in the Pilot, which will be available on the EHR Incentive Program Web site, available at *http://www.cms.gov/ehrincentiveprograms/*, as well as the Physician Quality Reporting System Web site, available at *https://www.cms.gov/PQRS/*.

Based on the comments received and for the reasons stated previously, we are finalizing our method to indicate election to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot as proposed.

I. Establishment of the Value-Based Payment Modifier and Improvements to the Physician Feedback Program

1. Overview

In the proposed rule, we described the statutory requirements governing the Physician Feedback Program and the Physician Value-Based Payment Modifier (''value modifier''), which will be applied to the Physician Fee Schedule starting in 2015 for certain physicians and groups of physicians and, starting in 2017 for all physicians and other eligible professionals as the Secretary determines appropriate (76 FR 42908). In particular, we proposed that certain of the quality of care measures in the Physician Quality Reporting System and the Electronic Health Records (EHR) Incentive Program be used to evaluate the quality of care in the value modifier (76 FR 42909 through 42912). In addition, we described how the quality of care measures that

physicians report in the Physician Quality Reporting System will be used in the confidential feedback reports we provide to physicians under the Physician Feedback Program (76 FR 42903 through 42907). We explained that we are using the Physician Feedback Program reports to help develop and test different methodologies that we could use to calculate the value modifier.

In this final rule with comment period, we emphasize the connection between our physician quality programs—the Physician Quality Reporting System, the EHR Incentive Program, the value modifier, and the Physician Feedback Program. Our primary interests in aligning these programs are to increase the quality of care for Medicare beneficiaries, to provide a common basis to do so that does not increase physician reporting burden, and to provide fair and meaningful information to physicians on ways to improve the quality of care they furnish.

We also emphasized in the proposed rule that given the complexity of measuring physician performance and calculating the value modifier, we are proceeding cautiously with transparency and outreach in a variety of ways to obtain stakeholder input. We discuss in this final rule with comment period several ways we plan to engage stakeholders to obtain input as we move forward to implement the value modifier over the coming years.

2. The Value-Based Payment Modifier

Section 1848(p) of the Act requires the Secretary to ''establish a payment modifier that provides for differential payment to a physician or a group of physicians'' under the physician fee schedule ''based upon the quality of care furnished compared to cost * * * during a performance period.'' The provision requires that ''such payment modifier be separate from the geographic adjustment factors'' established for the physician fee schedule. In addition, section 1848(p)(4)(C) of the Act requires that the value modifier be implemented in a budget-neutral manner. Budget neutrality means that payments will increase for some physicians but decrease for others, but the aggregate amount of Medicare spending in any given year for physicians' services will not change as a result of application of the value modifier.

Section 1848(p)(4)(B)(iii) of the Act requires the Secretary to apply the value modifier beginning January 1, 2015 to specific physicians and groups of physicians the Secretary determines appropriate. This section also requires the Secretary to apply the value modifier with respect to all physicians and groups of physicians (and may apply to eligible professionals as defined in subsection (k)(3)(B) of the Act as the Secretary determines appropriate) beginning not later than January 1, 2017.

We view the value modifier as an important component in revamping how care and services are paid for under the physician fee schedule. Currently, payments under the physician fee schedule are generally based on the relative resources involved with furnishing each service, and are adjusted for differences in resource inputs among geographic areas. Thus, all physicians in a geographic area are paid the same amount for individual services regardless of the quality of care or outcomes of services they furnish.

Although the fee schedule payments will soon be adjusted depending upon whether eligible professionals are satisfactory reporters of Physician Quality Reporting System quality measures, successful electronic prescribers and meaningful users of electronic health records (EHRs), these adjustments do not currently take into account performance on the quality measures collected under these programs. In addition, the fee schedule does not take into account the overall costs of services furnished or ordered by physicians for individual Medicare beneficiaries. These limitations mean that the physician fee schedule does not contain incentives for physicians to focus on: (1) The quality and outcomes of all the care furnished to beneficiaries; (2) the relative value of each service they furnish or order; or (3) the cumulative costs of their own services and the services that their beneficiaries receive from other providers.

We noted in the proposed rule that Medicare is beginning to implement value-based payment adjustments for other types of services, including hospital services, skilled nursing facilities, home health agencies, and ambulatory surgical centers (76 FR 42908). In implementing value-based purchasing initiatives generally, we seek to meet the following goals:

- Improving quality.

++ Value-based payment systems and public reporting should rely on a mix of standards, processes, outcomes, and patient experience 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 outcome and patient experience measures. To the extent practicable and appropriate, we believe these 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 readiness and statutory requirements and authorities, measures should be aligned across Medicare and Medicaid's public reporting and payment systems. We seek to evolve a focused core set of measures appropriate to each specific provider category that reflects the level of care and the most important areas of service and measures for a particular 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 us 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.

- Lowering per-capita growth in expenditures.

++ Providers should be accountable for the costs of care, and be rewarded for reducing unnecessary expenditures and be responsible for excess expenditures.

++ In reducing excess expenditures, reductions should not compromise patient care and providers should continually improve the quality of care they deliver.

++ To the extent possible, and recognizing differences in payers' value based purchasing initiatives, providers should apply -quality-improving and cost-reducing redesigned care processes to their entire patient population.

Section 1848(p)(4)(A) of the Act requires us to publish, not later than January 1, 2012, three items related to the establishment of the value modifier: (a) the quality of care and cost measures established by the Secretary for purposes of the modifier; (b) the dates for implementation of the value modifier; and (c) the initial performance period for application of the value modifier in 2015. In the proposed rule we made proposals for each of these requirements and we discuss each below.

a. Measures of Quality of Care and Costs

(1). Quality of Care Measures

Section 1848(p)(2) of the Act requires that physician quality of care be

evaluated, to the extent practicable, based on a composite of measures of the quality of care furnished. Section 1848(p)(2)(B) of the Act requires that the Secretary establish appropriate measures of the quality of care furnished by a physician or a group of physicians to Medicare beneficiaries such as measures that reflect health outcomes. The statute requires the measures to be risk adjusted as determined appropriate by the Secretary. Section 1848(p)(2)(B)(ii) of the Act requires the Secretary to seek endorsement of the quality of care measures by the entity with a contract under section 1890(a) of the Act, which is the National Quality Forum.

(A) Quality of Care Measures for the Value-Modifier

For purposes of section 1848(p)(4)(A)(i) of the Act, we proposed to use performance on: (1) The measures in the core set of the Physician Quality Reporting System for 2012; (2) all measures in the Group Practice Reporting Option of the Physician Quality Reporting System for 2012; and (3) the core measures, alternate core, and 38 additional measures in the EHR Incentive Program measures for 2012 (76 FR 42909). We requested comment on the proposed measures, on our interest to establish a core measure set for the value modifier, and whether to include additional (or exclude) measures from the Physician Quality Reporting System in the quality of care measures for the value modifier.

We also proposed that, to the extent that the 2013 measures adopted for the Physician Quality Reporting System and EHR Incentive Program are different than those used in 2012, we would consider, through rulemaking next year, revising the value modifier quality measures applicable to 2013 to be consistent with the revisions made to the measures for those programs.

Comment: Most commenters appreciated CMS' proposal to use a consistent set of quality of care measures across various quality programs. Despite this support, some commenters recommended using either one core set of measures or multiple sets of core measures for different types of physicians or conditions. For example, one commenter recommended requiring physicians to report on only a ''small set of core measures that would be applicable to all physicians plus some limited number of applicable measures chosen by the physician or group practice.'' Other commenters suggested that we start with a small core set of measures initially and then transition to a larger set over time. By contrast, many commenters urged CMS to use a different core set of measures for different physician specialties (rather than the same measures for all physicians) in the value modifier.

MedPAC suggested that ''the use of a large number of [quality] measures in the value modifier could increase the year-to-year statistical variability, and therefore uncertainty, into the annual calculation of each physician's or physician group's value modifier.'' MedPAC recommended that we concentrate on a few key population-based outcomes, patient experience, and clinical process measures. A few commenters supported including outcome measures that assess the rate of potentially preventable hospital admissions for six ambulatory care sensitive conditions at the group practice level: diabetes, bacterial pneumonia, dehydration, COPD, urinary tract infection, and heart failure.

Many physician specialty societies indicated that the proposed quality measures did not have measures relevant to the practice of their physicians or to the conditions they treat and, therefore, it would not be possible to calculate a quality composite for them. Most prominently in this category were surgeons and surgical specialties, hospital-based physicians, and medical subspecialists. Some medical specialists, for example cardiologists and endocrinologists, commented that proposed measures which seemed applicable to them did not measure the quality of care provided by subspecialists. These commenters stated that they would work with us to develop relevant clinical measures and to assist in obtaining National Quality Forum endorsement of new measures.

Of the proposed measures in the EHR Incentive program set for 2012, several commenters opposed including PQRS measure #200 (Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation) because clinical guidelines have been updated and those changes are not currently reflected in the PQRS measure.

A number of commenters suggested that the value modifier's quality of care measures should directly correspond to the proposed condition-specific cost measures. One commenter suggested that for hospital-based physicians, CMS align the quality measures in the hospital value-based purchasing program with the physician value modifier.

Response: We appreciate commenters' support for our proposals to use a consistent set of measures across quality improvement programs and to use of a core set of measures for the value modifier. We recognize that the proposed core sets of quality measures for individual physicians—the Physician Quality Reporting System core set (which focuses on cardiovascular conditions) and the core, alternative core, and additional EHR Incentive Program measures (which focus on several chronic conditions and preventive measures)—and the core set for physicians in groups—the Group Practice Reporting Option measures (which also focus on chronic conditions and preventive measures)—do not cover the full range of conditions prevalent in the Medicare population or varied physician specialties. We have focused on these quality of care measures for the value modifier because they assess highly prevalent and high-cost conditions in the Medicare population and we encourage physicians to take these conditions into account when treating their patients. We further believe that the proposed measures are an appropriate starting point for the value modifier because they also include preventive services and thus, are important measures of the quality of care that these beneficiaries receive.

We agree with commenters' concerns about PQRS measure #200 and we will not include it in the value modifier for the initial performance period because its specifications have not been updated.

We anticipate assessing physician performance for more conditions and/or by specialty in subsequent years after the methodological issues surrounding the value modifier are finalized. We believe that we will ultimately need to include quality of care measures applicable to most physicians and highly prevalent conditions, as well as measures for specific types of physicians, in order to calculate a value modifier for every physician by 2017. We agree with commenters that we should concentrate on outcome, patient experience, and clinical process measures in the value modifier. As a first step in that direction, we will include outcome measures that assess the rate of potentially preventable hospital admissions for two of the six ambulatory care sensitive conditions at the group practice level that we have used in the Physician Feedback Program reports: heart failure and chronic obstructive pulmonary disease. We have chosen these two measures because they are important conditions among Medicare FFS beneficiaries and, based on our 2010 Physician Feedback Program group reports, contain sample sizes sufficient for reliable measurement.

In addition, we also clarify that we do not seek to evaluate individual physicians on each measure we proposed or include in a future set of measures, but rather to assess physician performance using quality of care measures for the types of care they provide and the measures they report.

Nonetheless, we agree with commenters that we should match our quality of care measures with the cost measures that we have proposed for specific conditions. In the discussion below, we proposed per capita cost measures for beneficiaries with four chronic conditions (chronic obstructive pulmonary disease; heart failure; coronary artery disease; and diabetes) in the value modifier. To match these cost measures with the quality of care measures, we anticipate that we will propose in next year's rulemaking to include the additional measures for each of these conditions from the Physician Quality Reporting System measure groups that are not already included in the measure set we are finalizing in this final rule with comment period.

We agree that we should use NQF-endorsed measures of quality where appropriate. In addition, we will reach out to physician specialty organizations for conditions where we lack measures or for conditions where we have cost measures but insufficient quality measures in order to develop a robust value modifier.

We are finalizing our proposal, for individual physicians to whom the value modifier will apply, to include the core set of the Physician Quality Reporting System for 2012 and the core measures, alternate core, and additional measures in the EHR incentive program for 2012 (except for PQRS measure #200 as discussed previously). These measures are listed in Table 80.

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TABLE 80: QUALITY OF CARE MEASURES FOR INDIVIDUAL PHYSICIANS

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	EHR Incentive Program	PQRS Core
110	Preventative Care and Screening: Influenza Immunization	0041	X	
111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older	0043	X	
112	Preventive Care and Screening: Screening Mammography	0031	X	
113	Preventive Care and Screening: Colorectal Cancer Screening	0034	X	
128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up	0421	X	
TBD	Preventive care: Cholesterol-LDL test performed	N/A	X	
TBD	Cervical Cancer Screening	0032	X	
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	0028	X	X
53	Asthma Pharmacologic Therapy	0047	X	
64	Asthma Assessment	0001	X	
TBD	Use of Appropriate Medications for Asthma	0036	X	
1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus(>9%)	0059	X	
2	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus	0064	X	X
19	Diabetes Retinopathy: Communication with the physician managing ongoing diabetes care	0089	X	
3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus	0061	X	
117	Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient	0055	X	
119	Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients	0062	X	
163	Diabetes Mellitus: Foot Exam	0056	X	
TBD	Diabetes: Hemoglobin A1c Control (<8.0%)	575	X	
18	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy	0088	X	
236	Controlling High Blood Pressure	0018	X	X
237	Hypertension (HTN): Blood Pressure Measurement	0013	X	
TBD	Preventative Care & Screening for High Blood Pressure	N/A	X	X
6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD	0067	X	
197	Coronary Artery Disease (CAD): Lipid Control	0074	X	

Physician Quality Reporting System Number	Measure Title	NQF Measure Number	EHR Incentive Program	PQRS Core
7	Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI)	0070	X	
5	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0081	X	
8	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0083	X	
201	Ischemic Vascular Disease (IVD): Blood Pressure Management Control	0073	X	
204	Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic	0068	X	X
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100 mg/dl	0075	x	X
239	Weight Assessment and Counseling for Children and Adolescents	0024	X	
240	Childhood Immunization Status	0038	X	
66	Appropriate Testing for Children with Pharyngitis	0002	X	
TBD	Prenatal Care: Screening for Human Immunodeficiency Virus (HIV)	0012	X	
TBD	Prenatal Care: Anti-D Immune Globulin	0014	X	
71	Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	0387	X	
72	Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients	0385	X	
102	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0389	X	
TBD	Anti-depressant medication management: (a) Effective Acute Phase Treatment, (b) Effective Continuation Phase Treatment	0105	X	
TBD	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement	0004	X	
TBD	Low Back Pain: Use of Imaging Studies	0052	X	
TBD	Chlamydia Screening for Women	0033	X	
12	Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation	0086	X	

For physicians practicing in groups, the measures we are finalizing for the value modifier include all measures in the Group Practice Reporting Option of the Physician Quality Reporting System for 2012 and the rates of potentially preventable hospital admissions for two ambulatory care sensitive conditions at the group practice level: heart failure and chronic obstructive pulmonary disease. These measures are listed in Table 81.

TABLE 81: QUALITY OF CARE MEASURES FOR PHYSICIAN GROUPS

Measure Number	Measure Title	NQF Measure Number	Measure Developer
Care Coordination/ Patient Safety			
PQRS 46	Medication Reconciliation	NQF 0097	AMA-PCPI
PQRS TBD	Falls: Screening for Falls Risk	NQF 0101	NCQA
Preventative Health			
PQRS 110	Influenza Immunization	NQF 0041	AMA-PCPI
PQRS 111	Pneumonia Vaccination	NQF 0043	NCQA
PQRS 112	Mammography Screening	NQF 0031	NCQA
PQRS 113	Colorectal Cancer Screening	NQF 0034	NCQA
PQRS TBD	Blood Pressure Measurement	N/A	CMS
PQRS 128	Adult Weight Screening and Follow up	NQF 0421	CMS-QIP
PQRS 226	Tobacco Use Assessment and Cessation	NQF 0028	AMA-PCPI
Diabetes			
PQRS 1	Hemoglobin A1c Poor Control (>9)	NQF 0059	AMA-PCPI
PQRS TBD	Diabetes: Aspirin Use	NQF 0729	MN Community Measurement
PQRS 3	Blood Pressure Control Blood Pressure < 140/90 mm/hg	NQF 0061	NCQA
PQRS TBD	Hemoglobin A 1 c Control (<8.0%)	NQF 0575	NCQA
PQRS 2	LDL Control	NQF 0064	NCQA
PQRS 117	Dilated Eye Exam	NQF 0055	NCQA
PQRS 163	Foot Exam	NQF 0056	NCQA
PQRS TBD	Tobacco Non-Use	NQF 0729	MN Community Measurement
Hypertension			
PQRS 236	Blood Pressure Control Blood Pressure < 140/90 mm/hg	NQF 0018	NCQA
Heart Failure			
PQRS 8	Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	NQF 0083	AMA-PCPI
PQRS 198	Left Ventricular Function (LVF) Assessment	NQF 0079	AMA-PCPI
PQRS 5	Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction	NQF 0081	AMA-PCPI
PQRS 199	Patient Education	NQF 0082	AMA-PCPI
PQRS 228	Left Ventricular Function (LVF) Testing	N/A	CMS
Coronary Artery Disease			
PQRS 197	Drug Therapy for Lowering LDL	NQF 0074	AMA-PCPI
PQRS 118	Angiotensin-Converting	NQF 0066	AMA-PCPI

Measure Number	Measure Title	NQF Measure Number	Measure Developer
	Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)		
PQRS 6	Oral Antiplatelet Therapy Prescribed for Patients with CAD	NQF 0067	AMA-PCPI
Chronic Obstructive Pulmonary Disease			
PQRS 52	Bronchodilator Therapy based on FEV1	NQF 0102	AMA-PCPI
Ischemic Vascular Disease			
PQRS TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100 mg/dl	NQF 0075	NCQA
PQRS 204	Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic	NQF 0068	NCQA
Ambulatory Care Sensitive Conditions			
PQI 05	COPD	NQF 0275	AHRQ
PQI 08	Heart Failure	NQF 0277	AHRQ

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We expect to update these quality of care measures based on the measures finalized in subsequent rulemaking under the Physician Quality Reporting System and the EHR Incentive Program for the initial performance year. By doing so, we anticipate the value modifier would use the same quality of care measures that are included in the Physician Quality Reporting System and/or the EHR Incentive Program for the initial performance year. To the extent physicians are already reporting the quality of care measures under the Physician Quality Reporting System and/or the EHR Incentive Program, this step would reduce program inconsistencies and reduce the reporting burden on physicians.

(B) Potential Quality of Care Measures for Additional Dimensions of Care in the Value Modifier

We explained in the proposed rule that one of the goals of this notice and comment rulemaking is to identify potential measures that could provide a richer picture of the quality of care furnished by a physician (76 FR 42911). For example, we indicated that we are interested in quality measures that assess the care provided by specialists. We specifically requested comment from specialists about measures that were not included in the list of proposed measures. In addition, we also requested comment on outcome, care coordination/transition, patient safety, patient experience, and functional status measures (which are discussed below) as well as the 28 administrative claims measures (described below with respect to the 2010 Physician Feedback reports disseminated in 2011) and whether we should include them in the value modifier. We especially urged the physician community and private payers that have been engaged in pay-for-performance programs to identify other quality measures that they have used and to describe their experience with these measures. We requested comment on how these measures align with current private sector quality measurement initiatives.

Comment: As previously noted commenters supported CMS' efforts to develop quality measures applicable to specialists. The commenters urged CMS to add measures that provide an accurate and comprehensive view of how physicians perform in practice. Commenters, including the surgical community, suggested measures related to vascular surgery lower extremity bypass, surgical site infection, urinary tract infection, colon surgery, and surgery in the elderly. The anesthesiology community suggested perioperative and pain management measures. Pathologists suggested very specific measures related to Barrett's esophagus and radical prostatectomy reporting as well as immunohistochemical evaluation for breast cancer. Other commenters suggested adding measures for adult immunization (including Hepatitis A and B), stroke, rheumatoid arthritis, pelvic prolapse, infection prevention as well as measures to prevent unnecessary emergency room visits and decrease hospital readmissions. The commenters recommended CMS develop a process to address outdated elements among proposed measures. Several commenters opposed use of administrative claims-based measures because of their inability to capture information that may influence a physician's care. Several commenters questioned the use of the proposed cardiac and diabetes measures, because they believed these measures do not reflect the specialized care given. Additionally, commenters opposed the claims-based measure ''Use of high risk medication in the Elderly'' because the list of medications has not been updated regularly.

Response: We thank commenters for sharing their views. We will be working internally and reaching out to stakeholders to consider these comments and to make proposals in future rulemakings to refine the quality measures included in the value modifier. We do not plan at this time to include the 28 administrative claims-based measures we used in the individual 2010 Physician Feedback

Program reports in the value modifier: thus the ''Use of High Risk medications in the Elderly'' measure will not be included in the value modifier. A substantial number of these 28 administrative claims-based measures rely on drug-related data that we cannot obtain for all Medicare beneficiaries because not all Medicare beneficiaries are enrolled in a Medicare Part D plan. In addition, some of the administrative claims-based measures overlap with the Physician Quality Reporting System measures we are adopting for the value modifier, and thus are duplicative.

(i) Outcome Measures

As discussed previously, we sought comment on the use of measures in the future that assess the rate of potentially preventable hospital admissions for six ambulatory care-sensitive conditions at the practice group level: diabetes, bacterial pneumonia, dehydration, chronic obstructive pulmonary disease (COPD), urinary tract infection, and heart failure (76 FR 42912). We also sought comment on an all-cause hospital readmission measure.

We also sought suggestions on other outcome measures that would be appropriate measures of the quality of care furnished for purposes of the value modifier, such as measures that examine emergency room use for ambulatory care sensitive conditions. We indicated we were interested in outcome measures that can be calculated from existing Medicare claims data and do not require additional reporting by physicians. In addition, we stated we were particularly interested in comments on potential measures of complications that would be appropriate to include in the value modifier (76 FR 42912).

Comment: The majority of commenters supported CMS' interest in moving to a system that focuses on outcome measures. They strongly emphasized such measures should be indicative of physician performance and control. Many commenters suggested that all outcome measures must be risk-adjusted appropriately to account for the complexity and severity of the patient's condition(s). Commenters urged us to ensure that the risk adjustment methodology would be sufficient such that physicians are not discouraged from caring for the highly complex patients. The commenters noted that physicians should not be held accountable for patient factors outside of their control that may influence outcomes such as patient adherence or other patient attributes (such as education, literacy, socioeconomic status). Two commenters expressed concern with an all-cause hospital readmission measure that had not yet been developed and which would assess physicians on an event over which physicians do not have complete control.

Response: We thank commenters for their support for outcome measures. We agree with commenters that we should move toward including in the value modifier quality of care measures that assess patient outcomes. As discussed previously, as a first step in that direction we are finalizing outcome measures that assess the rate of potentially preventable hospital admission at the group practice level for heart failure and chronic obstructive pulmonary disease. We anticipate proposing in next year's rulemaking to include outcome measures that assess the rate of potentially preventable hospital admissions for other ambulatory care sensitive conditions at the group practice level. As we move forward, we will take concerns about risk adjustment of these measures into consideration as we incorporate them into the value modifier.

(ii) Care Coordination/Transition Measures

We also noted in the proposed rule that care transitions such as transition of a beneficiary from an inpatient setting to the community or to a post-acute setting are important aspects of quality of care furnished (76 FR 42912). We requested input about these and other potential aspects of care coordination/transitions for which measures could be developed and/or used for purposes of the value modifier.

Comment: Many commenters generally supported the use of care coordination and transition measures but cited the need for a robust risk-adjustment methodology with these measures. Conversely, several commenters opposed the use of care coordination/transition measures, citing that use of these measures ''requires a level of coordination which may only be found in highly integrated care systems such as an accountable care organization (ACO) or comprehensive medical homes.'' Indeed, many commenters recommended that we focus on integrated groups and systems of care where care coordination was implemented and could be measured. The commenters also voiced concern over creating care coordination measures when providers are not presently reimbursed for this type of care. Many commenters, especially hospital-based providers, also pointed out that data was often simply not available to them or did not exist (that is, the patient had no primary care physician with whom to communicate).

Response: We thank the commenters for their suggestions. As we noted in the proposed rule, to the extent that we develop care coordination/transition measures, we will propose them in future rulemaking for inclusion in the value modifier. We continue to believe that care coordination/transitions are important aspects of quality of care furnished and we will be working with stakeholders to develop appropriate measures.

(iii) Patient Safety, Patient Experience, and Functional Status

We explained in the proposed rule that measures of patient safety, patient experience, and functional status were important dimensions of care for the value modifier (76 FR 42912). We sought comment about potential patient safety measures that could be developed and/or used for purposes of the value modifier. To the extent commenters were aware of potential measures of patient safety, patient experience, or functional status that we could use, we welcomed such suggestions.

Comment: Many commenters favored the inclusion of patient safety, experience of care, and functional status measures in the value modifier and offered general suggestions for inclusion of such measures. Many commenters supported patient experience measures for general and specialty physicians and there were also recommendations for the use of standard assessment tools and patient experience tools which could be used.

Response: We thank commenters for their suggestions and agree that this is an important area for development of measures and the infrastructure to support them. We will consider them in the future as we focus on additional areas where physician value can be improved.

(2) Cost Measures

Section 1848(p)(3) of the Act requires that cost measures used in the value modifier be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary. This composite would eliminate the effect of geographic adjustments in payment rates and account for risk factors and other factors so that physicians and groups of physicians would be compared on an equal basis. In other words, comparisons of the quality of care furnished compared to cost would be on an ''apples-to-apples'' basis so that physicians in high cost areas would not be penalized unfairly and

physicians in low-cost areas would not be rewarded unjustly.

(A) Cost Measures for the Value Modifier

We proposed to use total per capita cost measures and per capita cost measures for beneficiaries with four chronic conditions (COPD; heart failure; coronary artery disease; and diabetes) in the value modifier (76 FR 42913). Our 2010 Physician Feedback Program reports use a total per capita cost measure and per capita cost measures for the overall costs for beneficiaries with these four chronic conditions. These per capita cost measures are adjusted for geographic differences and they are risk adjusted to ensure geographic and clinical comparability, as required by section 1848(p)(3) of the Act.

We explained that these cost measures would be compared to the quality of care furnished for use in determining the value modifier.

Comment: Most commenters agreed with our proposal to use in the initial years of the value modifier both total per capita cost measures and per capita cost measures for COPD; heart failure; coronary artery disease; and diabetes. Commenters urged CMS to clarify which beneficiaries will be included for assessing costs in each of these four chronic conditions. Many commenters suggested CMS move quickly to the use of episode-based cost measures. Commenters also requested that CMS move forward with the episode grouper in a transparent fashion and suggested that CMS have public sessions through an appropriate venue to apprise the public of our progress.

Several commenters questioned CMS' methodology to eliminate geographic differences in Medicare's payment and, in particular, how the Geographic Price Cost Indices (GPCIs) would be handled. In addition, commenters stated that the risk adjustment methodology we currently use for the cost measures in the Physician Feedback Program was not sufficiently robust to adequately account for the differences among patient populations especially those that cared for high acuity populations. Many commenters said that until a risk adjustment methodology could adequately adjust for patient factors outside of the physician's control like severity of disease or patient adherence, it would not be possible to calculate a meaningful composite of cost for the value modifier. Many commenters expressed the desire for increased communication and transparency about the methodology for the composites that will comprise the value modifier.

Response: We believe that total per capita cost measures are useful overall measures of the volume of healthcare services furnished to beneficiaries. In addition, the total per capita costs for patients with diabetes, coronary artery disease, COPD, and heart failure can provide information on the volume of care provided to these patients. We also agree that episode-specific costs of care are valuable measures and we intend to evaluate how to include them in the value modifier in future years, as further discussed below.

We believe that the current risk adjustment methodology, the hierarchal condition categories model (HCC), reasonably predicts high- and low-cost beneficiaries.[1] In addition, the model's explanatory power has increased over recent years and it is recalibrated regularly for more recent diagnoses and expenditure data. We are unaware of generally used risk adjustment models that can adjust broadly for patient factors cited by the commenters; nor did commenters present evidence that the HCC model was inadequate or disadvantages physicians that care for certain types of patients.

The methodology we currently use in the Physician Feedback Program reports to ensure we compare Medicare payments on an ''apples-to-apples'' basis equalizes the differences in payment rates due to geography among the same class of providers.[2] Thus, the effects of the GPCIs are removed from our payments. In other words, actual Medicare payments are adjusted such that a given service is priced at the same level across all providers within the same facility type or setting, regardless of geographic area or differences in Medicare payment rates among facilities.

We agree with commenters that our risk adjustment and price standardization methodologies must be transparent. In the next several months, we will host public events to further gather input on the value modifier and explain the price standardization and risk adjustment methodologies so that physicians and other stakeholders have a full understanding of our efforts to ensure fair and accurate calculation of per capita costs.

After consideration of the public comments we received, we are finalizing our proposal to use total per capita cost measures and per capita cost measures for beneficiaries with four specific chronic conditions (chronic obstructive pulmonary disease, heart failure, coronary artery disease, and diabetes) in the value modifier.

(B) Potential Cost Measures for Future Use in the Value Modifier

Section 1848(n)(9)(A) of the Act requires us to develop by January 1, 2012, an episode grouper that combines separate, but clinically related items and services into an episode of care for an individual, as appropriate. We explained that during 2012 we will test and plan how to use an ''episode grouper'' (76 FR 42913).

As a transition to implementing the episode grouper, we explained that we could use cost measures based on the inpatient hospital Medicare Severity Diagnosis Related Groups (MS–DRG) classification system. We requested comment on whether we should pursue the MS–DRG approach in the near term while we develop episode-based cost measures for a significant number of high-cost and high-volume conditions in the Medicare program. In addition, we specifically sought comment on the resource and cost measures used in private sector initiatives and how they are used to profile physicians compared to the quality of care provided.

Comment: Commenters indicated that CMS should rapidly transition to episode-based cost measures and also communicate with stakeholders frequently about the status of the episode grouper and the methodology as it evolves. A number of commenters did not think that the use of an MS–DRG approach in the short run was useful.

Response: We agree with commenters that the use of episode-based costs can be a valuable input into the value modifier. Prior to incorporating episode-based costs into the value modifier, we will hold stakeholder events to share our progress on the episode grouper to ensure transparency of the methodology underlying any grouping of the costs of various items and services.

b. Implementation of the Value Modifier

We explained in the proposed rule that there a number of issues related to the implementation of the value modifier including steps for both measurement of performance and application of payment adjustments (76 FR 42913). Although we did not make

[1] RTI, ''Evaluation of the CMS–HCC Risk Adjustment Methodology,'' (March 2011), available at: *https://www.cms.gov/MedicareAdvtgSpecRateStats/downloads/Evaluation_Risk_Adj_Model_2011.pdf* (recent overview of the HCC model and the development of the methodology over the past several years).

[2] For additional information about price standardization, see ''Methodology and Process Specifications for the Physician Quality Reporting System Group Practice Reporting Option Quality and Resource Use Reports'' (September 2011) available at: *http://www.cms.gov/PhysicianFeedbackProgram/Downloads/2010_GPRO_QRUR_Detailed_Methodology.pdf.*

proposals, we stated that our plan is to begin implementing the value modifier through the rulemaking process during 2013 as required by section 1848(p)(4)(B)(i) of the Act. We requested input from stakeholders as we work on these issues.

Comment: Many commenters doubted whether meaningful composites of quality and cost that capture physician ''value'' could be developed in time for 2017, if ever. Many commenters cited the challenges of how to assign patients to physicians and the adequacy of risk adjustment methods to ensure that physicians are not discouraged from caring for patients with highly complex conditions. Others cited the lack of meaningful quality measures for many types of physicians as a challenge to the calculation of the value modifier. Many commenters suggested that we appeal to the Congress for a substantial delay in the timeline for implementation of the physician value modifier.

Response: We appreciate commenters' concerns and recognize the challenges before us as we move to a payment system that begins to encourage physicians to focus on the relative value of each service they furnish or order, the cumulative cost of their own services and services that their beneficiaries receive, and the quality and outcomes of the care furnished to beneficiaries.

We realize that for some physicians, the transition to a focus on value will require a new way of thinking about the practice of medicine. And, it is important that value is being assessed in a manner which acknowledges and takes into account the diversity of patient conditions and physician practices. Given this backdrop, we stated that we intend to move deliberately and carefully because we recognize the complexities of calculating a reliable and valid measure of value that could be used to differentiate payment.

Notwithstanding this caution, we have used the 2010 Physician Feedback Program reports to help develop attribution methodologies for physicians and physician groups and to use them as a mechanism to gain feedback into the value modifier and its methodologies. In addition, we have standardized Medicare costs and applied the HCC risk adjustment model to physician per capita costs in these reports. As discussed previously, we will be convening public events to further explore these issues and to gather stakeholder input based on these reports and the methodologies we have applied.

We also will use the next several months, before the 2013 physician fee schedule rulemaking process begins, to explore various ways to develop composites of cost and quality that could be used in the value modifier and to hold listening sessions and engage in other activities with stakeholders to gain input into the value modifier. We will continue our work to implement the statutory directives and plan to propose in next year's physician fee schedule rulemaking a methodology for the value modifier.

Comment: Many commenters stated that CMS should focus the value modifier in 2015 and 2016 on large integrated group practices. Some commenters supported that CMS focus initially on cost and quality outliers. Other commenters recommended that we focus on physicians who treat patients with the most prevalent and costly conditions. Other commenters suggested that because the proposed quality of care measures focused on chronic conditions, we should apply the value modifier starting in 2015 to physicians treating these conditions.

Response: We thank these commenters for their comments and will address these issues in future rulemaking.

c. Initial Performance Period

Section 1848(p)(4)(B)(ii)(I) of the Act requires the Secretary to specify an initial performance period for the application of the value modifier with respect to 2015. We proposed that the initial performance period be the full calendar year 2013, that is, January 1, 2013 through December 31, 2013 (76 FR 42913). The value modifier that would apply to items and services furnished by specific physicians and groups of physicians under the 2015 physician fee schedule would be based on performance during 2013. We proposed this performance period because some claims for 2013 (which could be used in cost or quality measures) may not be fully processed until 2014. As such, we will need adequate lead time to collect performance data, assess performance, and construct and compute the value modifier during 2014 so that it can be applied to specific physicians starting January 1, 2015, as required by statute. As we have done in other payment systems, we plan to use claims that are paid within a specified time period, such as, 90 days after 2013, for assessment of performance and application of the value modifier for 2015. We will propose the specific cut-off period as part of the more detailed methodology for computation and application of the value modifier in future rulemaking(s). We requested comment on this proposed performance period.

Comment: Commenters strongly opposed the use of 2013 as the initial performance period given ''the myriad methodological issues involved.'' Many commenters stated it was unfair to have the initial performance period begin January 1, 2013 before the methodology to compute the value modifier is finalized in November 2013. Some commenters suggested that the gap between the performance period and the payment adjustment period was too long. Some commenters suggested we were not required to use a full year as the performance period. Other commenters suggested that ''unless and until there is evidence that it is possible to accurately measure value without penalizing those physicians who treat the most difficult patients,'' CMS should not move forward with specifying a performance year. Other commenters suggested CMS designate calendar year 2015 as a ''practice year'' to allow for additional physician acceptance of the methodology we use to calculate the value modifier.

Response: Section 1848(p)(4)(B)(iii) of the Act requires us to apply the payment modifier to specific physicians and physician groups the Secretary determines appropriate for items and services furnished beginning January 1, 2015. We proposed calendar year 2013 as the initial performance period because it provides physicians with substantial lead time to participate in the Physician Quality Reporting System and the EHR Incentive Program and to begin to take the necessary steps to report quality and use the results to improve the quality of their care. Indeed, there is still an opportunity to participate in the Physician Quality Reporting System program for the 2011 program year, two years before the initial performance period for the value modifier. As we discussed above, we do not seek to evaluate individual physicians on each of the quality of care measures used in the value modifier, but rather assess physician performance using quality of care measures for the types of care they provide. We strongly encourage physicians to participate in the Physician Quality Reporting System program and the EHR Incentive Program sooner rather than later and to choose to report quality of care measures that best reflect their practice and patient population. Although we have not yet proposed the value modifier methodology, our primary interest at this point is to increase the quality of care for Medicare beneficiaries. We note that we also plan to propose a value modifier in rulemaking during 2012,

prior to the initial performance period. Thus, we believe it is reasonable to encourage physicians to report appropriate quality measures well in advance and irrespective of the exact value modifier methodology at this time.

We explored using 2015 as the performance period and making retroactive adjustments in 2016 to claims paid for care furnished in 2015. This retroactive approach would require us to reprocess all 2015 claims so that each claim shows actual amounts paid. Additionally, retroactive adjustments affect beneficiary cost sharing amounts, which also would need to be adjusted retrospectively. Requiring physicians to collect or refund small cost sharing amounts is operationally complex and confusing for beneficiaries. These same two issues arise if we were to use calendar year 2014 as the performance period for the 2015 payment adjustment year.

We also examined whether we could use an abbreviated period (such as, 6 months) or a period that crossed years (such as, July 1–June 30) as the performance period. The former approach is unlikely to yield sufficient volume of cases to develop reliable measures for individual physicians and the latter approach is inconsistent with reporting periods currently established for the Physician Quality Reporting System and the EHR Incentive Program.

Despite these challenges, we are still seeking other ways to close the gap between the performance period and the payment adjustment period. In the interim, however, we are finalizing our proposal that calendar year 2013 be the initial performance period, because it aligns with the Physician Quality Reporting System and the EHR Incentive Program and because the alternatives are more onerous to physicians and beneficiaries than our original proposal. We will reexamine the initial performance period in future rulemakings as we seek to provide more timely feedback to physicians.

d. Other Issues

We also requested comment on two issues related to the development of the value modifier, although we did not make proposals to address either issue in the proposed rule. First, section 1848(p)(5) of the Act requires the Secretary, as appropriate, to apply the value-based modifier in a manner that promotes systems-based care. We sought comment on how we might determine the scope of systems-based care and how best to promote it in applying the value modifier. Second, section 1848(p)(6) of the Act requires the Secretary in applying the value modifier, as appropriate, to take into account the special circumstances of physicians or groups of physicians in rural areas and other underserved communities. We requested comment on how we should identify physicians or groups of physicians in rural areas and other underserved communities, the specific special circumstances they face, and once identified, how these special circumstances should be taken into account for purposes of applying the value modifier (76 FR 42914).

Comment: CMS received many comments promoting systems-based care. These commenters suggested that applying the value modifier at the group level reinforced systems-based care. Hospital-based physicians stated that aligning the value modifier and the hospital value based purchasing program on both cost and quality would encourage systems-based care. Another commenter suggested that using a value modifier that would apply to all physicians in a specific region would encourage systems-based care. Other commenters indicated that establishment of medical homes and ''Independence at Home'' for the sickest, most costly patients encouraged systems-based care. Commenters stated that these two programs emphasize coordination of care by providing services early before beneficiary medical conditions become more serious and costly to treat. Other commenters supported the concept of a coordinated surgical home model. Another commenter encouraged CMS to work with specialty societies to define systems-based care for the purpose of the value modifier.

Response: We thank these commenters for their comments and will take them into account as we progress in our thinking of ways to promote systems-based care in the value modifier program, and particularly how to incorporate care transition/coordination measures into the program.

Comment: One commenter said we should expand our inquiry beyond identifying rural physicians and examine whether beneficiaries in rural areas have sufficient access to care by looking at the breadth and level of services available to them. This commenter also emphasized the importance of mid-level providers such as nurse practitioners and physician assistants and that the value modifier should apply to them. Commenters stressed that rural providers are already overworked and the value modifier should be simple and not require additional staff or technology. One commenter suggested we work with the Veterans Administration due to their extensive experience and analytic capabilities. CMS also received comment to consult and work with the Indian Health Service to understand the organizational structures of tribal hospitals and clinics. One commenter also suggested that a modifier that reflects a regional practice mode would ''facilitate measurement in rural and underserved communities because it emphasizes a broader perspective and one that is more relevant for providers and patients.''

Response: We thank these commenters for their input and will take these comments and the information provided into account as we progress with the methodology for the value modifier.

3. Physician Feedback Program

Section 1848(n) requires us to provide confidential reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. Section 1848(n)(1)(A)(iii) of the Act also authorizes us to include information on the quality of care furnished to Medicare beneficiaries by a physician or group of physicians. We have completed two phases of the Physician Feedback Program. By the end of 2011, we intend to implement Phase III of the Physician Feedback Program by providing reports on both resource use and quality measures to physician groups that participated in the Group Practice Reporting Option (GPRO–1) in 2010 and to physicians practicing in the following States: Iowa, Kansas, Missouri, and Nebraska. As we explained previously, many of the methodological issues that we are addressing in the Physician Feedback Program reports will assist us as we implement the value modifier.

a. Alignment of Physician Quality Reporting System Quality of Care Measures With the Physician Feedback Reports

We explained in the proposed rule that we are using the quality measures reported in the Physician Quality Reporting System in the Physician Feedback Program reports that we disseminate this year (76 FR 42903). We took this step because use of Physician Quality Reporting System measures aligns both quality initiatives and reduces potential program inconsistencies, ensures we do not measure the same clinical process or outcome using different data sources or methodologies, and does not place new reporting burdens on physicians. Although we did not make any proposals in this area, we requested

comment on using the performance data in the Physician Quality Reporting System in the Physician Feedback Program.

Comment: Most commenters supported using the Physician Quality Reporting System's quality measures in the Physician Feedback Program reports. These commenters frequently also requested a closer alignment of all of our physician quality improvement programs. A number of commenters, including hospital-based physicians such as hospitalists, surgeons, and certain specialists and sub-specialists, noted that the Physician Quality Reporting System measures did not include measures to assess their performance or apply to elements of their practice. Many commenters expressed interest in working with us to identify the measures that captured the seminal elements of their practice.

Response: We plan to continue to use the quality of care measures reported in the Physician Quality Reporting System to reduce physician burden, align physician reporting and support a common infrastructure for the measurement of physician value. We appreciate the commenter's interest in working with us as we refine the Physician Feedback Program to make the reports more meaningful and relevant to more physicians.

b. 2010 Physician Group and Individual Reports Disseminated in 2011

We described in the proposed rule how we intended to create physician feedback reports for the 35 large medical group practices (each with 200 or more physicians) that chose to participate in the Physician Quality Reporting System Group Practice Reporting Option (GPRO–1) in 2010 (76 FR 42903). In addition, we described how we planned to disseminate Physician Feedback Program reports to individual physicians paid under the Physician Fee Schedule within four States: Iowa, Kansas, Missouri, and Nebraska (76 FR 42904). We explained that we chose these four States because the Medicare Administrative Contractor serving these States could assist us in emailing these reports to a substantial number of physicians because of its robust electronic communications infrastructure.

We stated in the proposed rule that deciding which physician(s) is/are responsible for the care of which beneficiaries is an important aspect of measurement (76 FR 42907). When attributing beneficiary cost information to physicians, we stated that we must balance between costs for delivered services that are within the physician's control and costs for delivered services that are not within their control. We recognized that attribution rules have the potential to alter incentives regarding how physicians coordinate and deliver care to beneficiaries and seek to encourage better care coordination and accountability for patient outcomes. In addition, determining how to make relevant comparisons of physicians to a standard or to their peers is also an important policy aspect of the Physician Feedback Program.

In light of these issues, we indicated that the individual physician reports that we are disseminating this year will allow more Medicare beneficiaries to be matched to physicians for purposes of assessing the quality of care furnished and the associated resources. In addition, we indicated that the reports will stratify physicians by specialty and by the conditions they treat, which allow both cost and clinical measures to reflect procedures and services that best portray physician practice patterns. Finally, we stated we intended to examine whether to provide reports to groups of physicians who submit Medicare claims under a single tax identification number (TIN) to see if we can provide feedback reports that cover more physicians. Although we did not make any proposals in this area, we requested comment on these and any other issues to ensure that the future Physician Feedback Program reports provide meaningful and actionable information.

Comment: Many commenters agreed with our examination of alternative attribution methods to assign beneficiaries that would allow increased numbers of beneficiaries to be matched to physicians but they also questioned our ability to do so. Many commenters cited the recent Government Accountability Office (GAO) report, ''Medicare Physician Feedback program: CMS Faces Challenges with Methodology and Distribution of Physician Reports,'' that described the challenges involved with developing and disseminating physician feedback reports.[3] In particular, the GAO recommended that we use methodological approaches that increase the number of physicians eligible to receive a report, such as: (1) Multiple provider attribution methods, which could also enhance credibility of the reports with physicians; and (2) distributing feedback reports that include only resource use information, if quality information is unavailable.

Response: We worked closely with the GAO in its review of the Physician Feedback Program by providing them our plans to improve and expand the program, and we concur with their recommendations to:

- Use methodological approaches that increase the number of physicians eligible to receive a report, such as (a) multiple provider attribution methods, which could also enhance credibility of the reports with physicians and (b) distributing feedback reports that include only resource use information, if quality information is unavailable.
- Conduct statistical analyses of the impact of key methodological decisions on reliability.
- Identify factors that may have prevented physicians from accessing their reports and, as applicable, develop strategies to improve the process for distributing reports and facilitating physicians' access to them.
- Obtain input from a sample of physicians who received feedback reports on the usefulness and credibility of the performance measures contained in the reports and consider using this information to revise future reports.

As we discussed with GAO, we are taking steps this year to address many of the issues that they raised regarding the first two phases of the Physician Feedback program.

For example, on September 26, 2011, we distributed physician reports to the physician groups that participated in the Group Reporting Option in the Physician Quality Reporting System in 2010. These reports represent the first time performance on a wide-range of quality of care and cost measures can be viewed in the same report for Medicare beneficiaries in large group practices across the country. As recommended by the GAO, we invited all report recipients to provide us input on the usefulness and credibility of the performance measures contained in the report so that we could improve the reports for future years. We will be releasing publicly the general findings from these reports. This analysis will include statistical analysis of the impact of key methodological decisions on reliability that the GAO recommended that we conduct.

In addition, the reports that we are producing for individual physicians in Iowa, Kansas, Missouri, and Nebraska will contain quality performance data on the 28 administrative claims-based measures described in the proposed rule (76 FR 42904 through 42907) for all physicians and performance on the Physician Quality Reporting System

[3] *Medicare Physician Feedback Program: CMS Faces Challenges with Methodology and Distribution of Physician Reports,* GAO–11–720 (August 12, 2011), available at *http://www.gao.gov/new.items/d11720.pdf*

measures for those physicians who satisfactorily reported in 2010. For the cost measures, we will categorize physicians' Medicare fee for service patients based on the level of care provided to them in 2010 as measured by outpatient Evaluation and Management (''E/M'') office visits and total professional costs. Using this approach, we expect to be able to attribute all Medicare beneficiaries who were enrolled in Medicare for at least one full year to physicians practicing in those four States during 2010.

This approach addresses the GAO's recommendations to use methodological approaches to increase the number of physicians eligible to receive a report. We will invite report recipients to provide us input to increase the usefulness and credibility of future individual physician reports and we will be conducting statistical analysis of the impact of our methodological decisions on reliability as recommended by the GAO. In addition, we have taken steps this year to overcome the barriers that have prevented physicians from accessing their reports in the past and we will be working on developing future strategies to improve the process for distributing the reports in the future, as recommended by the GAO.

Comment: Many commenters supported measuring physician performance and creating peer groups for comparisons based on specialty or even more narrowly, subspecialty. By contrast, other commenters supported measuring physician performance and creating peer groups for comparisons by patient condition. In either case, many commenters stated that without a method to identify and compare physicians caring for the highest acuity patients, we might be unfairly biasing any cost comparisons or encouraging physicians to avoid caring for the most complex Medicare patients. Commenters varied in their support of group versus individual physician level reporting. Several commenters cited the need for large enough numbers of cases to apply confidence intervals and noted that reliable results were critical to acceptance of the Physician Feedback Program reports.

Response: Using the data from the 2010 group and individual physician feedback reports disseminated in 2011, we plan to evaluate the reliability for quality of care and cost measures and comparison groups included in the reports. We will use this analysis to inform how we move forward with the Physician Feedback Program to ensure that they contain valid and reliable measures that are fair and meaningful to physicians' efforts to improve quality while reducing costs.

J. Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

2. Annual Update to the Code List

a. Background

In § 411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS publications. The DHS categories defined and updated in this manner are as follows:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- Dialysis-related drugs furnished in or by an ESRD facility (§ 411.355(g)).
- Preventive screening tests, immunizations, or vaccines (§ 411.355(h)).

The definition of DHS at § 411.351 excludes services that are reimbursed by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and other dialysis-related drugs furnished by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration) are being paid under the ESRD PPS promulgated in the final rule published on August 12, 2010 in the **Federal Register** (75 FR 49030). Drugs for which there are no injectable equivalents or other forms of administration will be payable under the ESRD PPS beginning January 1, 2014.

The Code List was last updated in Addendum J of the CY 2011 PFS final rule with comment period (75 FR 73831 through 73841) and revised in a subsequent correction notice (76 FR 1670).

b. Response to Comments

We received no public comments relating to the Code List that became effective January 1, 2011.

c. Revisions Effective for 2012

The updated, comprehensive Code List effective January 1, 2012, is listed as Addendum J in this final rule with comment period and is available on our Web site at *http://www.cms.gov/PhysicianSelfReferral/40_List_of_Codes.asp#TopOfPage*.

Additions and deletions to the Code List conform the Code List to the most recent publications of CPT and HCPCS and to changes in Medicare coverage policy and payment status.

The following Tables 83 and 84, identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2012. Tables 83 and 84 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis–related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

In Table 82, we specify additions that reflect new CPT and HCPCS codes that become effective January 1, 2012, or that became effective since our last update. We also include additions that reflect changes in Medicare coverage policy or

payment status that become effective January 1, 2012, or that became effective since our last update.

Table 83 reflects the deletions necessary to conform the Code List to the most recent publications of the CPT and HCPCS, and to changes in Medicare coverage policy and payment status. In addition, we are deleting CPT code 96110 from the category of ''physical therapy, occupational therapy, and outpatient speech-language pathology services'' because the code was revised. It has been replaced by HCPCS code G0451, which is listed in Table 82.

We will consider comments regarding the codes listed in 83 and 84. Comments will be considered if we receive them by the date specified in the ''DATES'' section of this final rule with comment period. We will not consider any comment that advocates a substantive change to any of the DHS defined in § 411.351.

TABLE 82: ADDITIONS TO THE PHYSICIAN SELF-REFERRAL LIST OF CPT[1/]HCPCS CODES

CLINICAL LABORATORY SERVICES
0279T Ctc test
0280T Ctc test w/i & r
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
G0451 Devlopment test interpt & rep
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
74174 Computed tomographic angiography
78226 Hepatobiliary system imaging
78227 Hepatobil syst image w/drug
78582 Lung ventilat&perfus imaging
78579 Lung ventilation imaging
78597 Lung perfusion differential
78598 Lung perf&ventilat diferentl
93998 Noninvas vasc dx study proc
A9584 Iodine I-123 ioflupane
RADIATION THERAPY SERVICES AND SUPPLIES
[No additions]
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
[No additions]
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
90654 Flu vaccine no preserv, ID

[1]CPT codes and descriptions only are copyright 2011 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 83: DELETIONS TO THE PHYSICIAN SELF-REFERRAL LIST OF CPT[1/]HCPCS CODES

CLINICAL LABORATORY SERVICES
{No deletions}
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
96110 Developmental test lim
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
77079 Ct bone density peripheral
77083 Radiographic absorptiometry
78220 Liver function study
78223 Hepatobiliary imaging
78584 Lung V/Q image single breath
78585 Lung V/Q imaging
78586 Aerosol lung image single
78587 Aerosol lung image multiple
78588 Perfusion lung image
78591 Vent image 1 breath 1 proj
78593 Vent image 1 proj gas
78594 Vent image mult proj gas
78596 Lung differential function
93875 Extracranial study
RADIATION THERAPY SERVICES AND SUPPLIES
{No deletions}
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No deletions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
{No deletions}

[1] CPT codes and descriptions only are copyright 2011 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

K. Technical Corrections

1. Outpatient Speech-Language Pathology Services: Conditions and Exclusions

We proposed and are now finalizing a technical correction to the heading of the condition of coverage at § 410.62(b) for outpatient speech-language pathology services. The heading was inadvertently changed in the course of rulemaking for CY 2009 when a new paragraph was added at § 410.62(c) to recognize speech-language pathologists in private practice. The section heading at § 410.62(b) currently reads ''Special provisions for services furnished by speech-language pathologists in private practice.'' We did not receive public comments on our proposal to make a technical correction to § 410.62(b), as such, we are finalizing the change to reinstate the correct heading at § 410.62(b) to read ''Condition for coverage of outpatient speech-language pathology services furnished to certain inpatients of a hospital or a CAH or SNF.''

2. Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements

We proposed to make two technical corrections to Subpart H of the regulations for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements at § 410.140 to the definition of ''deemed entity'' and at § 410.141(b)(1) entitled ''training orders''. We did not receive public comments on either proposal; as a result we are finalizing both of these technical corrections as proposed and discussed below.

a. Changes to the Definition of Deemed Entity

We proposed and are now finalizing the following technical corrections to the definition of ''deemed entity'' in § 410.140 to—

- Remove the following phrases to clarify the purpose of the reference to an approved entity:

++ ''[B]y CMS to furnish and receive Medicare payment for the training''.

++ ''Upon being approved''.

++ ''CMS refers to this entity as an ''approved entity''''.

- Remove an incorrect reference to § 410.141(e) and replacing it with § 410.145(b).

The final revisions read as follows:

Deemed entity means an individual, physician, or entity accredited by an approved organization, but that has not yet been approved by CMS under § 410.145(b) to furnish training.

b. Changes to the Condition of Coverage Regarding Training Orders

We proposed and are now finalizing the following technical correction to § 410.141(b)(1) entitled ''training orders'' to:

- Remove the cross-reference ''§ 410.32(a)'' and adding the cross-reference ''§ 410.32(a)(2)''.
- Remove the term ''it'' and adding the phrase ''the training'' in its place.

The final revisions read as follows:

Training orders. Following an evaluation of the beneficiary's need for the training, the training is ordered by the physician (or qualified nonphysician practitioner) (as defined in § 410.32(a)(2)) treating the beneficiary's diabetes.

3. Practice Expense Relative Value Units (RVUs)

In the CY 2012 PFS proposed rule (76 FR 42920), we proposed technical corrections to the regulation at § 414.22(b) to include examples of the settings in which the facility or nonfacility practice expense (PE) RVUs are applied and to clarify that the settings list was not exhaustive. We proposed adding ''hospice'' after ''community mental health center'' under § 414.22(b)(5)(i)(A) as a setting in which facility PE RVUs apply. We proposed revising the language under § 414.22(b)(5)(i)(B) to include ''comprehensive outpatient rehabilitation facility (CORF)'' as a setting in which nonfacility PE RVUs are applied, and we proposed to revise the description of outpatient therapy services.

Comment: We received one comment from an association representing speech-language pathologists and audiologists requesting that we add audiology services in our proposed revision of paragraph (b)(5)(i)(C) of the regulation at § 414.22(b) that specifies the nonfacility practice expense RVUs are always applied to outpatient therapy services and CORF services billed under the physician fee schedule. Following this logic, the commenters requested that we remove the facility practice expense RVUs from 15 of the CPT codes on the Audiology Code list at *http://www.cms.gov/PhysicianFeeSched/* and always pay for audiology services at the nonfacility practice expense RVU amount.

Response: Our proposed revision to the regulation at § 414.22(b)(5)(i)(C) was merely a technical change to reflect more accurately our current policy to apply the nonfacility PE RVUs for outpatient therapy and CORF services billed under the PFS, and to add a parenthetical description of outpatient therapy services. We did not propose to make any changes in our current policy regarding the settings in which the facility or nonfacility PE RVUs are applied. Under sections 1833(a)(8) and (9), and 1834(k) of the Act, payment for all outpatient therapy services, including physical therapy, occupational therapy, speech-language pathology and CORF services, is made at the ''applicable fee schedule amount'' which is the payment amount determined under the PFS. Audiology services are not included within the definition of outpatient therapy services subject to this payment basis. As a result, we will continue to pay for audiology services under the physician fee schedule, applying nonfacility or facility PE RVUs, as appropriate based on the setting in which services are furnished.

We are finalizing the following technical corrections to the regulation at § 414.22(b):

- In paragraphs (b)(5)(i)(A) and (B), we—

++ Included additional examples of the settings in which the facility or nonfacility practice expense (PE) RVUs are applied, respectively; and

++ Clarified that the lists of settings are not exhaustive; and amended these lists to include additional place of service examples.

- In paragraph (b)(5)(i)(A) we added ''hospice'' to the list of places of service after ''community mental health center.''
- In paragraph (b)(5)(i)(B), we—

++ Revised the language to be more consistent with (b)(5)(i)(A) and to include the ''comprehensive outpatient rehabilitation facility (CORF)'' as a place of service example; and

++ Clarified this provision by removing the text regarding the use of the nonfacility PE RVUs for services in '' * * * a facility or institution other than the hospital, skilled nursing facility, community mental health center, or ASC'' because this phrase does not accurately reflect the places of service where the nonfacility PE RVUs are applied.

- In paragraph (b)(5)(i)(C), we—

++ Revised the paragraph introduction by adding ''and CORF'' after ''outpatient therapy'' and before ''services'' and, to more accurately define the term ''outpatient therapy services,'' to add ''(including physical therapy, occupational therapy and speech-language pathology services)'' after ''therapy services'' and before ''CORF services billed under * * *''.

The final revisions to § 414.22(b)(5)(i)(A), (B), and (C) read as follows:

(A) *Facility practice expense RVUs.* The facility practice expense RVUs apply to services furnished to patients in places of service including, but not limited to, a hospital, a skilled nursing facility, a community mental health center, a hospice, or an ambulatory surgical center.

(B) *Nonfacility practice expense RVUs.* The nonfacility practice expense RVUs apply to services furnished to patients in places of service including, but not limited to, a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility (CORF).

(C) *Outpatient therapy and CORF services.* Outpatient therapy services (including physical therapy, occupational therapy, and speech-language pathology services) and CORF services billed under the physician fee schedule are paid using the nonfacility practice expense RVUs.

VII. Waiver of Proposed Rulemaking and Collection of Information Requirements

A. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national drug coding system comprised of Level I (CPT) codes and Level II (HCPCS National Codes) that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. Level I (CPT) codes are copyrighted by the AMA and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures. The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS, including both Level I and Level II codes, is similarly updated annually on a CY basis. Annual coding changes are not available to the public until the Fall immediately preceding the annual January update of the PFS. Because of the timing of the release of these new codes, it is impracticable for us to provide prior notice and solicit comment on these codes and the RVUs assigned to them in advance of publication of the final rule that implements the PFS. Yet, it is imperative that these coding changes be

accounted for and recognized timely under the PFS for payment because services represented by these codes will be provided to Medicare beneficiaries by physicians during the CY in which they become effective. Moreover, regulations implementing HIPAA (42 CFR parts 160 and 162) require that the HCPCS be used to report health care services, including services paid under the PFS. We assign interim RVUs to any new codes based on a review of the AMA RUC recommendations for valuing these services. We also assign interim RVUs to certain codes for which we did not receive specific AMA RUC recommendations, but that are components of new combined codes. We set interim RVUs for the component codes in order to conform them to the value of the combined code. Finally, we assign interim RVUs to certain codes for which we received AMA RUC recommendations for only one component (work or PE) but not both. By reviewing these AMA RUC recommendations for the new codes, we are able to assign RVUs to services based on input from the medical community and to establish payment for them, on an interim basis, that corresponds to the relative resources associated with furnishing the services. We are also able to determine, on an interim final basis, whether the codes will be subject other payment policies. If we did not assign RVUs to new codes on an interim basis, the alternative would be to either not pay for these services during the initial CY or have each Medicare contractor establish a payment rate for these new codes. We believe both of these alternatives are contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to our establishing payment for these codes on an interim basis. Therefore, we believe it would be contrary to the public interest to delay establishment of fee schedule payment amounts for these codes.

For the reasons previously outlined in this section, we find good cause to waive the notice of proposed rulemaking for the interim RVUs for selected procedure codes identified in Addendum C and to establish RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

Section II.C. of this final rule with comment period discusses the identification and review of potentially misvalued codes by the AMA RUC, as well as our review and decisions regarding the AMA RUC recommendations. Similar to the AMA RUC recommendations for new and revised codes previously discussed, due to the timing of the AMA RUC recommendations for the potentially misvalued codes, it was impracticable for CMS to solicit public comment regarding specific proposals for revision prior to this final rule with comment period. We believe it is in the public interest to implement the revised RVUs for the codes that were identified as misvalued, and that have been reviewed and re-evaluated by the AMA RUC, on an interim final basis for CY 2012. The revisions of RVUs for these codes will establish a more appropriate payment that better corresponds to the relative resources associated with furnishing these services. A delay in implementing revised values for these misvalued codes would not only perpetuate the known misvaluation for these services, it would also perpetuate a distortion in the payment for other services under the PFS. Implementing the changes now allows for a more equitable distribution of payments across all PFS services. We believe a delay in implementation of these revisions would be contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to the AMA RUC's recommendation to CMS. For the reasons previously described, we find good cause to waive notice and comment procedures with respect to the misvalued codes identified in Tables 19 through 22 and to revise RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

We ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d)), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in the effective date if the Secretary finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued (5 U.S.C. 553(d)(3); 5 U.S.C. 808(2)).

B. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Section 4103 of the Affordable Care Act expanded Medicare Part B to include coverage for an annual wellness visit providing personalized prevention plan services (hereinafter referred to as an annual wellness visit) in section 1861(s)(2)(FF) of the Act, effective January 1, 2011. In 42 CFR 410.15, we adopted the components of the annual wellness visit, consistent with the statutory elements described in section 1861(hhh)(2) of the Act. The first and subsequent annual wellness visits, as defined in 42 CFR 410.15(a), are meant to represent a beneficiary visit focused on prevention. Among other things, the annual wellness visit encourages beneficiaries to obtain the preventive services covered by Medicare that are appropriate for them. First and subsequent annual wellness visits also include elements that focus on the furnishing of personalized health advice and referral, as appropriate, to health education, preventive counseling services, programs aimed at improving self-management, and community-based lifestyle interventions.

Medicare beneficiaries will likely need assistance from physician office staff in completing an HRA as envisioned in the CDC interim guidance. The physician office staff time for assisting a beneficiary in completing an HRA is estimated to be 10 minutes (.16 hours) for a first annual wellness visit. During subsequent annual wellness visits, we would typically expect that the HRA would be updated, making physician staff time estimated at 5 minutes (.08 hours). The number of beneficiaries that received the annual wellness visit during the first 10 months of 2011 was 1.6 million. Based on this information, the estimated hour burden for the initial HRA is 256,000 total hours. However, for purposes of OMB review and approval, the average annual burden which accounts both the initial HRA and subsequent HRAs is 200,000

hours. An average burden of 7.5 minutes (0.125 hours) multiplied by 1.6 million beneficiaries.

The final rule with comment period imposes collection of information requirements as outlined in the regulation text and specified in various section of this final rule with comment period. However, this final rule with comment period also makes reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections, some of which have already received OMB approval.

1. Part B Drug Payment

The discussion of average sales price (ASP) issues in section VI.A.1 of this final rule with comment period pertains to payment for Medicare Part B drugs and biologicals under the ASP methodology. Drug manufacturers are required to submit ASP data to us on a quarterly basis. The ASP reporting requirements are set forth in section 1927(b) of the Act. In order to facilitate more accurate and consistent ASP data reporting from manufacturers, we proposed the following:

- To revise existing reporting fields and add new fields to the Addendum A template.
- To add a macro to the Addendum A template that will allow manufacturers to validate the format of their data prior to submission.
- To maintain a list of HCPCS codes for which manufacturer's report ASPs for NDCs on the basis of a specified unit.
- A clarification to existing regulation text at § 414.802. Current regulation text states that ''Unit means the product represented by the 11 digit National Drug Code.'' We proposed to update the definition to account for situations when an alternative unit of reporting must be used.

Additionally, we will also be revising our instructions for the reporting of dermal grafting products in a user guide available on the ASP Web site at: *http://www.cms.gov/McrPartBDrugAvgSalesPrice/*.

The burden associated with this requirement is the time and effort required by manufacturers of Medicare Part B drugs and biologicals to calculate, record, and submit the required data to CMS. The Addendum A template is currently approved under OMB control number 0938–0921. For the first year, we estimate that collection of the additional data elements will take approximately 2 additional hours for each submission of data, or 12 hours per response, at a cost of $252 per response. Based on the current number of respondents, we estimate that this requirement will affect approximately 180 manufacturers. Since manufacturers will respond 4 times per year, we estimate that, on an annual basis, the annual number of responses will be 720 (180 manufacturers × 4 responses) and the total annual hours burden will be 8,640 hours (720 annual responses × 12 annual hours per response). Please note that this is a corrected annual hour burden estimate; the 34,560 hour estimate in the proposed rule (76 FR 42921) resulted from a mathematical error. We estimate the annual cost burden to be $181,440 ($252 per response × 720 responses). Once manufacturers adjust to the changes associated with electronic reporting after the first year, we anticipate that the burden estimate will decrease.

We invited comments on this burden analysis, including the underlying assumptions used in developing our burden estimates and received no comments. We have corrected a mathematical error associated with the total annual burden which decreases the hourly burden. The cost estimate remains unchanged. Operational aspects and comments regarding the ASP template were discussed in section VI.A.3 of this rule where we finalized our proposal to amend the Addendum A template, including the use of a data validation macro with the expansion of the ''Alternate ID'' field. A companion Users' Guide, and other documents will be posted on the CMS ASP Web site.

2. The Physician Quality Reporting System

Section VI.F.1. of this final rule with comment period discusses the background of the Physician Quality Reporting System, provides information about the measures and reporting mechanisms that will be available to eligible professionals and group practices who choose to participate in the 2012 Physician Quality Reporting System, and the criteria for satisfactory reporting in 2012.

a. Estimated Participation in the 2012 Physician Quality Reporting System

With respect to satisfactory submission of data on quality measures by eligible professionals, eligible professionals include physicians, other practitioners as described in section 1842(b)(18)(c) of the Act, physical and occupational therapists, qualified speech-language pathologists, and qualified audiologists. Eligible professionals may choose whether to participate and, to the extent they satisfactorily submit data on quality measures for covered professional services, they can qualify to receive an incentive payment. To qualify to receive an incentive payment for 2012, the eligible professional (or group practice) must meet one of the criteria for satisfactory reporting described in section VI.F.1.e. or VI.F.1.f. of this final rule with comment period (or section VI.F.1.g. for group practices).

Because this is a voluntary program, it is difficult to accurately estimate how many eligible professionals will opt to participate in the Physician Quality Reporting System in CY 2012. Information from the ''Physician Quality Reporting System 2009 Reporting Experience Report'' (hereinafter 2009 Experience Report) which is available on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.hhs.gov/pqrs,* indicates that eligible professionals from nearly 120,000 unique TIN/NPI combinations satisfactorily submitted Physician Quality Reporting System quality measures data for the 2009 Physician Quality Reporting System. Therefore, for purposes of conducting a burden analysis for the 2012 Physician Quality Reporting System, we will assume that all eligible professionals who attempted to participate in the 2009 Physician Quality Reporting System will also attempt to participate in the 2012 Physician Quality Reporting System.

We invited but received no public comment on our estimates regarding the projected participation in the 2012 Physician Quality Reporting System. However, for the reasons explained below, we believe that more eligible professionals will participate in the Physician Quality Reporting System in 2012 than in 2009.

According to the 2009 Experience Report, the number of eligible professionals eligible to participate and actually participating in the Physician Quality Reporting System has increased each year from 2007 through 2009. Participation in the Physician Quality Reporting System has increased from 98,696 out of 621,840 eligible professionals in 2007 to 164,828 out of 977,415 eligible professionals in 2008 to 221,858 out of 1,042,260 eligible professionals in 2009.

With respect to participation in 2008, 66,132 more eligible professionals participated in the 2008 Physician Quality Reporting System (then called the Physician Quality Reporting Initiative or PQRI) than in 2007. The percentage of eligible professionals participating in 2008 also increased from 16 percent in 2007 to 17 percent in 2008. We believe that this increase

was due to a number of factors, including but not exclusive to:

- An increased number of professionals eligible to participate in the Physician Quality Reporting System in 2008: The number of professionals eligible to participate increased from 621,840 to 977,415 professionals from 2007 to 2008.
- Increased familiarity with the program: The Physician Quality Reporting System was first implemented in 2007. As such, we believe that our efforts to educate the public on the Physician Quality Reporting System through education and outreach efforts as well as general increased familiarity of the availability of earning incentives by satisfactorily reporting Physician Quality Reporting System measures led to an increase in program participation.
- The introduction of the registry-based reporting mechanism: In 2007, the claims-based reporting mechanism was the only reporting mechanism available for reporting Physician Quality Reporting System quality measures. In 2008, eligible professionals were able to submit data on Physician Quality Reporting System quality measures via the registry-based reporting mechanism as well.
- The introduction of reporting Physician Quality Reporting System quality measures via measures groups in addition to reporting measures individually: The reporting of Physician Quality Reporting System quality measures via measures groups was not available in 2007. However, in 2008, eligible professionals had the option of reporting Physician Quality Reporting System quality measures via measures groups via claims and registry.
- An increased number of measures and measures groups available for reporting under the Physician Quality Reporting System.

With respect to participation in 2009, 64,648 more eligible professionals participated in the 2009 Physician Quality Reporting System (then called the Physician Quality Reporting Initiative or PQRI) than in 2008. The percentage of eligible professionals participating in 2008 also increased from 17 percent in 2008 to 21 percent in 2009. We believe that this increase was due to a number of factors, including but not exclusive to:

- An increased number of professionals eligible to participate in the Physician Quality Reporting System in 2008: The number of professionals eligible to participate increased from 977,415 to 1,042,260 professionals from 2008 to 2009.
- Increased familiarity with the program.
- An increased incentive payment amount for satisfactory reporting from 1.5 percent in 2008 to 2.0 percent in 2009.
- An increased number of measures and measures groups available for reporting under the Physician Quality Reporting System.

Accordingly, we expect participation in the 2012 Physician Quality Reporting System to increase due to a number of factors, including but not exclusive to:

- Increased familiarity with the program: 2012 will mark the 6th year since the Physician Quality Reporting System was first implemented.
- The availability of the EHR-based reporting mechanism: As described in further detail in section VI.F.1.d.3 of this final rule with comment period, for 2012, we finalized two options under EHR-based reporting mechanism by which eligible professionals may utilize to submit data on Physician Quality Reporting System quality measures: The EHR data submission vendor and direct EHR options.
- An increased number of measures and measures groups available for reporting under the Physician Quality Reporting System: As described in further detail in section VI.F.1.f of this final rule with comment period, we have added additional measures available for claims, registry, and/or EHR-based reporting as well as additional measures groups available for claims and/or registry reporting.
- The establishment of CY 2013 as the reporting period for the 2015 payment adjustment. As described in greater detail in section VI.F.1.j of this final rule with comment period, we finalized our proposal to establish CY 2013 as the reporting period for the 2015 payment adjustment. We expect that more eligible professionals will attempt to meet the criteria for satisfactory reporting in 2012 before the 2015 payment adjustment reporting period commences on January 1, 2013.
- Alignment and incorporation of certain Physician Quality Reporting System reporting requirements under other CMS programs, such as the EHR Incentive Program and the Medicare Shared Savings Program. In an effort to align various CMS quality reporting programs, we have created reporting requirements under other CMS programs that are similar or identical to those required under the Physician Quality Reporting System. For example, as described in greater detail under section VI.F.1.e.3 of this final rule with comment period, we established reporting criteria that satisfy both the Physician Quality Reporting System incentive and fulfill the CQM requirement for achieving meaningful use under the EHR Incentive Program (75 FR 44409 through 44411). In addition, as described in section VI.F.4 of this final rule with comment period, the EHR Incentive Program established the Physician Quality Reporting System-Medicare EHR Incentive Pilot, whereby eligible professionals may data on the same sample of beneficiaries to fulfill the requirements for satisfactory reporting under the Physician Quality Reporting System while also fulfilling the CQM reporting requirements for achieving meaningful use under the EHR Incentive Program.

As finalized in the final rule entitled ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations,'' displayed in the **Federal Register** on October 20, 2011, the Medicare Shared Savings Program also incorporated certain Physician Quality System reporting requirements and incentives whereby eligible professionals within Accountable Care Organizations (ACOs) may earn under a group practice reporting option (GPRO) a Physician Quality Reporting System incentive under the Medicare Shared Savings Program.

Furthermore, as stated in section VI.I of this final rule, under the Physician Feedback Program, we plan to use the Physician Quality Reporting System quality measures in the Physician Feedback reports we disseminate, and we are finalizing certain measures from the Physician Quality Repoting System and EHR Incentive Program for purposes of the Physician value modifier, which will be applied beginning in CY 2015.

According to the 2009 Experience Report, we have seen a 1 percent and 4 percent increase in participation in the Physician Quality Reporting System from 2007 to 2008 and 2008 to 2009 respectively. Based on our above assumptions, we believe we will see at least a 1 percent increase in the number of eligible professionals participating in the Physician Quality Reporting System from 2011 to 2012. Information on participation rates for the 2010 and 2011 Physician Quality Reporting System is not yet available. Therefore, for purposes of determining how many eligible professionals will participate in 2012, we will assume a 1 percent increase in participation each program year from 2009 through 2012. Therefore, we assume that 224,076 eligible professionals (a 1 percent increase from 221,858) participated in the 2010 Physician Quality Reporting System. We then assume that 226,316 eligible professionals participated in the 2011 Physician Quality Reporting System (a 1

percent increase from 224,076). Based on these assumptions, we estimate that at least 228,579 eligible professionals will participate in the 2012 Physician Quality Reporting System (a 1 percent increase from 226,316).

b. Burden Estimate on Participation in the 2012 Physician Quality Reporting System—Individual Eligible Professionals

As we stated in the proposed rule (76 FR 42921), we believe that the burden for eligible professionals who are participating in the Physician Quality Reporting System for the first time in 2012 will be considerably higher than the burden for eligible professionals who have participated in the Physician Quality Reporting System in prior years. As described below, some preparatory steps are needed to begin participating in the Physician Quality Reporting System. To the extent that we did not retire the measures that an eligible professional has reported in a prior year and there are no changes to the measure's specifications from a prior year, such preparatory steps will not need to be repeated in subsequent years.

For individual eligible professionals, in the proposed rule (76 FR 42922), we noted that the burden associated with the requirements of this reporting initiative will be the time and effort associated with eligible professional's practice identifying applicable Physician Quality Reporting System quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to report the eligible professional's or group practice's measures.

We believe it is difficult to definitively quantify the burden because eligible professionals may have different processes for integrating the data collection for the Physician Quality Reporting System measures into their practice's work flows. Moreover, we expect that the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows will vary along with the number of measures that are potentially applicable to a given professional's practice.

Since a majority of eligible professionals participate via claims or registry-based reporting of individual measures, they will generally be required to report on at least three measures to earn a Physician Quality Reporting System incentive. Therefore, we will assume that each eligible professional who attempts to submit Physician Quality Reporting System quality measures data via claims or registry reporting is attempting to earn a Physician Quality Reporting System incentive payment and reports on an average of three measures for this burden analysis.

This burden analysis focuses on those new to the Physician Quality Reporting System. We will assign 5 hours as the amount of time needed for eligible professionals to review the 2012 Physician Quality Reporting System Measures List, review the various reporting options, select the most appropriate reporting option, identify the applicable measures or measures groups for which they can report the necessary information, review the measure specifications for the selected measures or measures groups, and incorporate reporting of the selected measures or measures groups into the office work flows. This estimate is based on our assumption that an eligible professional will need up to 2 hours to review the 2012 Physician Quality Reporting System Measures List, review the reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications for up to 3 selected measures or up to 1 selected measures group and to develop a mechanism for incorporating reporting of the selected measures or measures group into the office work flows.

In the proposed rule (76 FR 42922), based on information from the Physician Voluntary Reporting Program (PVRP), which was a predecessor to the Physician Quality Reporting System, we provided an estimated labor cost of $60/hour. However, in an effort to provide a more accurate labor cost estimate of participation for the 2012 Physician Quality Reporting System, we conducted an informal poll among a small sample of participants in the 2011 Physician Quality Reporting System to determine what employees within an eligible professional's practice are involved with Physician Quality Reporting System activities. The poll revealed that a billing clerk typically handles administrative details with respect to participating under the Physician Quality Reporting System (such as submitting self-nomination statements), whereas a computer analyst typically handles the reporting of Physician Quality Reporting System quality measures. Based on this information, we are changing our estimated labor costs associated with participating in the Physician Quality Reporting System.

For purposes of this burden estimate, we will assume that a billing clerk will handle the administrative duties associated with participating in the 2012 Physician Quality Reporting System. According to information published by the Bureau of Labor Statistics, available at *http://www.bls.gov/oes/current/oes433021.htm,* the mean hourly wage for a billing clerk is $16.00/hour. Therefore, for purposes of handling administrative duties, we estimate an average labor cost of $16.00/hour.

In addition, for purposes of this burden estimate, we will assume that a computer analyst will engage in the duties associated with the reporting of 2012 Physician Quality Reporting System quality measures. According to information published by the Bureau of Labor Statistics, available at *http://www.bls.gov/oes/current/oes151121.htm,* the mean hourly wage for a computer analyst is $39.06/hour, or approximately $40.00/hour. Therefore, for purposes of reporting on 2012 Physician Quality Reporting System quality measures, we estimate an average labor cost of $40.00/hour.

We continue to expect the ongoing costs associated with Physician Quality Reporting System participation to decline based on an eligible professional's familiarity with and understanding of the Physician Quality Reporting System, experience with participating in the Physician Quality Reporting System, and increased efforts by CMS and stakeholders to disseminate useful educational resources and best practices. We also continue to expect the ongoing costs associated with Physician Quality Reporting System participation to decline as we align the participation requirements in the Physician Quality Reporting System with the reporting requirements in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program such that an eligible professional may only need to submit data to CMS one time for multiple purposes.

We believe the burden associated with actually reporting the Physician Quality Reporting System quality measures will vary depending on the reporting mechanism selected by the eligible professional.

(1) Burden Estimate on Participation in the 2012 Physician Quality Reporting System via the Claims-Based Reporting Mechanism—Individual Eligible Professionals

For the claims-based reporting option being finalized, eligible professionals must gather the required information, select the appropriate quality data codes

(QDCs), and include the appropriate QDCs on the claims they submit for payment. The Physician Quality Reporting System will collect QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN: 0938–0999). We do not anticipate any new forms and or any modifications to the existing transaction or form. We also do not anticipate changes to the 837–P or CMS Form 1500 for CY 2012.

Based on our experience with the PVRP, we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for a measure) on claims will ranges from 15 seconds (0.25 minutes) to over 12 minutes for complicated cases and/or measures, with the median time being 1.75 minutes. At an average labor cost of $40/hour per practice, the cost associated with this burden will range from $0.17 in labor to about $8.00 in labor time for more complicated cases and/or measures, with the cost for the median practice being $1.67.

The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported. In previous years, when we required reporting on 80 percent of eligible cases for claims-based reporting, we found that on average, the median number of reporting instances for each of the Physician Quality Reporting System measures was 9. Since we are reducing the required reporting rate by over one-third to 50 percent in this final rule, then for purposes of this burden analysis we will assume that an eligible professional will need to report each selected measure for 6 reporting instances. The actual number of cases on which an eligible professional is required to report quality measures data will vary, however, with the eligible professional's patient population and the types of measures on which the eligible professional chooses to report (each measure's specifications includes a required reporting frequency).

Based on the assumptions discussed previously, we estimate the total annual reporting burden per individual eligible professional associated with claims-based reporting will range from 4.5 minutes (0.25 minutes per measure × 3 measures × 6 cases per measure) to 180 minutes (12 minutes per measure × 3 measures × 6 cases per measure), with the burden to the median practice being 31.5 minutes (1.75 minutes per measure × 3 measures × 6 cases). We estimate the total annual reporting cost per eligible professional associated with claims-based reporting will range from $3.06 ($0.17 per measure × 3 measures × 6 cases per measure) to $144.00 ($8.00 per measure × 3 measures × 6 cases per measure), with the cost to the median practice being $30.06 per eligible professional ($1.67 per measure × 3 measures × 6 cases per measure).

b. Burden Estimate on Participation in the 2012 Physician Quality Reporting System via the Registry-Based Reporting Mechanism—Individual Eligible Professionals

For registry-based reporting, there will be no additional time burden for eligible professionals to report data to a registry as eligible professionals opting for registry-based reporting will more than likely already be reporting data to the registry for other purposes and the registry will merely be re-packaging the data for use in the Physician Quality Reporting System. Little, if any, additional data will need to be reported to the registry solely for purposes of participation in the 2012 Physician Quality Reporting System. However, eligible professionals will need to authorize or instruct the registry to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. We estimate that the time and effort associated with this will be approximately 5 minutes per eligible professional.

Registries interested in submitting quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf in 2012 will need to complete a self-nomination process in order to be considered qualified to submit on behalf of eligible professionals unless the registry was qualified to submit on behalf of eligible professionals for prior program years and did so successfully. We estimate that the self-nomination process for qualifying additional registries to submit on behalf of eligible professionals for the 2012 Physician Quality Reporting System will involve approximately 1 hour per registry to draft the letter of intent for self-nomination. We estimate that each self-nominated entity will also spend 2 hours for the interview with CMS officials and 2 hours calculating numerators, denominators, and measure results for each measure the registry wishes to report using a CMS-provided measure flow. However, the time it takes to produce calculated numerators, denominators, and measure results using the CMS-provided measure flows could vary depending on the registry's experience and the number and type of measures for which the registry wishes to submit on behalf of eligible professionals. Additionally, part of the self-nomination process involves the completion of an XML submission by the registry, which we estimate to take approximately 5 hours, but may vary depending on the registry's experience. We estimate that the registry staff involved in the registry self-nomination process will have an average labor cost of $16/hour. Therefore, assuming the total burden hours per registry associated with the registry self-nomination process is 10 hours, we estimate that the total cost to a registry associated with the registry self-nomination process will be approximately $160 ($16 per hour × 10 hours per registry).

The burden associated with the registry-based reporting requirements of the Physician Quality Reporting System will be the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its participants and submitting the quality measures results and numerator and denominator data on quality measures to CMS on behalf of their participants. We expect that the time needed for a registry to review the quality measures and other information, calculate the measures results, and submit the measures results and numerator and denominator data on the quality measures on their participants' behalf will vary along with the number of eligible professionals reporting data to the registry and the number of applicable measures. However, we believe that registries already perform many of these activities for their participants. Therefore, there may not necessarily be a burden on a particular registry associated with calculating the measure results and submitting the measures results and numerator and denominator data on the quality measures to CMS on behalf of their participants. Whether there is any additional burden to the registry as a result of the registry's participation in the Physician Quality Reporting System will depend on the number of measures that the registry intends to report to CMS and how similar the registry's measures are to CMS' Physician Quality Reporting System measures.

(2) Burden Estimate on Participation in the 2012 Physician Quality Reporting System via the EHR-Based Reporting Mechanism—Individual Eligible Professionals

For EHR-based reporting for the CY 2012 Physician Quality Reporting System, the individual eligible professional may either submit the quality measures data directly to CMS

from their EHR or utilize an EHR data submission vendor to submit the data to CMS on the eligible professionals' behalf. To submit data to CMS directly from their EHR, the eligible professional must have access to a CMS-specified identity management system, such as IACS, which we believe takes less than 1 hour to obtain. Once an eligible professional has an account for this CMS-specified identity management system, he or she will need to extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse. With respect to the requirement for an eligible professional to submit a test file, we believe that doing so will take less than 1 hour. With respect to submitting the actual 2012 data file in 2013, we believe that this will take an eligible professional no more than 2 hours, depending on the number of patients on which the eligible professional is submitting. We believe that once the EHR is programmed by the vendor to allow data submission to CMS, the burden to the eligible professional associated with submission of data on Physician Quality Reporting System quality measures should be minimal as all of the information required to report the measure should already reside in the eligible professional's EHR. We did not introduce the EHR-based reporting mechanism into the Physician Quality Reporting System until 2010. We are still in the process of analyzing 2010 data. As such, we believe it is difficult to predict how many eligible professionals may choose to participate in the 2012 Physician Quality Reporting System via the EHR-based reporting mechanism.

An EHR vendor interested in having their product(s) used by eligible professionals to submit the Physician Quality Reporting System quality measures data to CMS or interested in submitting data obtained from an EHR to CMS on behalf of eligible professionals is required to complete a self-nomination process in order for the vendor and/or its product(s) to be considered qualified for 2012. It is difficult to definitively quantify the burden associated with the EHR self-nomination process as there is variation regarding the technical capabilities and experience among vendors. For purposes of this burden analysis, however, we estimate that the time required for an EHR vendor to complete the self-nomination process will be similar to the time required for registries to self-nominate, which is approximately 10 hours at $16/hour for a total of $160/EHR vendor ($16/hour × 10 hours/EHR vendor).

The burden associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the eligible professional must submit to CMS for purposes of reporting 2012 Physician Quality Reporting System quality measures will be dependent on the EHR vendor's familiarity with the Physician Quality Reporting System, the vendor's system capabilities, as well as the vendor's programming capabilities. Some vendors already have these necessary capabilities and for such vendors, we estimate that the total burden hours will be 40 hours at a rate of $40/hour for a total burden estimate of $1,600 ($40/hour × 40 hours per vendor). However, given the variability in the capabilities of the vendors, we believe those vendors with minimal experience will have a burden of approximately 200 hours at $40/hour, for a total estimate of $8,000 per vendor ($40/hour × 200 hours/EHR vendor).

(3) Burden Estimate on Participation in the 2012 Physician Quality Reporting System—Group Practices

With respect to the criteria for satisfactorily reporting data on the quality measures for group practices under the 2012 Physician Quality Reporting System discussed in section VI.F.1. of this final rule with comment period, group practices interested in participating in the 2012 Physician Quality Reporting System through the group practice reporting option (GPRO) must complete a self-nomination process similar to the self-nomination process required of registries and EHR vendors. Therefore, assuming it takes 2 hours for a group practice to decide whether to participate as a group or individually, approximately 2 hours per group practice to draft the letter of intent for self-nomination, gather the requested information, and provide this requested information, and an additional 2 hours undergoing the vetting process with CMS officials, we estimate a total of 6 hours associated with the self-nomination process. Assuming that the group practice staff involved in the group practice self-nomination process have the same average practice labor cost as the average practice labor cost estimates we used for individual eligible professionals of $16/hour, we estimate that the total cost to a group practice associated with the group practice self-nomination process will be approximately $96 ($16/hour × 6 hours per group practice).

The burden associated with the group practice reporting requirements for the 2012 Physician Quality Reporting System is the time and effort associated with the group practice submitting the quality measures data. For practices participating under the GPRO, this will be the time associated with the physician group completing the data collection tool. The information collection components of this data collection tool have been reviewed by OMB and are currently approved under OMB control number 0938–0941, with an expiration date of December 31, 2011, for use in the Physician Group Practice, Medicare Care Management Performance (MCMP), and EHR demonstrations. Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimate the burden associated with a physician group completing the data collection tool will be approximately 79 hours per physician group. Based on an average labor cost of $40 per physician group, we estimate the cost of data submission per physician group associated with participating in the 2012 Physician Quality Reporting System GPRO will be $3,160 ($40/hour × 79 hours per group practice).

(4) Burden Estimate on Participation in the Maintenance of Certification Program Incentive

Eligible professionals who wish to qualify for the additional 0.5 percent incentive payment authorized under section 1848(m)(7) of the Act (''Additional Incentive Payments'') for 2012 will need to more frequently than is required to qualify for or maintain board certification status participate in a qualified Maintenance of Certification Program for 2012 and successfully complete a qualified Maintenance of Certification Program practice assessment for 2012. We believe that a majority of the eligible professionals who will attempt to qualify for this additional 0.5 percent incentive payment will be those who are already enrolled and participating in a Maintenance of Certification Board. The amount of time that it will take for the eligible professional to participate in the Maintenance of Certification Program more frequently than is required to qualify for or maintain board certification status will vary based on what each individual board determines constitutes ''more frequently.'' We expect that the amount of time needed to complete a qualified Maintenance of Certification Program practice assessment will be spread out over time since a quality improvement component is often required. Information from an informal poll of a few ABMS member

boards indicates that the time an individual eligible professional spends to complete the practice assessment component of the Maintenance of Certification ranges from 8 to 12 hours.

We requested comments on this burden analysis for physicians participating in the Maintenance of Certification Program incentive, including the underlying assumptions used in developing our burden estimates. Below is a summary of the comments we received.

Comment: One commenter believed that a more disciplined approach for estimating the time and effort it takes to earn an incentive under the Maintenance of Certification Program incentive should be adopted. Another commenter stated that our estimates regarding the length of time it takes to complete the processes required to earn a Maintenance of Certification Program incentive does not fully encompass all activities necessary to participate in a Maintenance of Certification Program.

Response: We appreciate the commenters' feedback. As noted above, it is difficult to determine the time and effort it takes to earn an incentive under the Maintenance of Certification Program incentive due to varying specialties, as well as degrees of experience, and therefore, varying requirements for participation. We also note that, for purposes of this burden estimate, we did not take into account the time and effort it takes for a physician to maintain board certification status under an established Maintenance of Certification Program. Rather, we provided an estimate based on the additional time and effort it will take for eligible professionals to meet the additional requirements for earning the additional 0.5 percent Maintenance of Certification Program incentive.

3. Electronic Prescribing (eRx) Incentive Program

a. Estimate on Participation in the 2012, 2013, and 2014 eRx Incentive Program

The electronic prescribing measure was first reportable under the Physician Quality Reporting System before it was used for the eRx Incentive Program, which began in 2009. According to the 2009 Experience Report, the number of eligible professionals participating reporting the electronic prescribing measure increased from 4,973 out of approximately 500,000 eligible professionals to 92,132 out of 670,000 eligible professionals from 2008 to 2009. This is an increase of least 12 percent (from 1 percent in 2008 to 13 percent in 2009). As discussed in section VI.F.2.h.1 in this final rule, we finalized limitations whereby a 2013 or 2014 payment adjustment will not apply to an eligible professional. However, we still believe that, due to the implementation of the 2013 and 2014 payment adjustments, as well as the expansion of the reporting mechanisms for purposes of reporting the electronic prescribing measure for the 2013 and 2014 payment adjustments, we expect that there will be a significant increase in eligible professionals who participate in the eRx Incentive Program for CYs 2012 through 2014 from 2009 participation rates. Therefore, for purposes of conducting a burden analysis for the 2012 through 2014 eRx Incentive Program, we will assume that, based on participation rates in 2009, there will be an increase of at least 12 percent of eligible professionals participating in the eRx Incentive Program from 2012 through 2014. Therefore, for purposes of this burden analysis, we estimate that more than 100,800 unique TIN/NPI combinations will participate in the 2012, 2013, and 2014 eRx Incentive Program for purposes of the 2013 and 2014 payment adjustment (see the ''2009 Reporting Experience,'' which is available on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.hhs.gov/pqrs*). Although this estimate only accounts for approximately 15 percent of all professionals eligible to participate in the eRx Incentive Program, we believe that participation may be offset by the limitations and significant hardship exemptions we are finalizing for the 2013 and 2014 payment adjustment.

b. Burden Estimate on Participation in the eRx Incentive Program—Individual Eligible Professionals

Section VI.F.2. of this final rule with comment period discusses the background of the eRx Incentive Program. For the programs for 2012 through 2014, eligible professionals and group practices may choose whether to participate and, to the extent they meet—(1) certain thresholds with respect to the volume of covered professional services furnished; and (2) the criteria for being a successful electronic prescriber described in section VI.F.2. of this final rule with comment period, they will qualify to receive an incentive payment for 2012 and 2013 and/or avoid being subject to the 2013 and 2014 payment adjustment.

In section VI.F.2.g. of this final rule with comment period, we describe the requirements for eligible professionals and group practices to be successful electronic prescribers in order to earn a 2012 and/or 2013 incentive payment. For the 2012 and 2013 incentives, as discussed in section VI.F.2.g.2. of this final rule with comment period, each eligible professional must to report the electronic prescribing measure's numerator indicating that at least one prescription generated during an encounter was electronically submitted at least 25 instances during the reporting period in association with a denominator-eligible visit.

In section VI.F.2.h. of this final rule with comment period, we finalized additional requirements for eligible professionals and group practices can meet for the 2013 payment adjustment, as well as finalized requirements for being a successful electronic prescriber for the 2014 payment adjustment. For the 2013 and 2014 payment adjustment, each eligible professional must report the electronic prescribing measure's numerator at least 10 instances during the reporting period.

We expect the ongoing costs associated with participation in the eRx Incentive Program to decline based on an eligible professional's understanding of the eRx Incentive Program, experience with participating in the eRx Incentive Program, and increased efforts by CMS and stakeholders to disseminate useful educational resources and best practices.

Similar to the Physician Quality Reporting System, one factor in the burden to individual eligible professionals is the time and effort associated with individual eligible professionals reviewing the electronic prescribing measure to determine whether it is applicable to them, reviewing and selecting one of the available reporting options (for purposes of the 2012 and 2013 incentives and the 2013 and 2014 payment adjustments, the electronic prescribing quality measure is reportable through claims-based reporting, registry-based reporting, or through EHRs) and selecting one, gathering the required information, and incorporating reporting of the measure into their office work flows. Since the eRx Incentive Program consists of only 1 measure to report, we estimate 2 hours as the amount of time that will be needed for individual eligible professionals to prepare for participation in the eRx Incentive Program. At an average cost of approximately $40/hour per practice, we estimate the total preparation costs to individual eligible professionals will be approximately $80 (2 hours × $40/hour).

Another factor that we believe influences the burden to eligible professionals is how they choose to report the electronic prescribing

measure. Our burden estimates for participating in the eRx Incentive Program via each of three finalized reporting mechanisms (that is, claims, registry, and EHR) are described in this section.

(1) Burden Estimate on Participation in the eRx Incentive Program via the Claims-Based Reporting Mechanism—Individual Eligible Professionals

For eligible professionals who choose to do so via claims, we estimate that the burden associated with the requirements of this incentive program will be the time and effort associated with gathering the required information and identifying when it is appropriate to include the measure's quality data code (QDC) on the claims they submit for payment. For claims-based reporting, the measure's QDC will be collected as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500. We do not anticipate any new forms and or modifications to the existing transaction or form. We also do not anticipate changes to the 837–P or CMS Form 1500 for CY 2012.

Based on the information from the PVRP for the amount of time it takes a median practice to report one measure one time on claims (1.75 minutes) and our requirement that eligible professionals report the measure 25 times for purposes of the incentive payment, we estimate the burden associated with claims-based data submission to will be 43.75 minutes (1.75 minutes per case × 1 measure × 25 cases per measure). This equates to a cost of approximately $29.17 (1.75 minutes per case × 1 measure × 25 cases per measure × $40/hour) per individual eligible professional. For purposes of the 2013 and 2014 eRx payment adjustment, an eligible professional is required to report the measure only 10 times, and therefore, we estimate the burden associated with claims-based submission will be 17.5 minutes (1.75 minutes per case × 1 measure × 10 cases per measure). This equates to a cost of approximately $9.67 (1.75 minutes per case × 1 measure × 10 cases per measure × $40/hour) per individual eligible professional.

(2) Burden Estimate on Participation in the eRx Incentive Program via the Registry-Based Reporting Mechanism—Individual Eligible Professionals and Group Practices

Because registry-based reporting of the electronic prescribing measure to CMS was added to the eRx Incentive Program for 2010 and eligible professionals are not required to indicate how they plan to report the electronic prescribing measure each year, it is difficult to accurately estimate how many eligible professionals will opt to participate in the eRx Incentive Program through the registry-based reporting mechanism in CYs 2012 through 2014. We do not anticipate, however, any additional burden for eligible professionals to report data to a registry as eligible professionals opting for registry-based reporting will more than likely already be reporting data to the registry for other purposes. Little, if any, additional data will need to be reported to the registry for purposes of participation in the 2012, 2013, and 2014 eRx Incentive Program since the only information that the registry will need to report to us is the number of times the eligible professional electronically prescribed. However, eligible professionals will need to authorize or instruct the registry to submit quality measures results and numerator and denominator data on the electronic prescribing measure to CMS on their behalf. We estimate that the time and effort associated with this will be approximately 5 minutes for each eligible professional that wishes to authorize or instruct the registry to submit quality measures results and numerator and denominator data on the electronic prescribing measure to CMS on their behalf.

Based on our final decision to consider only registries qualified to submit Physician Quality Reporting System quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf for the 2012 and 2013 Physician Quality Reporting System reporting periods to be qualified to submit results and numerator and denominator data on the electronic prescribing measure for the respective eRx Incentive Program reporting periods that occur in 2012 and 2013, there will be no need for a registry to undergo a separate self-nomination process for the eRx Incentive Program and therefore, no additional burden associated with the registry self-nomination process.

There will also be a burden to the registry associated with the registry calculating results for the electronic prescribing measure from the data submitted to the registry by its participants and submitting the quality measures results and numerator and denominator data on the electronic prescribing quality measure to CMS on behalf of their participants. We expect that the time needed for a registry to review the electronic prescribing measure's specifications, calculate the measure's results, and submit the measure's results and numerator and denominator data on their participants' behalf will vary along with the number of eligible professionals reporting data to the registry. However, we believe that registries already perform many of these activities for their participants. Since the eRx Incentive Program consists of only one measure, we believe that the burden associated with the registry reporting the measure's results and numerator and denominator to CMS on behalf of their participants will be minimal.

(3) Burden Estimate on Participation in the eRx Incentive Program via the EHR-Based Reporting Mechanism—Individual Eligible Professionals and Group Practices

For the EHR-based reporting mechanism, the eligible professional must either extract the necessary clinical data from his or her EHR and submit the necessary data to the CMS-designated clinical data warehouse or have an EHR data submission vendor extract the necessary clinical data from his or her EHR and submit the necessary data to CMS on the professional's behalf. Because this manner of reporting quality data to CMS was first added to the eRx Incentive Program in 2010 and eligible professionals are not required to (and were not previously required to) indicate to us how they intend to report the electronic prescribing measure, it is difficult to estimate how many eligible professionals will opt to participate in the eRx Incentive Program through the EHR-based reporting mechanism for reporting periods that occur in CYs 2012 and 2013. We believe that once an eligible professional's EHR is programmed by the vendor to allow data submission to CMS, the burden to the eligible professional associated with submission of data on the electronic prescribing measure should be minimal. The eligible professional who chooses to submit the electronic prescribing measure data directly to CMS from his or her EHR will have to have access to a CMS-specified identity management system, such as IACS. We believe it takes less than 1 hour to obtain access to the identity management system.

Because only EHR products and data submission vendors qualified for 2012 and 2013 Physician Quality Reporting System reporting periods may be used to submit data on the electronic prescribing measure for the respective eRx Incentive Program reporting periods that occur in CYs 2012 and 2013, there is no need for EHR vendors and/or their products to undergo a separate self-nomination process for the eRx Incentive Program and therefore, no

additional burden associated with the self-nomination process for the eRx Incentive Program.

There will also be a burden to the EHR vendor associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the eligible professional and/or vendor will need to submit to CMS for purposes of reporting the electronic prescribing measure. The time needed for an EHR vendor to review the measure's specifications and program its product to submit data on the measure to the CMS-designated clinical data warehouse will be dependent on the EHR vendor's familiarity with the electronic prescribing measure, the vendor's system capabilities, as well as the vendor's programming capabilities. Since only EHR products qualified for 2012 and 2013 Physician Quality Reporting System reporting periods will qualify for the respective eRx Incentive Program reporting periods that occur in CY 2012 or 2013, and the eRx Incentive Program consists of only one measure, we believe that any burden associated with the EHR vendor to program its product(s) to submit data on the electronic prescribing measure to the CMS-designated clinical data warehouse will be minimal.

(4) Burden Estimate on Participation in the eRx Incentive Program—Group Practices

Finally, with respect to the criteria for group practices to be successful electronic prescribers for the 2012 and 2013 incentive, as well as with regard to the 2013 and 2014 payment adjustments, as discussed in section VI.F.2. of this final rule with comment period, respectively, group practices have the same options as individual eligible professionals in terms of the form and manner for reporting the electronic prescribing measure (that is, group practices have the option of reporting the measure through claims, a qualified registry, or a qualified EHR product). There are only 2 differences between the requirements for an individual eligible professional and a group practice: (1) The fact that a group practice must self-nominate; and (2) a difference in the number of times that a group practice must report the electronic prescribing measure.

We do not anticipate any additional burden associated with the group practice self-nomination process since we limit the group practices to those selected to participate in the Physician Quality Reporting System GPRO. The practice only will need to indicate its desire to participate in the eRx GPRO at the same time it self-nominates for the Physician Quality Reporting System GPRO and indicate how it intends to report the electronic prescribing measure.

In terms of the burden to group practices comprised of 25 to 99 eligible professionals associated with submission of the electronic prescribing measure, we believe that this will be similar to the burden to individual eligible professionals for submitting the electronic prescribing measure. In fact, overall, there could be less burden associated with a practice participating as a group rather than as individual eligible professionals because the total number of reporting instances required by the group could be less than the total number of reporting instances that will be required if each member of the group separately reported the electronic prescribing measure. Thus, we believe that the burden to a group practice associated with reporting the electronic prescribing measure could range from almost no burden (for groups who choose to do so through a qualified EHR or registry) to 18.22 hours (1.75 minutes per measure $\times$ 1 measure $\times$ 625 cases per measure) for a group practice that chooses to report the electronic prescribing measures through the claims submission process. Consequently, the total estimated cost per group practice to report the electronic prescribing measure could be as high as $1,043.75 ($1.67 per measure $\times$ 1 measure $\times$ 625 cases per measure).

In terms of the burden to group practices comprised of 100 or more eligible professionals associated with submission of the electronic prescribing measure, we believe that this will be similar to the burden to individual eligible professionals for submitting the electronic prescribing measure. In fact, overall, there could be less burden associated with a practice participating as a group rather than as individual eligible professionals because the total number of reporting instances required by the group could be less than the total number of reporting instances that will be required if each member of the group separately reported the electronic prescribing measure. Thus, we believe that the burden to a group practice associated with reporting the electronic prescribing measure could range from almost no burden (for groups who choose to do so through a qualified EHR or registry) to 72.92 hours (1.75 minutes per measure $\times$ 1 measure $\times$ 2500 cases per measure) for a group practice that chooses to report the electronic prescribing measures through the claims submission process. Consequently, the total estimated cost per group practice to report the electronic prescribing measure could be as high as $4,175 ($1.67 per measure $\times$ 1 measure $\times$ 2500 cases per measure).

As with individual eligible professionals, we believe that group practices that choose to participate in the eRx GPRO through the registry-based reporting mechanism of the electronic prescribing measure will more than likely already be reporting data to the registry. Little, if any, additional data will need to be reported to the registry for purposes of participation in the eRx Incentive Program for CYs 2012 through 2014 beyond authorizing or instructing the registry to submit quality measures results and numerator and denominator data on the electronic prescribing measure to CMS on their behalf. We estimate that the time and effort associated with this registry option will be approximately 5 minutes for each group practice that wishes to authorize or instruct the registry to submit quality measures results and numerator and denominator data on the electronic prescribing measure to CMS on their behalf.

For group practices that choose to participate in the eRx Incentive Program for CYs 2012 through 2014 via the EHR-based reporting of the electronic prescribing mechanism, once the EHR is programmed by the vendor to allow data submission to CMS, the burden to the group practice associated with submission of data on the electronic prescribing measure should be minimal.

4. Medicare Electronic Health Record (EHR) Incentive Program for Eligible Professionals for the 2012 Payment Year

The EHR Incentive Program (discussed in section VI.H. of this final rule with comment period) is a voluntary program whereby eligible professionals (EPs) may earn an incentive payment for demonstrating meaningful use of certified EHR technology, which includes among other requirements, the submission of clinical quality measures (CQMs). The ''Electronic Health Record Incentive Program'' final rule (75 FR 44314 through 75 FR 44588) describes the CQMs and the CQM reporting mechanisms that will be available to EPs who choose to participate in the EHR Incentive Program (75 FR 44380) and established the criteria for achieving meaningful use in Stage 1, which includes CY 2012. In that final rule, for CY 2012, we estimated that approximately 385,954 Medicare EPs will be eligible to receive an incentive under the EHR Incentive Program (75 FR 44518). Section VI.H.2. of this final rule with comment period finalizes

changes to the EHR Incentive Program for EPs for the 2012 payment year with respect to the reporting of CQMs for purposes of achieving meaningful use. Aside from continuing the attestation method of reporting CQMs, we will allow the reporting of CQMs for purposes of meeting the CQM objective for demonstrating meaningful use through participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot. Eligible professionals may participate in the Pilot by submitting CQMs via (1) a Physician Quality Reporting System qualified EHR data submission vendor or (2) an EHR-based reporting option using the EP's certified EHR technology, which must also be a Physician Quality Reporting System qualified EHR.

Because the EHR Incentive Program is a voluntary program, EPs may choose whether to participate and attest that they have met the meaningful use objectives and measures. Registration for the EHR Incentive Program opened in January 2011. At this time, we do not have sufficient data available on participation in the EHR Incentive Program by EPs to revise the final rule's estimate of how many EPs will opt to participate in the EHR Incentive Program for payment year 2012.

We believe the burden associated with actually reporting CQMs will vary depending on the reporting mechanism selected by the EP. Attestation to the objectives and measures is the only method available for EPs to demonstrate that they have met the meaningful use criteria in 2011. Attestation was first available on April 18, 2011 and we do not yet have sufficient data on the 2011 participation in the EHR Incentive Program. Therefore, it is difficult to estimate the level of participation in the Pilot versus the number of EPs that will prefer to attest to the CQMs. However, we believe that the number of EPs who choose to participate via attestation will largely be those who are not participating in both the EHR Incentive Program and Physician Quality Reporting System. This is because EPs participating in the Physician Quality Reporting System will be more likely to participate in the Pilot.

As we estimated in the EHR Incentive Program final rule, we estimate that it will take 8 hours and 52 minutes for an EP to attest that during the EHR reporting period, the EP used certified EHR technology, specify the technology, and satisfied all Stage 1 meaningful use core criteria for payment year 2012 (75 FR 44518). We estimate that it will further take an additional 0.5 hours to select and attest to the clinical quality measures, in the format and manner specified by CMS (75 FR 44517).

There will be no additional time burden for eligible professionals to report CQM data to a qualified EHR data submission vendor as EPs who choose this option for the Pilot will more than likely already be reporting data to the qualified EHR data submission vendor for other purposes, such as the Physician Quality Reporting System, and the qualified EHR data submission vendor will merely be re-packaging the data for use in the EHR Incentive Program. Furthermore, EPs more than likely will not need to authorize or instruct the qualified EHR data submission vendor to submit CQM data to CMS on their behalf because this likely will have already been done as a requirement for reporting via a qualified EHR data submission vendor under the Physician Quality Reporting System.

Qualified EHR data submission vendors interested in submitting CQM data to CMS on their participants' behalf will not need to complete a self-nomination process in order to be considered qualified to submit on behalf of EPs as this process will have already been performed for the Physician Quality Reporting System. Therefore, we believe that there is no additional burden aside from the burden associated with being a Physician Qualified Reporting System qualified EHR data submission vendor for such vendors to submit CQMs on behalf of EPs.

For EPs who choose to participate in the Pilot via direct data submission to CMS from the EP's certified EHR technology, an EP must have access to a CMS-specified identity management system, such as IACS, to participate in the Physician Quality Reporting System or eRx Incentive Program. EPs that choose the EHR-based reporting pilot to report CQMs will do so only if they are participating in the Physician Quality Reporting System. As such, we believe there will be no additional burden on EPs to have access to a CMS-specified identity management system if the EP is already participating in the Physician Quality Reporting System. With respect to submitting the actual 2012 data file in 2013, we believe that this will take an EP no more than 2 hours, depending on the number of patients on which the EP is submitting. We believe that once the EHR is programmed by the vendor to allow data submission to CMS and the EP participates in the Physician Quality Reporting System, the additional burden to the EP associated with electronic submission of the CQMs should be minimal. Since this is a new reporting mechanism for the EHR Incentive Program 2012 payment year, it is difficult to predict the level of participation in EHR-based reporting. However, we believe that the number of EPs who choose to participate in the EHR-based reporting option for the Pilot will be the same as the number of eligible professionals who choose the EHR-based reporting mechanism for the Physician Quality Reporting System. This is primarily because in addition to being certified EHR technology, the technology used under this reporting option will need to be qualified according to the Physician Quality Reporting System qualification process.

The burden associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the EP or vendor needs to submit to CMS for purposes of reporting CQMs will be dependent on the EHR vendor's familiarity with the EHR Incentive Program and Physician Quality Reporting System, the vendor's system capabilities, as well as the vendor's programming capabilities. As we already are requiring qualified EHRs vendors to perform these functions under the Physician Quality Reporting System, the burden for submitting CQMs under the EHR Incentive Program will be similar to the EHR vendor reporting burden under the Physician Quality Reporting System. For vendors who already have these necessary capabilities, we estimate the total burden hours to be 40 hours at a rate of $40/hour for a total burden estimate of $800 ($40/hour × 40 hours per vendor). However, given the variability in the capabilities of the vendors, those vendors with minimal experience will have a burden of approximately 200 hours at $40/hour, for a total estimate of $8,000 per vendor ($40/hour × 200 hours per EHR vendor).

To obtain copies of the supporting statement and any related forms for the paperwork collections referenced above, access CMS' Web site at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage* or email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at (410) 786–1326.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this final rule with comment period; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and

Budget, Attention: CMS Desk Officer, [CMS–1524–FC] Fax: (202) 395–5806; or Email: *OIRA_submission@omb.eop.gov.*

VIII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IX. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period is necessary in order to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Affordable Care Act and MIPPA and other statutory changes. This final rule with comment period is also necessary to make changes to the Part B drug payment policy and other related Part B related policies.

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 (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) 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). This final rule with comment period has been designated as ''economically'' significant, under section 3(f)(1) of Executive Order 12866 and hence also a major rule under the Congressional Review Act. Accordingly, the rule has been reviewed by the Office of Management and Budget. We have prepared an RIA, that to the best of our ability presents the costs and benefits of the final rule with comment period. We solicited comment on the RIA provided. We received one comment regarding the RIA.

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 hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year (for details see the SBA's Web site at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity. The RFA requires that we analyze regulatory options for small businesses and other entities. A RFA analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

For purposes of the RFA, physicians, NPPs, and suppliers including IDTFs are considered small businesses if they generate revenues of $10 million or less based on SBA size standards. Approximately 95 percent of physicians are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS.

Because we acknowledge that many of the affected entities are small entities, the analysis provided here and throughout the preamble of this final rule with comment period constitutes our Final Regulatory Flexibility Act (FRFA) analysis for the remaining provisions. This includes alternatives considered for the various final policies in this rule. We solicited public comment on the IRFA analysis provided in the proposed rule, but did not receive any comments that were in scope. We conclude that this final rule with comment has a significant 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 with comment period would 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 final rule with comment period does not contain mandates that will impose any costs on State, local, or tribal governments in aggregate, or by the private sector, of $136 million respectively.

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. This final rule with comment period will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

We have prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule with comment period; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule with comment period, we are implementing a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services. We provide information for each of the policy changes in the relevant sections of this final rule with comment period. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this final rule with comment period. The relevant sections of this final rule with comment period contain a

description of significant alternatives if applicable.

C. RVU Impacts

1. Resource-Based Work, PE, and Malpractice RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2011 with final payment rates for CY 2012 using CY 2010 Medicare utilization for all years. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different than those shown in Table 84. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician furnishes. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 85 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Table 84 shows only the payment impact on PFS services. We note that these impacts do not include the effect of the January 2012 conversion factor changes under current law. The annual update to the PFS conversion factor is calculated based on a statutory formula that measures actual versus allowed or ''target'' expenditures, and applies a sustainable growth rate (SGR) calculation intended to control growth in aggregate Medicare expenditures for physicians' services. This update methodology is typically referred to as the ''SGR'' methodology, although the SGR is only one component of the formula. Medicare physician fee schedule payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted to eventually bring actual expenditures back in line with targets. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased. We currently estimate that the statutory formula used to determine the physician update will result in a CY 2012 conversion factor of 24.6712 which represents a PFS update of −27.4 percent. By law, we are required to make these reductions in accordance with section 1848(d) and (f) of the Act, and these reductions can only be averted by an Act of the Congress. While the Congress has provided temporary relief from these reductions for every year since 2003, a long-term solution is critical. We are committed to working with the Congress to permanently reform the SGR methodology for Medicare physician fee schedule updates so doctors and patients no longer have to worry about the stability and adequacy of their payments from Medicare.

The following is an explanation of the information represented in Table 84:

- *Column A (Specialty):* The Medicare specialty code as reflected in our physician/supplier enrollment files.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2010 utilization and CY 2011 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work and Malpractice (MP) RVU Changes):* This column shows the estimated CY 2012 impact on total allowed charges of the changes in the work and malpractice RVUs, including the impact of changes due to potentially misvalued codes. These impacts are primarily due to the multiple procedure payment reduction (MPPR) for the professional component of advanced imaging services.
- *Column D (Impact of PE RVU Changes—Full):* This column shows the estimated CY 2012 impact on total allowed charges of the changes in the PE RVUs if there were no remaining transition to the full use of the PPIS data.
- *Column E (Impact of PE RVU Changes—Tran):* This column shows the estimated CY 2012 impact on total allowed charges of the changes in the PE RVUs under the third year of the 4-year transition to the full use of the PPIS data. This column also includes the impact of the MPPR policy and, and the impact of changes due to potentially misvalued codes.
- *Column F (Combined Impact—Full):* This column shows the estimated CY 2012 combined impact on total allowed charges of all the changes in the previous columns if there were no remaining transition to the new PE RVUs using the PPIS data.
- *Column G (Combined Impact—Tran):* This column shows the estimated CY 2012 combined impact on total allowed charges of all the changes in the previous columns under the third year of the 4-year transition to the new PE RVUs using the PPIS data. These are the combined impacts for CY 2012.

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TABLE 84: CY 2012 PFS FINAL RULE WITH COMMENT PERIOD TOTAL ALLOWED CHARGE ESTIMATED IMPACT FOR RVU AND MPPR CHANGES*

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Specialty	Allowed Charges (in millions)	Impact of Work and MP RVU Changes	Impact of PE RVU Changes		Combined Impact	
			Full	Tran	Full	Tran
TOTAL	$83,313	0%	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	$196	0%	-1%	-1%	-1%	-1%
ANESTHESIOLOGY	$1,756	0%	2%	1%	2%	1%
CARDIAC SURGERY	$386	0%	-2%	-2%	-3%	-2%
CARDIOLOGY	$6,808	0%	-3%	-1%	-3%	-2%
COLON AND RECTAL SURGERY	$147	0%	3%	2%	3%	1%
CRITICAL CARE	$255	0%	0%	0%	0%	-1%
DERMATOLOGY	$2,950	0%	1%	1%	1%	1%
EMERGENCY MEDICINE	$2,677	0%	-1%	-1%	0%	-1%
ENDOCRINOLOGY	$416	0%	2%	1%	2%	1%
FAMILY PRACTICE	$5,689	0%	2%	1%	2%	1%
GASTROENTEROLOGY	$1,852	0%	1%	0%	1%	0%
GENERAL PRACTICE	$655	0%	2%	1%	2%	1%
GENERAL SURGERY	$2,285	0%	1%	0%	1%	0%
GERIATRICS	$203	0%	2%	1%	3%	1%
HAND SURGERY	$123	0%	2%	1%	2%	1%
HEMATOLOGY/ONCOLOGY	$1,922	0%	-1%	0%	-1%	0%
INFECTIOUS DISEASE	$601	0%	2%	1%	2%	1%
INTERNAL MEDICINE	$10,826	0%	2%	1%	2%	1%
INTERVENTIONAL PAIN MGMT	$450	-2%	0%	0%	-1%	-2%
INTERVENTIONAL RADIOLOGY	$208	-1%	-3%	-1%	-4%	-2%
MULTISPECIALTY CLINIC/OTHER	$91	1%	0%	0%	1%	1%
NEPHROLOGY	$2,022	0%	0%	0%	0%	0%
NEUROLOGY	$1,533	0%	3%	2%	3%	1%
NEUROSURGERY	$650	-1%	0%	0%	-1%	-1%
NUCLEAR MEDICINE	$54	0%	-3%	-1%	-3%	-1%
OBSTETRICS/GYNECOLOGY	$679	0%	1%	1%	1%	1%
OPHTHALMOLOGY	$5,328	0%	3%	2%	3%	1%
ORTHOPEDIC SURGERY	$3,584	-1%	0%	0%	0%	-1%
OTOLARNGOLOGY	$1,003	0%	2%	1%	2%	1%
PATHOLOGY	$1,129	0%	-2%	-1%	-2%	-1%
PEDIATRICS	$68	0%	1%	0%	1%	0%
PHYSICAL MEDICINE	$933	0%	2%	1%	2%	1%
PLASTIC SURGERY	$343	0%	2%	1%	1%	0%
PSYCHIATRY	$1,154	0%	0%	0%	0%	0%
PULMONARY DISEASE	$1,769	-1%	-1%	-1%	-1%	-2%
RADIATION ONCOLOGY	$1,981	0%	-10%	-6%	-10%	-6%
RADIOLOGY	$4,716	-1%	-4%	-2%	-5%	-3%
RHEUMATOLOGY	$528	0%	-1%	0%	-1%	-1%

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Specialty	Allowed Charges (in millions)	Impact of Work and MP RVU Changes	Impact of PE RVU Changes		Combined Impact	
			Full	Tran	Full	Tran
THORACIC SURGERY	$369	-1%	-2%	-1%	-3%	-2%
UROLOGY	$1,925	0%	-3%	-2%	-3%	-2%
VASCULAR SURGERY	$745	0%	-2%	-1%	-2%	-1%
AUDIOLOGIST	$57	1%	-8%	-5%	-7%	-4%
CHIROPRACTOR	$752	0%	2%	2%	2%	2%
CLINICAL PSYCHOLOGIST	$567	0%	-5%	-3%	-5%	-3%
CLINICAL SOCIAL WORKER	$394	0%	-6%	-3%	-6%	-3%
DIAGNOSTIC TESTING FACILITY	$839	0%	-8%	-3%	-8%	-3%
INDEPENDENT LABORATORY	$1,057	0%	-3%	-1%	-3%	-1%
NURSE ANES / ANES ASST	$738	0%	3%	2%	3%	2%
NURSE PRACTITIONER	$1,385	0%	2%	1%	2%	1%
OPTOMETRY	$990	0%	4%	2%	4%	2%
ORAL/MAXILLOFACIAL SURGERY	$44	0%	3%	2%	3%	2%
PHYSICAL/OCCUPATIONAL THERA	$2,349	0%	6%	4%	6%	4%
PHYSICIAN ASSISTANT	$1,021	0%	1%	0%	1%	0%
PODIATRY	$1,921	0%	4%	2%	4%	2%
PORTABLE X-RAY SUPPLIER	$99	0%	5%	4%	5%	4%
RADIATION THERAPY CENTERS	$74	0%	-11%	-6%	-11%	-6%
OTHER	$18	0%	3%	3%	3%	3%

* Table 84 shows only the payment impact on PFS services. We note that these impacts do not include the effects of the January 2012 conversion factor change under current law.

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2. CY 2012 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to several factors. First, as discussed in section II.A.2. of this final rule with comment period, we are currently implementing the third year of the 4-year transition to new PE RVUs using the PPIS data that were adopted in the CY 2010 PFS final rule with comment period. The impacts of the third year of the transition are generally consistent with the impacts that would be expected based on the impacts displayed in the CY 2011 PFS final rule with comment period.

The second general factor contributing to the CY 2012 impacts shown in Table 84 is a secondary effect of the CY 2011 rescaling of the RVUs so that, in the aggregate, they match the work, PE, and malpractice proportions in the revised and rebased MEI for CY 2011. That is, the rebased MEI had a greater proportion attributable to malpractice and PE and, correspondingly, a lesser proportion attributable to work. Specialties that have a high proportion of total RVUs attributable to work, such as emergency medicine, experienced a decrease in aggregate payments as a result of this rescaling, while specialties that have a high proportion attributable to PE, such as diagnostic testing facilities, experienced an increase in aggregate payments. (For further details on the MEI rebasing, see the discussion beginning on (75 FR 73262) in the CY 2011 PFS final rule.)

Table 86 also includes the impacts resulting from our expansion of the current MPPR policy to the professional component of advanced imaging services. We estimate that this policy will redistribute approximately $50 million through a small increase in the conversion factor and a small adjustment to all PE RVUs. We estimate that this change would primarily reduce payments to the specialties of radiology and interventional radiology. Finally, Table 84 also reflects the impacts of our final adjustments to improve the accuracy of the time associated with the work RVUs for certain services, including group therapy services, as discussed previously in section II.A. of this final rule with comment period.

Comment: We received comments asking for clarification of the secondary effect of the CY 2011 rescaling of the RVUs for the revised and rebased MEI.

Response: As stated in the CY 2012 PFS proposed rule (ADD CITATION TO PAGE), a general factor contributing to the CY 2012 impacts is an effect of the CY 2011 rescaling of the RVUs so that, in the aggregate, they match the work, PE, and malpractice proportions in the revised and rebased MEI for CY 2011. That is, the rebased MEI had a greater proportion attributable to malpractice and PE and, correspondingly, a lesser proportion attributable to work. Specialties that have a high proportion of total RVUs attributable to work, such as emergency medicine, experienced a decrease in aggregate payments as a result of this rescaling, while specialties that have a high proportion attributable to PE, such as diagnostic testing facilities, experienced an increase in aggregate payments. This occurs because we allocate indirect practice expenses to the code level partly on the basis of the direct practice expenses and the physician work RVUs. The rescaling of the RVUs for the revised and rebased MEI slightly increased the proportion of the indirect allocation based on the direct practice expenses and decreased the proportion based on the work RVUs.

b. Combined Impact

Column G of Table 84 displays the estimated CY 2012 combined impact on total allowed charges by specialty of all the final RVU and MPPR changes. These impacts range from an increase of 4 percent for physical/occupational therapy and portable x-ray suppliers to

a decrease of 6 percent for radiation oncology and radiation therapy centers. Again, these impacts are estimated prior to the application of the negative CY 2012 Conversion Factor (CF) update applicable under the current statute.

Table 85 shows the estimated impact on total payments for selected high-volume procedures of all of the changes discussed previously. We have included CY 2012 payment rates with and without the effect of the CY 2012 negative PFS CF update for comparison purposes. We selected these procedures because they are the most commonly furnished by a broad spectrum of physician specialties. There are separate columns that show the change in the facility rates and the nonfacility rates. For an explanation of facility and nonfacility PE, we refer readers to Addendum A of this final rule with comment period.

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TABLE 85: IMPACT OF FINAL RULE WITH COMMENT PERIOD AND ESTIMATED PHYSICIAN UPDATE ON CY 2012 PAYMENT FOR SELECTED PROCEDURES

CPT/ HCPCS[1]	MOD	Short Descriptor	Facility					Nonfacility				
			CY 2011[2]	CY 2012[3] (pre-update)	% Change (pre-update)	CY 2012[4]	% Change (post-update)	CY 2011[2]	CY 2012[3] (pre-update)	% Change (pre-update)	CY 2012[4]	% Change (post-update)
11721		Debride nail 6 or more	$25.82	$25.19	-2%	$18.26	-29%	$41.79	$43.57	4%	$31.58	-24%
17000		Destruct premalg lesion	$55.38	$56.16	1%	$40.71	-26%	$79.50	$81.01	2%	$58.72	-26%
27130		Total hip arthroplasty	$1,440.26	$1,445.57	0%	$1,047.79	-27%	NA	NA	NA	NA	NA
27244		Treat thigh fracture	$1,224.51	$1,231.48	1%	$892.60	-27%	NA	NA	NA	NA	NA
27447		Total knee arthroplasty	$1,539.47	$1,544.28	0%	$1,119.33	-27%	NA	NA	NA	NA	NA
33533		Cabg arterial single	$1,984.22	$1,950.35	-2%	$1,413.66	-29%	NA	NA	NA	NA	NA
35301		Rechanneling of artery	$1,128.70	$1,112.35	-1%	$806.25	-29%	NA	NA	NA	NA	NA
43239		Upper gi endoscopy biopsy	$174.64	$174.61	0%	$126.56	-28%	$345.20	$351.95	2%	$255.10	-26%
66821		After cataract laser surgery	$296.95	$307.70	NA	$223.03	-25%	$314.62	$326.42	4%	$236.60	-25%
66984		Cataract surg w/iol 1 stage	$742.38	$760.74	2%	$551.40	-26%	NA	NA	NA	NA	NA
67210		Treatment of retinal lesion	$647.59	$504.10	-22%	$365.38	-44%	$669.00	$524.18	-22%	$379.94	-43%
71010		Chest x-ray	NA	NA	NA	NA	NA	$23.78	$23.83	0%	$17.27	-27%
71010	26	Chest x-ray	$8.83	$8.85	0%	$6.41	-27%	$8.83	$8.85	0%	$6.41	-27%
77056		Mammogram both breasts	NA	NA	NA	NA	NA	$110.76	$112.32	1%	$81.41	-26%
77056	26	Mammogram both breasts	$43.49	$42.55	-2%	$30.84	-29%	$43.49	$42.55	-2%	$30.84	-29%
77057		Mammogram screening	NA	NA	NA	NA	NA	$81.20	$81.35	0%	$58.96	-27%
77057	26	Mammogram screening	$35.00	$34.38	-2%	$24.92	-29%	$35.00	$34.38	-2%	$24.92	-29%
77427		Radiation tx management x5	$180.41	$177.00	-2%	$128.29	-29%	$180.41	$177.00	-2%	$128.29	-29%
88305	26	Tissue exam by pathologist	$36.35	$36.08	-1%	$26.15	-28%	$36.35	$36.08	-1%	$26.15	-28%
90801		Psy dx interview	$123.33	$119.81	-3%	$86.84	-30%	$153.91	$152.49	-1%	$110.53	-28%
90862		Medication management	$44.85	$44.25	-1%	$32.07	-28%	$57.76	$58.54	1%	$42.43	-27%
90935		Hemodialysis one evaluation	$74.75	$72.84	-3%	$52.80	-29%	NA	NA	NA	NA	NA
92012		Eye exam established pat	$50.62	$51.40	2%	$37.25	-26%	$79.84	$82.71	4%	$59.95	-25%
92014		Eye exam & treatment	$77.13	$78.29	2%	$56.74	-26%	$115.86	$119.81	3%	$86.84	-25%
92980		Insert intracoronary stent	$873.19	$837.66	-4%	$607.16	-30%	NA	NA	NA	NA	NA
93000		Electrocardiogram complete	NA	NA	NA	NA	NA	$19.71	$19.06	-3%	$13.82	-30%
93010		Electrocardiogram report	$8.83	$8.51	-4%	$6.17	-30%	$8.83	$8.51	-4%	$6.17	-30%

CPT/ HCPCS[1]	MOD	Short Descriptor	Facility					Nonfacility				
			CY 2011[2]	CY 2012[3] (pre-update)	% Change (pre-update)	CY 2012[4]	% Change (post-update)	CY 2011[2]	CY 2012[3] (pre-update)	% Change (pre-update)	CY 2012[4]	% Change (post-update)
93015		Cardiovascular stress test	NA	NA	NA	NA	NA	$92.42	$88.50	-4%	$64.15	-31%
93307	26	Tte w/o doppler complete	$47.57	$45.95	-3%	$33.31	-30%	$47.57	$45.95	-3%	$33.31	-30%
93458	26	L hrt artery/ventricle angio	$320.06	$315.87	-1%	$228.95	-28%	$320.06	$315.87	-1%	$228.95	-28%
98941		Chiropractic manipulation	$30.92	$30.63	-1%	$22.20	-28%	$35.34	$36.08	2%	$26.15	-26%
99203		Office/outpatient visit new	$74.75	$74.88	0%	$54.28	-27%	$102.95	$105.18	2%	$76.23	-26%
99213		Office/outpatient visit est	$49.27	$49.69	1%	$36.02	-27%	$68.97	$70.46	2%	$51.07	-26%
99214		Office/outpatient visit est	$75.77	$76.24	1%	$55.26	-27%	$102.27	$104.15	2%	$75.49	-26%
99222		Initial hospital care	$132.17	$133.09	1%	$96.46	-27%	NA	NA	NA	NA	NA
99223		Initial hospital care	$194.01	$195.38	1%	$141.61	-27%	NA	NA	NA	NA	NA
99231		Subsequent hospital care	$38.39	$38.12	-1%	$27.63	-28%	NA	NA	NA	NA	NA
99232		Subsequent hospital care	$69.31	$69.78	1%	$50.58	-27%	NA	NA	NA	NA	NA
99233		Subsequent hospital care	$99.55	$100.07	1%	$72.53	-27%	NA	NA	NA	NA	NA
99236		Observ/hosp same date	$214.05	$212.05	-1%	$153.70	-28%	NA	NA	NA	NA	NA
99239		Hospital discharge day	$101.25	$103.13	2%	$74.75	-26%	NA	NA	NA	NA	NA
99283		Emergency dept visit	$61.16	$60.25	-1%	$43.67	-29%	NA	NA	NA	NA	NA
99284		Emergency dept visit	$115.52	$114.71	-1%	$83.14	-28%	NA	NA	NA	NA	NA
99291		Critical care first hour	$217.11	$217.16	0%	$157.40	-28%	$264.34	$267.19	1%	$193.67	-27%
99292		Critical care addl 30 min	$109.06	$108.92	0%	$78.95	-28%	$118.92	$119.47	0%	$86.60	-27%
99348		Home visit est patient	NA	NA	NA	NA	NA	$82.22	$82.03	0%	$59.46	-28%
99350		Home visit est patient	NA	NA	NA	NA	NA	$169.54	$171.21	1%	$124.10	-27%
G0008		Immunization admin	NA	NA	NA	NA	NA	$23.10	$24.17	5%	$17.52	-24%

[1] CPT codes and descriptions are copyright 2011 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.

[2] Payments based on the 2011 conversion factor of 33.9764

[3] Payments based on the 2011 conversion factor of 33.9764, adjusted to 34.0375 to include the budget neutrality adjustment.

[4] Payments based on the 2012 conversion factor of 24.6712, which includes the budget neutrality adjustment.

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D. Effects of Annual Review Process for Potentially Misvalued Codes Under the PFS

The process we are adopting in this final rule with comment period to consolidate the Five-Year Reviews of Work and PE RVUs with the annual review of potentially misvalued codes, is not anticipated to have a budgetary impact in CY 2012. As noted previously, to the extent that we have finalized revised RVUs for codes identified under the potentially misvalued codes initiative for CY 2012, Table 84 includes the estimated CY 2012 impact on total allowed charges of the changes in the RVUs for these codes.

E. Effect of Final Revisions to Malpractice RVUs

As discussed in section III.B.3.b. of this final rule with comment period, we revised the malpractice risk factors assigned to a limited number of cardiothoracic surgery services. The utilization of many of these services is zero, while the others have a very low utilization. Therefore, we estimate no significant budgetary impact from the final changes to the MP RVUs due to the very low utilization of these services.

F. Effect of Final Changes to Geographic Practice Cost Indices (GPCIs)

As discussed in section II.D. of this final rule with comment period, we are required to update the GPCI values at least every 3 years and phase in the adjustment over 2 years (if there has not been an adjustment in the past year). For CY 2012, we are finalizing revisions to the PE GPCIs for each Medicare locality, as well as the cost share weights for all three GPCI components. Moreover, the final revised PE GPCI values are a result of our analysis of the PE methodology as required by section 1848(e)(1)(H)(iv) of the Act. The final GPCIs rely upon the 2006–2008 American Community Survey (ACS) data to determine the relative cost differences in the office rent component of the PE GPCIs. In addition, we are finalizing the use of 2006–2008 Bureau of Labor and Statistics (BLS) Occupational Employment Statistics (OES) data to determine the employee compensation component. Further, we are finalizing that the occupations to be used in the calculation of the employee compensation component will include the full range of non-physician occupations which are employed within the offices of physicians industry. Lastly, we are finalizing a purchased services index that will be used to geographically adjust for differences in the labor-related share of the industries occupying the ''All Other Services'' and ''Other Professional Expenses'' 2006-based MEI categories.

We are finalizing a cost share weight for the PE GPCIs of 47.439 percent. For the employee compensation portion of the PE GPCIs, we are using the non-physician employee compensation category weight of 19.153 percent. The fixed capital and utilities MEI categories were combined to achieve a total office rent weight of 10.223 percent. In order to calculate the purchased services index, we are finalizing our proposal to merge the corresponding weights of the ''All Other Services'' and ''Other Professional Expenses'' MEI categories to form a combined purchased services weight of 8.095. We are finalizing a cost share weight for the medical equipment, supplies, and other miscellaneous expenses component of 9.968 percent. Furthermore, the physician compensation cost category and its weight of 48.266 percent reflects the work GPCI cost share weight; the professional liability insurance weight of 4.295 percent reflects the malpractice GPCI cost share weight. A more detailed discussion on the final CY 2012 GPCI cost share weights can be found in section II.D. of this final rule with comment period.

Additionally, section 1848(e)(1)(E) of the Act (as amended by section 103 of the Medicare and Medicaid Extenders Act of 2010) extended the 1.000 work GPCI floor through December 31, 2011. Therefore, the CY 2012 GPCIs reflect the sunset of the 1.000 work GPCI floor. Section 1848(e)(1)(G) of the Act (as amended by section 134(b) of the MIPPA) established a permanent 1.500 work GPCI floor in Alaska beginning January 1, 2009; therefore, the 1.500 work GPCI floor in Alaska will remain in place for CY 2012. Moreover, section 1848(e)(1)(I) of the Act (as added by section 10324(c) of the Affordable Care Act) established a permanent 1.000 PE GPCI floor for services furnished in frontier States effective January 1, 2011.

Addendum D to this final rule with comment period shows the estimated effects of the revised GPCIs on locality Geographic Adjustment Factors (GAFs) for CY 2012. The GAFs reflect the use of revised GPCI data and the updated cost share weights. The GAFs are a weighted composite of each locality's work, PE, and malpractice GPCIs using the national GPCI cost share weights. While we do not actually use the GAFs in computing the PFS payment for a specific service, they are useful in comparing the estimated overall costs and payments for different localities. The cumulative effects of all of the GPCI revisions, including the updated underlying GPCI data, updated cost share weights, and provisions of the Affordable Care Act, are reflected in the CY 2012 GPCI values that are displayed in Addendum E in this final rule with comment period.

Table 86 illustrates the impact of moving from the current law CY 2011 GAFs to the final CY 2012 GAFs by PFS locality. The table first shows the impact under current law and regulation, and then shows the impact due to the final rule modifications. As shown in the table, the primary driver of the CY 2012 impact is the current law expiration of the non-budget neutral increases to the CY 2011 GPCIs for lower cost areas that was required by the Affordable Care Act and the MMEA. The table is sorted by total impact from largest reductions to largest increases. When the overall impacts directly resulting from our final changes to the PE GPCI are isolated, these final rule impacts are much smaller (Column F) than the impacts due to current law and regulation. Specifically, the PE GPCI final rule changes cause a change in GAF values of less than or equal to one percentage point for approximately nine out of ten localities. The following description explains the information represented in Table 86 in more detail:

- *Column (A):* Medicare Locality—The PFS geographic locality.
- *Column (B):* CY 2011 GAF—The current CY 2011 Geographic Adjustment Factor for the locality, which includes the non-budget neutral increases to the CY 2011 GPCIs for lower expense areas authorized by the Affordable Care Act and the Medicare and Medicaid Extenders Act. These figures also reflect the first year of the 2-year transition to the latest GPCIs that began in 2011.
- *Column (C):* CY 2012 GAF (Current Law/Reg)—The CY 2012 Geographic Adjustment Factor for the locality under current law and regulations, which includes the expiration of the non-budget neutral increases to the CY 2011 GPCIs for lower expense areas authorized by the Affordable Care Act and the MMEA. These numbers also reflect the end of the transition to the latest GPCIs that began in 2011.
- *Column (D):* CY 2012 GAF (Final):—The final CY 2012 Geographic Adjustment Factor for each locality. The two largest drivers of the differences between the GAFs in column (C) and Column (D) are: The utilization of residential rent data from the Census Bureau's ACS data instead of the Department of Housing and Urban Development's FMR data, and the benchmarking of the GPCI practice expense weights to the 2006-based MEI

cost share weights. The Geographic Adjustment Factors in this column are for 2012 and do not reflect any temporary increases to work and practice expense required by the Affordable Care Act.

• *Column (E):* Percent Change CY 2011 to CY 2012 (current)—Impact of the expiration of the non-budget neutral increases to the CY 2011 GPCIs for lower expense areas authorized by the Affordable Care Act and the MMEA and the end of the transition to the latest GPCIs that began in 2011.

• *Column (F):* Percent Change CY 2012 (No NPRM) to CY 2012 (NPRM)—Impact of the four regulatory changes described previously.

• *Column (G):* Percent Change Combined Impact CY 2011 to CY 2012—Combined impact of all changes from CY 2011 to CY 2012.

TABLE 86: CY 2012 GEOGRAPHIC ADJUSTMENT FACTORS (GAFS) CHANGES UNDER CURRENT LAW AND THE FINAL RULE WITH COMMENT PERIOD

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Medicare Locality	**CY 2011 GAF**	**CY 2012 GAF (Current law/reg)**	**CY 2012 GAF (Final Rule)**	**% Change CY 2011 to CY 2012 (current)** Col (C)/ Col (B)-1	**% Change CY 2012 (Curr) to CY 2012 (Final)** Col (D)/ Col (C)-1	**% Change Combined Impact CY 2011 to CY 2012** Col (D)/ Col (B)-1
PUERTO RICO	0.903	0.786	0.771	-13%	-2%	-15%
WEST VIRGINIA	0.972	0.910	0.910	-6%	0%	-6%
OKLAHOMA	0.955	0.904	0.898	-5%	-1%	-6%
MISSISSIPPI	0.961	0.910	0.908	-5%	0%	-6%
REST OF MISSOURI	0.962	0.903	0.909	-6%	1%	-5%
ARKANSAS	0.945	0.893	0.896	-6%	0%	-5%
REST OF LOUISIANA	0.965	0.914	0.915	-5%	0%	-5%
IOWA	0.950	0.898	0.903	-5%	1%	-5%
KENTUCKY	0.959	0.917	0.914	-4%	0%	-5%
BEAUMONT, TX	0.978	0.925	0.933	-5%	1%	-5%
ALABAMA	0.949	0.905	0.908	-5%	0%	-4%
TENNESSEE	0.959	0.918	0.918	-4%	0%	-4%
NEBRASKA	0.947	0.905	0.909	-4%	0%	-4%
REST OF MAINE	0.961	0.922	0.923	-4%	0%	-4%
IDAHO	0.959	0.926	0.923	-3%	0%	-4%
SOUTH CAROLINA	0.959	0.925	0.925	-4%	0%	-4%
KANSAS	0.964	0.923	0.930	-4%	1%	-4%
INDIANA	0.966	0.928	0.932	-4%	0%	-4%
METROPOLITAN BOSTON	1.106	1.079	1.068	-2%	-1%	-3%
REST OF GEORGIA	0.970	0.936	0.937	-4%	0%	-3%
REST OF TEXAS	0.973	0.934	0.940	-4%	1%	-3%
NORTH CAROLINA	0.970	0.934	0.938	-4%	0%	-3%
UTAH	0.982	0.946	0.951	-4%	1%	-3%
MANHATTAN, NY	1.153	1.142	1.118	-1%	-2%	-3%
REST OF PENNSYLVANIA	0.986	0.957	0.958	-3%	0%	-3%
LOS ANGELES, CA	1.106	1.099	1.075	-1%	-2%	-3%
NEW ORLEANS, LA	1.005	0.980	0.977	-2%	0%	-3%
SOUTH DAKOTA**	0.978	0.952	0.951	-3%	0%	-3%
NEW MEXICO	0.979	0.949	0.954	-3%	1%	-3%
REST OF ILLINOIS	0.985	0.950	0.960	-4%	1%	-3%
REST OF MICHIGAN	0.985	0.962	0.962	-2%	0%	-2%
ALASKA*	1.289	1.289	1.259	0%	-2%	-2%
VENTURA, CA	1.113	1.105	1.091	-1%	-1%	-2%
REST OF NEW YORK	0.965	0.948	0.946	-2%	0%	-2%
CONNECTICUT	1.094	1.086	1.074	-1%	-1%	-2%
MONTANA**	0.996	0.976	0.978	-2%	0%	-2%
OHIO	0.992	0.970	0.975	-2%	1%	-2%
METROPOLITAN KANSAS CITY, MO	0.996	0.975	0.979	-2%	0%	-2%

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Medicare Locality	**CY 2011 GAF**	**CY 2012 GAF (Current law/reg)**	**CY 2012 GAF (Final Rule)**	**% Change CY 2011 to CY 2012 (current)** Col (C)/ Col (B)-1	**% Change CY 2012 (Curr) to CY 2012 (Final)** Col (D)/ Col (C)-1	**% Change Combined Impact CY 2011 to CY 2012** Col (D)/ Col (B)-1
NORTH DAKOTA**	0.979	0.964	0.963	-2%	0%	-2%
ANAHEIM/SANTA ANA, CA	1.129	1.129	1.111	0%	-2%	-2%
NYC SUBURBS/LONG I., NY	1.161	1.159	1.143	0%	-1%	-2%
SAN MATEO, CA	1.199	1.194	1.182	0%	-1%	-1%
REST OF FLORIDA	1.014	0.996	1.000	-2%	0%	-1%
HAWAII	1.074	1.091	1.060	2%	-3%	-1%
EAST ST. LOUIS, IL	1.016	0.997	1.003	-2%	1%	-1%
REST OF MASSACHUSETTS	1.040	1.039	1.027	0%	-1%	-1%
REST OF OREGON	0.968	0.950	0.956	-2%	1%	-1%
SAN FRANCISCO, CA	1.198	1.194	1.185	0%	-1%	-1%
WISCONSIN	0.965	0.949	0.955	-2%	1%	-1%
ARIZONA	0.989	0.977	0.979	-1%	0%	-1%
FORT WORTH, TX	0.991	0.981	0.982	-1%	0%	-1%
VERMONT	0.982	0.980	0.974	0%	-1%	-1%
METROPOLITAN ST. LOUIS, MO	0.988	0.971	0.980	-2%	1%	-1%
NORTHERN NJ	1.120	1.105	1.111	-1%	1%	-1%
SOUTHERN MAINE	0.997	0.993	0.990	0%	0%	-1%
MIAMI, FL	1.108	1.100	1.101	-1%	0%	-1%
AUSTIN, TX	0.992	0.979	0.986	-1%	1%	-1%
WYOMING**	1.002	0.994	0.996	-1%	0%	-1%
HOUSTON, TX	1.008	0.992	1.002	-2%	1%	-1%
METROPOLITAN PHILADELPHIA, PA	1.068	1.062	1.062	-1%	0%	-1%
OAKLAND/BERKELEY, CA	1.133	1.136	1.128	0%	-1%	0%
VIRGINIA	0.978	0.971	0.974	-1%	0%	0%
DETROIT, MI	1.060	1.047	1.056	-1%	1%	0%
REST OF NEW JERSEY	1.074	1.066	1.072	-1%	1%	0%
BRAZORIA, TX	0.996	0.977	0.995	-2%	2%	0%
RHODE ISLAND	1.042	1.039	1.041	0%	0%	0%
DC + MD/VA SUBURBS	1.124	1.125	1.123	0%	0%	0%
MARIN/NAPA/SOLANO, CA	1.119	1.127	1.119	1%	-1%	0%
DELAWARE	1.012	1.010	1.013	0%	0%	0%
DALLAS, TX	1.004	0.997	1.005	-1%	1%	0%
FORT LAUDERDALE, FL	1.061	1.062	1.063	0%	0%	0%
VIRGIN ISLANDS	0.998	0.997	1.000	0%	0%	0%
POUGHKPSIE/N NYC SUBURBS, NY	1.037	1.039	1.040	0%	0%	0%
NEW HAMPSHIRE	1.007	1.012	1.010	0%	0%	0%
QUEENS, NY	1.140	1.150	1.144	1%	-1%	0%
CHICAGO, IL	1.081	1.076	1.085	0%	1%	0%
ATLANTA, GA	1.002	0.997	1.006	0%	1%	0%
MINNESOTA	0.969	0.968	0.973	0%	1%	0%
GALVESTON, TX	0.997	0.995	1.002	0%	1%	1%
COLORADO	0.989	0.990	0.994	0%	0%	1%
REST OF CALIFORNIA	1.025	1.038	1.032	1%	-1%	1%
REST OF WASHINGTON	0.987	0.985	0.996	0%	1%	1%

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Medicare Locality	**CY 2011 GAF**	**CY 2012 GAF (Current law/reg)**	**CY 2012 GAF (Final Rule)**	**% Change CY 2011 to CY 2012 (current)** Col (C)/ Col (B)-1	**% Change CY 2012 (Curr) to CY 2012 (Final)** Col (D)/ Col (C)-1	**% Change Combined Impact CY 2011 to CY 2012** Col (D)/ Col (B)-1
NEVADA**	1.024	1.031	1.036	1%	0%	1%
SUBURBAN CHICAGO, IL	1.061	1.059	1.077	0%	2%	2%
BALTIMORE/SURR. CNTYS, MD	1.052	1.070	1.068	2%	0%	2%
PORTLAND, OR	0.991	0.995	1.007	0%	1%	2%
REST OF MARYLAND	1.004	1.024	1.021	2%	0%	2%
SANTA CLARA, CA	1.156	1.164	1.176	1%	1%	2%
SEATTLE (KING CNTY), WA	1.045	1.056	1.075	1%	2%	3%

*GAF reflects a 1.5 work GPCI floor in Alaska established by the MIPPA.

** GAFs reflect a 1.0 PE GPCI floor for frontier States as required by the Affordable Care Act.

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G. Effects of Final Changes to Medicare Telehealth Services Under the Physician Fee Schedule

As discussed in section II.E. of this final rule with comment period, we are finalizing our policy to add several new codes to the list of telehealth services and revise the criteria for adding services to the list of telehealth services. While we expect these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, we estimate no significant budgetary impact from the additions. In addition, the final revision to the telehealth criteria will be effective for CY 2013 PFS telehealth services, with no impact in CY 2012.

H. Effects of the Impacts of Other Provisions of the Final Rule With Comment Period

1. Part B Drug Payment: ASP Issues

Application of our proposals for ''ASP Reporting Template Update'' and ''Reporting of ASP Units and Sales Volume for Certain Products,'' as discussed in section VI.A. of this final rule with comment period involve revisions to the existing ASP reporting template which will facilitate the accuracy and efficiency of data transfer from manufacturers. Any impacts are dependent on the status and quality of quarterly manufacturer data submissions, so we cannot quantify associated savings.

Finally, as discussed in section VI.A. of this final rule with comment period, we provided for appropriate price substitutions that account for market-related pricing changes and would allow Medicare to pay based off lower market prices for those drugs and biologicals that consistently exceed the applicable threshold percentage. Based on estimates published in various OIG reports (see section VI.A. for a list of citations), we believe that this proposal will generate minor savings for the Medicare program and its beneficiaries since any substituted prices would be for amounts less than the calculated 106 percent of the ASP.

2. Chiropractic Services Demonstration

As discussed in section VI.B. of this final rule with comment period, we are continuing the recoupment of the $50 million in expenditures from this demonstration in order to satisfy the budget neutrality requirement in section 651(f)(1)(b) of the MMA. We initiated this recoupment in CY 2010 and this will be the third year. As discussed in the CY 2010 PFS final rule with comment period, we finalized a policy to recoup $10 million each year through adjustments to the PFS for all chiropractors in CYs 2010 through 2014. To implement this required budget neutrality adjustment, we are recouping $10 million in CY 2012 by reducing the payment amount under the PFS for the chiropractic CPT codes (that is, CPT codes 98940, 98941, and 98942) by approximately 2 percent.

3. Extension of Payment for Technical Component of Certain Physician Pathology Services

As discussed in section V.A. of this final rule with comment period, we are implementing the provision that specifies that for services furnished after December 31, 2011, an independent laboratory may not bill the Medicare contractor for the TC of physician pathology services furnished to a hospital inpatient or outpatient. The savings associated with implementing this provision are estimated to be approximately $80 million for CY 2012.

4. Section 4103: Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan: Incorporation of a Health Risk Assessment as Part of the Annual Wellness Visit

As discussed in section VI.E. of this final rule with comment period, section 1861(s)(2)(FF) of the Act, as described more fully in section 1861(hhh), of the Act (as added by section 4103 of the Affordable Care Act) provides Medicare coverage for an annual wellness visit. Regulations for Medicare coverage of the AWV are established at 42 CFR 410.15. The annual wellness visit is covered with no coinsurance or deductible when furnished by a health professional as that term is defined in 42 CFR 410.15. The annual wellness visit entails the creation of a personalized prevention plan for an individual and includes elements, such as updating medical and family history, identifying providers that regularly provide medical care to the individual, measurement of height, weight, and body mass index, identification of risk factors, the provision of personalized health advice, and development of a screening schedule (such as a checklist), and referrals as appropriate for additional preventive services. Section 1861(hhh)(1)(A) of the Act specifies that a personalized prevention plan for an individual includes a HRA that meets the guidelines established by the Secretary and takes into account the results of a HRA. We are proposing to incorporate the use and results of an HRA as part of the provision of personalized prevention plan services during the AWV. The estimated impact of incorporating the HRA as part of the

AWV is unknown for CY 2012. We specifically requested public comment on the following:

- The impact of use of the HRA on health professional practices.
- The burden on health professional practices of incorporating an HRA into subsequent AWVs, as well as the first AWV.
- The impact of the elements included in the definitions of first and subsequent AWVs.
- Modification of those AWV elements for which the Secretary has authority to determine appropriateness.

A discussion of the comments we received, our responses, and our final policy for CY 2012 is available in section VI.E. of this final rule with comment period. Our final policy to increase payment for the AWV to acknowledge the increased clinical staff time required to incorporate the HRA into the AWV is subject to budget neutrality.

5. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

As discussed in section VI.F.1 of this final rule with comment period, we are finalizing several different reporting options for eligible professionals who wish to participate in the 2012 Physician Quality Reporting System. Although there may be some cost incurred by CMS for maintaining the Physician Quality Reporting System measures and their associated code sets, and for expanding an existing clinical data warehouse to accommodate the final registry-based reporting, EHR-based reporting, and group practice reporting options for the 2012 Physician Quality Reporting System, we do not anticipate a significant cost impact on the Medicare program.

With respect to the potential incentive payments that may be made to satisfactory reporters under the 2012 Physician Quality Reporting System, we estimate this amount for individual eligible professionals would be approximately $60 million. This estimate is derived from looking at our 2009 incentive payment of approximately $235 million and then accounting for the fact that the 2009 incentive payment was 2.0 percent of an eligible professional's total estimated Medicare Part B PFS allowed charges for all such covered professional services furnished by the eligible professional during the 2009 reporting period. For 2012, the incentive payment is 0.5 percent of an eligible professional's total estimated Medicare Part B PFS allowed charges for all covered professional services furnished by an eligible professional during the 2012 reporting period. Although we expect that the lower incentive payment percentage for 2012 would reduce the total outlay by approximately one-fourth, we also expect more eligible professionals to participate in the 2012 Physician Quality Reporting System because we are finalizing multiple methods of data submission, additional alternative reporting methods, methods to align the Physician Quality Reporting System with the EHR Incentive Program and the Medicare Shared Savings Program, and CY 2013 as the reporting period for the 2015 payment adjustment. We also believe that some eligible professionals will qualify for the additional 0.5 percent incentive authorized under section 1848(m)(7) of the Act (''Additional Incentive Payment'').

With respect to estimated costs associated with reporting by individual eligible professionals, one factor that influences the cost to individual eligible professionals is the time and effort associated with identifying applicable Physician Quality Reporting System quality measures and reviewing and selecting a reporting option. This burden will vary with each individual eligible professional by the number of applicable measures, the eligible professional's understanding of the Physician Quality Reporting System, experience with Physician Quality Reporting System participation, and the method(s) selected by the eligible professional for reporting of the measures, and incorporating the reporting of the measures into the office work flows.

In the proposed rule (72 FR 42938), we estimated an average practice labor cost of $40/hour for our impact analysis. However, in an effort to provide a more accurate labor cost estimate of participation for the 2012 Physician Quality Reporting System, we conducted an informal poll among a small sample of participants in the 2011 Physician Quality Reporting System to determine what employees within an eligible professional's practice are involved with Physician Quality Reporting System activities. The poll revealed that a billing clerk typically handles administrative details with respect to participating under the Physician Quality Reporting System (such as submitting self-nomination statements), whereas a computer analyst typically handles the reporting of Physician Quality Reporting System quality measures. Based on this information, we are changing our estimated labor costs associated with participating in the Physician Quality Reporting System.

For purposes of this impact analysis, we will assume that a billing clerk will handle the administrative duties associated with participating in the 2012 Physician Quality Reporting System. According to information published by the Bureau of Labor Statistics, available at *http://www.bls.gov/oes/current/oes433021.htm,* the mean hourly wage for a billing clerk is $16.00/hour. Therefore, for purposes of handling administrative duties, we estimate an average labor cost of $16.00/hour.

In addition, for purposes of this impact analysis, we will assume that a computer analyst will engage in the duties associated with the reporting of 2012 Physician Quality Reporting System quality measures. According to information published by the Bureau of Labor Statistics, available at *http://www.bls.gov/oes/current/oes151121.htm,* the mean hourly wage for a computer analyst is $39.06/hour, or approximately $40.00/hour. Therefore, for purposes of reporting on 2012 Physician Quality Reporting System quality measures, we estimate an average labor cost of $40.00/hour.

Participation in the CY 2012 Physician Quality Reporting System by individual eligible professionals and group practices is voluntary and individual eligible professionals and group practices may have different processes for integrating the collection of the Physician Quality Reporting System measures into their practice's work flows. Given this variability and the multiple reporting options that we provide, it is difficult to definitively estimate the impact of the Physician Quality Reporting System on providers. Furthermore, we believe that costs for eligible professionals who are participating in the Physician Quality Reporting System for the first time in 2012 would be considerably higher than the cost for eligible professionals who participated in the Physician Quality Reporting System in prior years. Some preparatory steps are needed to begin participating in the Physician Quality Reporting System. To the extent that we are retaining measures that an eligible professional has reported in a prior year and there are no changes to the measure's specifications from a prior year, such preparatory steps do not need to be repeated in subsequent years. In addition, for many eligible professionals, the cost of participating in the Physician Quality Reporting System is offset by the incentive payment, if earned.

Assuming that it takes an individual eligible professional approximately 5 hours to review the Physician Quality

Reporting System quality measures, review the various reporting options, select the most appropriate reporting option, identify the applicable measures for which they can report the necessary information, and incorporate reporting of the selected measures into their office work flows, we estimate that the cost to eligible professionals associated with preparing to report Physician Quality Reporting System quality measures will be approximately $200 per individual eligible professional ($40 per hour × 5 hours).

Another factor that influences the cost to individual eligible professionals is how they choose to report the Physician Quality Reporting System measures (that is, whether they select the claims-based, registry-based or EHR-based reporting mechanism we are finalizing). For the claims-based reporting mechanism, estimates from the PVRP indicate the time needed to perform all the steps necessary to report quality data codes (QDCs) for 1 measure on a claim ranges from 15 seconds (0.25 minutes) to 12 minutes for complicated cases or measures. In previous years, when we required reporting on 80 percent of eligible cases for claims-based reporting, we found that on average, the median number of reporting instances for each of the Physician Quality Reporting System measures was 9. Since we reduced the required reporting rate by over one-third to 50 percent, then for purposes of this impact analysis we will assume that an eligible professional will need to report each selected measure for 6 reporting instances, or 6 cases. Assuming that an eligible professional, on average, will report 3 measures since a majority of eligible professionals participate in the Physician Quality Reporting System by reporting individual measures via claims or registry and that an eligible professional reports on an average of 6 reporting instances per measure, we estimate that the cost to an individual eligible professional associated with the claims-based reporting option of Physician Quality Reporting System measures will range from approximately $2.64 (0.25 minutes per reporting instance × 6 reporting instances per measure × 3 measures × $40/hour) to $144.00 (12 minutes per reporting instance × 6 reporting instances per measure × 3 measures × $40/hour). If an eligible professional satisfactorily reports, these costs will more than likely be negated by the incentive, if earned. For the 2009 Physician Quality Reporting System, which had a 2.0 percent incentive, the mean incentive amount was close to $2,000 for an individual eligible professional. For the registry-based reporting option, individual eligible professionals will generally incur a cost to submit data to registries. We estimate that fees for using a qualified registry will range from no charge, or a nominal charge, for an individual eligible professional to use a registry to several thousand dollars, with a majority of registries charging fees ranging from $500 to $1,000. However, our impact analysis is limited to the incremental costs associated with Physician Quality Reporting System reporting, which we believe are minimal. We believe that many eligible professionals who select the registry-based reporting option will already be utilizing the registry for other purposes and will not need to report additional data to the registry specifically for Physician Quality Reporting System. The registries also often provide the eligible professional services above and beyond what is required for the Physician Quality Reporting System.

For the EHR-based reporting option, an individual eligible professional generally will incur a cost associated with purchasing an EHR product. Although we do not believe that the majority of eligible professionals will purchase an EHR solely for the purpose of participating in Physician Quality Reporting System, cost estimates for EHR adoption by eligible professionals from the EHR Incentive Program final rule (75 FR 44549) show that an individual eligible professional who chooses to do so will have to spend anywhere from $25,000 to $54,000 to purchase and implement an EHR and up to $18,000 annually for ongoing maintenance.

Although we believe that the majority of eligible professionals attempting to qualify for the additional 0.5 percent incentive payment authorized by section 1848(m)(7) of the Act will be those who are already required by their Boards to participate in a Maintenance of Certification Program, individual eligible professionals who wish to qualify for the additional 0.5 percent incentive payment and are not currently participating in a Maintenance of Certification Program will also have to incur a cost for participating in a Maintenance of Certification Program. The manner in which fees are charged for participating in a Maintenance of Certification Program vary by specialty. Some Boards charge a single fee for participation in the full cycle of Maintenance of Certification Program. Such fees appear to range anywhere from over $1,100 to nearly $1,800 per cycle. Some Boards have annual fees that are paid by their diplomates. On average, ABMS diplomates pay approximately $200.00 per year for participating in Maintenance of Certification Program. Some Boards have an additional fee for the Maintenance of Certification Program Part III secure examination, but most Boards do not have additional charges for participation in practice/quality improvement activities.

With respect to the final group practice requirements for satisfactorily submitting quality measures data for the CY 2012 Physician Quality Reporting System discussed in section VI.F.1 of this final rule with comment period, group practices interested in participating in the CY 2012 Physician Quality Reporting System through the group practice reporting option (GPRO) may also incur a cost. However, for groups that satisfactorily report for the 2012 Physician Quality Reporting System, we believe these costs will be completely offset if the group practice earns the incentive payment since the group practice will be eligible for an incentive payment equal to 0.5 percent of the entire group's total estimated Medicare Part B PFS allowed charges for covered professional services furnished by the group practice during the reporting period.

One factor in the cost to group practices will be the costs associated with the self-nomination process. Similar to our estimates for staff involved with the claims-based reporting option for individual eligible professionals, we also estimate that the group practice staff involved in the group practice self-nomination process will have an average administrative labor cost of $16/hour. Therefore, assuming 2 hours for a group practice to decide whether to participate as a group or have members of the practice participate individually and 4 hours for the self-nomination process, we estimate the total cost to a group practice associated with the group practice self-nomination process will be approximately $96 ($16/hour × 6 hours per group practice).

For groups participating under the GPRO process that are comprised of 25 or more eligible professionals, another factor in the cost to the group will be the time and effort associated with the group practice completing and submitting the GPRO web interface. Based on the Physician Group Practice (PGP) demonstration's estimate that it takes approximately 79 hours for a group practice to complete the data collection, which uses the same data submission methods as those we have finalized, we estimate the cost

associated with a physician group completing the GPRO web interface will be approximately $4,740 ($40/hour × 79 hours per group practice).

In addition to costs incurred by individual eligible professionals and group practices, registries and EHR vendors may also incur some costs related to the final requirements for the 2012 Physician Quality Reporting System. Registries interested in becoming ''qualified'' to submit on behalf of individual eligible professionals will also have to incur a cost associated with the vetting process, calculating quality measures results from the data submitted to the registry by its participants, and submitting the quality measures results, as well as numerator and denominator data on quality measures, to CMS on behalf of their participants. We estimate the registry self-nomination process will cost approximately $400 per registry ($40 per hour × 10 hours per registry). This cost estimate includes the cost of submitting the self-nomination letter to CMS and completing the final CMS vetting process. Our estimate of $40 per hour average labor cost for registries is based on the assumption that registry staff include computer analysts. We do not believe that there are any additional costs for registries associated with a registry calculating quality measures results from the data submitted to the registry by its participants and submitting the quality measures results and numerator and denominator data on quality measures to CMS on behalf of their participants under the final program for 2012. We believe that the majority of registries already perform these functions for their participants.

An EHR vendor interested in having its product(s) be used by individual eligible professionals to submit the final Physician Quality Reporting System measures to CMS for 2012 will have to complete the vetting process during 2012 and program its EHR product(s) to extract the clinical data that the eligible professional will need to submit to CMS for purposes of reporting the final 2012 quality measures in 2013 as well. Previously qualified vendors will need to only update their electronic measure specifications and data transmission schema during 2012 to incorporate any new EHR measures we are finalizing to maintain their qualification for the 2012 Physician Quality Reporting System. Therefore, for EHR vendors that were not previously qualified, we estimate the cost associated with completing the self-nomination process, including the vetting process with CMS officials, will be $400 ($40/hour × 10 hours per EHR vendor). Our estimate of a $40 per hour average labor cost for EHR vendors is based on the assumption that vendor staff include computer analysts. We believe that the cost associated with the time and effort needed for an EHR vendor to review the quality measures and other information and program the EHR product to enable individual eligible professionals to submit Physician Quality Reporting System quality measures data to the CMS-designated clinical warehouse will be dependent on the EHR vendor's familiarity with the Physician Quality Reporting System, the vendor's system's capabilities, as well as the vendor's programming capabilities. Some vendors already have the necessary capabilities and for such vendors, we estimate the total cost will be approximately $1,600 ($40/hour × 40 hours per vendor). However, given the variability in the capabilities of the vendors, we believe an estimate for those vendors with minimal experience will be approximately $8,000 per vendor ($40/hour × 200 hours per EHR vendor).

TABLE 87: ESTIMATED COSTS TO PROFESSIONALS: PHYSICIAN QUALITY REPORTING

	Estimated Hours	Estimated Instances	Number of Measures	Hourly Rate	Total Cost
Individual Eligble Professional (EP): Preparation	5.0	1	N/A	$40	$200
Individual EP: Claims Reporting	0.2	6	3	$40	$144
Individual EP: Registry Reporting	N/A	1	N/A	N/A	$500 to $1,000
Individual EP: EHR Reporting	N/A	1	N/A	N/A	$25,000 - $54,000 initial start-up $18,000 annually for subsequent years
Group Practice: Self-Nomination	6.0	1	N/A	$16	$96
Group Practice: Reporting	79	1	N/A	$40	$3,160

TABLE 88: ESTIMATED COSTS TO VENDORS: PHYSICIAN QUALITY REPORTING

	Estimated Hours	Hourly Rate	Total Cost
Registry: Self-Nomination	10	$40	$400
EHR: Self-Nomination	10	$40	$400
EHR: Programming	40-200	$40	$1,600 - $8,000

6. Incentives for Electronic Prescribing (eRx)—The Electronic Prescribing Incentive Program

Section VI.F.2. of this final rule with comment period describes the Electronic Prescribing (eRx) Incentive Programs finalized for CYs 2012 through 2014. To be considered a successful electronic prescriber in CYs 2012 through 2014, an individual eligible professional must meet the final requirements described in section VI.F.2. of this final rule with comment period.

From 2009, over 90,000 eligible professionals participated in the eRx Incentive Program. We anticipate that despite a decrease in the applicable quality incentive percent from 2 percent in 2009 to 1 percent (of total estimated Medicare Part B allowed charges for covered professional services) in 2012 and 0.5 percent in 2013, more eligible professionals (and group practices) will choose to participate in the eRx Incentive Program due to the 2013 and 2014 payment adjustments of 1.5 percent and 2.0 percent, respectively (reduction of the physician fee schedule amount that would otherwise apply to such services in 2013 and 2014), for eligible professionals who are not successful electronic prescribers. In order to become a successful electronic prescriber for purposes of the 2013 and 2014 payment adjustments under the 6-month payment adjustment reporting periods, we are finalizing more opportunities to report on the electronic prescribing measure by concentrating only on the numerator of the measure. Similar to the percentage increase from the 2008 to 2009 eRx Incentive Program, as well as taking into account the limitations and significant hardship exemptions we are finalizing for the 2013 and 2014 payment adjustments, we anticipate a 12 percent increase in the number of eligible professionals participating in the eRx Incentive Program from 2012 through 2014. Therefore, for purposes of this burden analysis, we estimate that more than 100,800 unique TIN/NPI combinations will participate in the 2012, 2013, and 2014 eRx Incentive Program

Although, as we stated previously, we expect participation in the eRx Incentive Program to increase due to the implementation of the 2013 and 2014 payment adjustments, we do not believe this expected increase in participation will affect the number of eligible professionals participating in the eRx Incentive Program for purposes of earning an incentive. For the 2009 eRx Incentive Program, based on an incentive of 2.0 percent of eligible professionals' total estimated Medicare Part B allowed charges for covered professional services, approximately $148 million in total incentives were paid to eligible professionals with a mean incentive amount of approximately $3,000. Whereas the applicable quality incentive percent for 2009 was 2.0 percent, the applicable percent for the 2012 and 2013 incentives are 1.0 percent and 0.5 percent, respectively. Since the applicable quality percent for the 2012 incentive is half that of the 2009 incentive, we estimate that $74 million in total incentives will be paid to eligible professionals for the 2012 incentive. Since the applicable quality percent for the 2013 incentive is one-fourth that of the 2009 incentive, we estimate that $37 million in total incentives will be paid to eligible professionals for the 2013 incentive. Therefore, for the 2012 and 2013 incentives, we estimate that a total of $111 million will be distributed to eligible professionals who become successful electronic prescribers.

With respect to the costs of participating in the eRx Incentive Program for eligible professionals and group practices, we estimate that the cost impact of the eRx Incentive Programs for CYs 2012 through 2014 on the Medicare program will be the cost incurred for maintaining the electronic prescribing measure and its associated code set, and for maintaining the existing clinical data warehouse to accommodate the registry-based reporting and EHR-based reporting options for the electronic prescribing measure. However, we do not believe that the program for CYs 2012 through 2014 have a significant administrative cost impact on the Medicare program since much of this infrastructure has already been established for the eRx Incentive Program.

Individual eligible professionals and group practices may have different processes for integrating data collection on the electronic prescribing measure into their practices' work workflows. Given this variability and the multiple reporting options that we are finalizing, it is difficult to accurately estimate the impact of the eRx Incentive Program for CYs 2012 through 2014 on providers. Furthermore, we believe that costs for eligible professionals who will participate in the eRx Incentive Program for the first time will be considerably higher than the cost for eligible professionals who participated in the eRx Incentive Program in prior years, as there are preparatory steps that an eligible professional will need to take to begin participating in the program. In addition, for many eligible professionals (especially those who participated in the eRx Incentive Program in prior years), we believe the cost of participating in the eRx Incentive Program in 2012 or 2013 will be offset by the incentive payment, if earned. As a result of the payment adjustment that begins in 2012 and continues until 2014, the cost of not participating in the eRx Incentive Program for CYs 2012 through 2014 could be higher than the cost of participating in the form of reduced Medicare payments as a result of the payment adjustment (if applicable).

Any eligible professional who wishes to participate in the eRx Incentive Program must have a qualified electronic prescribing system in order to participate. Therefore, a one-time potential cost to some individual eligible professionals will be the cost of purchasing and using an electronic prescribing system, which varies by the commercial software package selected, the level at which the professional currently employs information technology in his or her practice and the training needed. One study indicated that a midrange complete electronic medical record with electronic prescribing functionality costs $2,500 per license with an annual fee of $90 per license for quarterly updates of the drug database after setup costs while standalone prescribing, messaging, and problem list system may cost $1,200 per physician per year after setup costs. Hardware costs and setup fees substantially add to the final cost of any software package. (Corley, S.T. (2003). ''Electronic prescribing: a review of costs and benefits.'' Topics in Health Information Management 24(1):29–38.). These are the estimates that we are using for our impact analysis.

Similar to the Physician Quality Reporting System, one factor in the cost to individual eligible professionals is the time and effort associated with individual eligible professionals reviewing the electronic prescribing measure to determine whether it is applicable to them, reviewing the available reporting options and selecting one, gathering the required information, and incorporating reporting of the measure into their office work flows. Since the eRx Incentive Program consists of only 1 quality measure, we estimate 2 hours as the amount of time needed for individual eligible professionals to prepare for participation in the eRx Incentive Program. Information obtained from the PVRP, which was a predecessor to the Physician Quality Reporting System and was the first step for physician quality

reporting through certain quality metrics, indicated an average labor cost per practice of approximately $40/hour. To account for salary increases over time, we use an average practice labor cost of $40/hour for our estimates, based on an assumption of an average annual increase of approximately 3 percent. At an average cost of approximately $40/hour, we estimate the total preparation costs to individual eligible professionals to be approximately $80 ($40/hour × 2 hours).

Another factor that influences the cost to individual eligible professionals is how they choose to report the electronic prescribing measure (that is, whether they select the claims-based, registry-based or EHR-based reporting mechanism). For claims-based reporting, there will be a cost associated with reporting the appropriate QDC on the claims an individual eligible professional submits for payment. Based on the information from the PVRP described previously for the amount of time it takes a median practice to report one measure one time (1.75 minutes) and the requirement to report 25 electronic prescribing events during 2012, we estimate the annual estimated cost per individual eligible professional to report the electronic prescribing measure via claims-submission will be $43.75 (1.75 minutes per case × 1 measure × 25 cases per measure × $40/hour). We believe that for most successful electronic prescribers who earn an incentive, these costs will be negated by the incentive payment received given that the average incentive for eligible professionals who qualified for a 2009 eRx incentive was around $3,000.

For eligible professionals who select the registry-based reporting mechanism, we do not anticipate any additional cost for individual eligible professionals to report data to a registry, as individual eligible professionals opting for registry-based reporting are more than likely already reporting data to the registry. Little if any, additional data will need to be reported to the registry for purposes of participation in the eRx Incentive Program for CYs 2012 through 2014. Individual eligible professionals using registries for Physician Quality Reporting System will likely experience minimal, if any, increased costs charged by the registry to report this 1 additional measure.

For EHR-based reporting, the eligible professional must extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse. Once the EHR is programmed by the vendor to allow data submission to CMS, the cost to the individual eligible professional associated with the time and effort to submit data on the electronic prescribing measure should be minimal.

With respect to the requirements for group practices for the 2012 and 2013 incentives and 2013 and 2014 payment adjustments discussed in section VI.F.2. of this final rule with comment period, group practices have the same options as individual eligible professionals in terms of the form and manner for reporting the electronic prescribing measure (that is, group practices have the option of reporting the measure through claims, a qualified registry, or a qualified EHR product). There are only 2 differences between the requirements for an individual eligible professional and a group practice: (1) the fact that a group practice must self-nominate; and (2) the number of times a group practice must report the electronic prescribing measure. Overall, there could be less cost associated with a practice participating in the eRx Incentive Program as a group rather than the individual members of the group separately participating. We do not believe that there are any additional costs associated with the group practice self-nomination process since we are limiting the group practices to those selected to participate in the 2012, 2013, and/or 2014 respective Physician Quality Reporting System GPRO. The practices only must indicate their desire to participate in the eRx GPRO at the time they self-nominate for the Physician Quality Reporting System GPRO.

The costs for a group practice reporting to an EHR or registry should be similar to the costs associated with registry and EHR reporting for an individual eligible professional, as the process is the same with the exception that more electronic prescribing events must be reported by the group. For similar reasons, the costs for a group practice reporting via claims should also be similar to the costs associated with claims-based reporting for an individual eligible professional. Therefore, we estimate that the costs for group practices who are selected to participate in the eRx Incentive Program for CYs 2012 through 2014 will range from $799.17 (1.75 minutes per case × 1 measure × 625 cases per measure × $40/hour) for groups comprised of 25–99 eligible professionals participating to $2,916.67 (1.75 minutes per case × 2500 cases per measure × $40/hour) for the groups comprised of 100 or more eligible professionals.

We believe that the costs to individual eligible professionals and group practices associated with meeting the requirements for the 2013 and 2014 payment adjustments will be similar to the costs of an eligible professional or group practice reporting the electronic prescribing measure for purposes of the 2012 and 2013 incentives. Specifically, we believe that the cost of reporting the electronic prescribing measure in one instance for purposes of the payment adjustment is identical to the cost of reporting the electronic prescribing measure for one instance on claims for purposes of the incentive payment. The only difference will be in the total costs for an individual eligible professional. Group practices are required to report the electronic prescribing measure for the same number of electronic prescribing events for both the 2012 and 2013 incentives and the 2013 and 2014 payment adjustments. Individual eligible professionals, however, are required to report the electronic prescribing measure for only 10 electronic prescribing events for purposes of the 2013 and 2014 payment adjustments, as opposed to 25 electronic prescribing events for purposes of the 2012 and 2013 incentives.

Based on our decision to consider only registries qualified to submit quality measures results and numerator and denominator data on quality measures to CMS on their participant's behalf for the 2012, 2013, and 2014 Physician Quality Reporting System to be qualified to submit results and numerator and denominator data on the electronic prescribing measure for eRx Incentive Program for CYs 2012, 2013, and 2014, respectively, we do not estimate any cost to the registry associated with becoming a registry qualified to submit the electronic prescribing measure for CYs 2012 through 2014.

The cost for the registry will be the time and effort associated with the registry calculating results for the electronic prescribing measure from the data submitted to the registry by its participants and submitting the quality measures results and numerator and denominator data on the eRx quality measure to CMS on behalf of their participants. We believe such costs will be minimal as registries will already be required to perform these activities for Physician Quality Reporting System.

Likewise, based on our decision to consider only EHR products qualified for the Physician Quality Reporting System for CYs 2012, 2013, and 2014 to be qualified to submit results and numerator and denominator data on the electronic prescribing measure for the eRx Incentive Program for CYs 2012, 2013, and 2014, there is no need for

EHR vendors to undergo a separate self-nomination process for the eRx Incentive Program. Therefore, there will be no additional cost associated with the self-nomination process.

The cost to the EHR vendor associated with the proposed EHR-based reporting requirements of this reporting initiative is the time and effort associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the individual eligible professional needs to submit to CMS for reporting the electronic prescribing measure. Since we determined that only EHR products qualified for the Physician Quality Reporting System are qualified for the eRx Incentive Program, and the eRx Incentive Program consists of only one measure, we believe that any burden associated with the EHR vendor to program its product(s) to enable individual eligible professionals to submit data on the electronic prescribing measure to the CMS-designated clinical data warehouse will be minimal.

7. Physician Compare Web Site

Section VI.G.2. of this final rule with comment period discusses the background of the Physician Compare Web site. As described in section VI.G.2. of this final rule with comment period, we are developing aspects of the Physician Compare Web Site in stages. We are finalizing our proposal to include performance information with respect to the 2012 Physician Quality Reporting System GPRO measures. As reporting of physician performance rates on the Physician Compare Web Site will be performed directly by us using the data that we collect under the 2012 Physician Quality Reporting System GPRO, we do not anticipate any notable impact on eligible professionals with respect to the posting of information on the Physician Compare Web Site.

8. Medicare EHR Incentive Program

Section VI.H.2. of this final rule with period finalizes changes to the EHR Incentive Program for EPs for the 2012 payment year with respect to the reporting of CQMs for achieving meaningful use. Aside from continuing the attestation method of reporting CQMs, we are allowing the reporting of CQMs for purposes of demonstrating meaningful use through participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot via— (1) a Physician Quality Reporting System qualified EHR data submission vendor or (2) using an EP's certified EHR technology, which also must be a Physician Quality Reporting System qualified EHR.

We believe the impact associated with actually reporting CQMs will vary depending on how the EP chooses to do so. We believe that the number of EPs who choose to participate via attestation will largely be those who are not participating in both the EHR Incentive Program and Physician Quality Reporting System as this is the method of reporting most favorable to EPs not participating in the Physician Quality Reporting System. EPs participating in the Physician Quality Reporting System will be more likely to participate in the pilot. Therefore, based on the previously mentioned assumptions, we do not believe there will be any additional impact on EPs that is specific to participation in the pilot. EPs must participate in the Physician Quality Reporting System in order to participate in the pilot.

9. Physician Feedback Program/Value Modifier Payment

The changes to the Physician Feedback Program in section VI.I. of this final rule with comment period would not impact CY 2012 physician payments under the Physician Fee Schedule. However, we expect that our decision to use the Physician Quality Reporting System quality measures in the Physician Feedback reports and in the value modifier to be implemented in CY 2015 may result in increased participation in the Physician Quality Reporting System in CY 2012. We anticipate that as we approach implementation of the value modifier, physicians will increasingly participate in the Physician Quality Reporting System to determine and understand how the value modifier could affect their payments.

10. Bundling of Payments for Services Provided to Outpatients Who Later Are Admitted as Inpatients: 3-Day Payment Window Policy and the Impact on Wholly Owned or Wholly Operated Physician Offices

Medicare collects ownership information obtained in the 855A and 855B enrollment forms completed upon a facility or a practitioner's Medicare enrollment. The 855 forms are self-selecting enrollment forms that may be updated as necessary. The enrollment forms do not specifically require complete information on whether a physician office is wholly owned or wholly operated by a hospital. While we believe that most hospital owned entities providing physician services will be considered part of the hospital and operating as hospital outpatient departments; there will be at least some hospital owned or operated entities that will meet the definition of ''wholly-owned or wholly-operated'' and will be subject to the 3-day payment window policy. We are unable to accurately estimate and verify the number of wholly owned or wholly operated entities enrolled in Medicare and furnishing health services to Medicare beneficiaries that will be subject to the 3-day payment window policy under the PFS because the 855 forms do not explicitly capture information on sole ownership or operation. We do not believe that our discussion in section V.B. of this final rule with comment period regarding the entities to which this policy applies changes our assessment that this policy would impact a small number of providers/suppliers. We note that the application of the 3-day window policy is limited to diagnostic or related nondiagnostic services that are provided during the defined payment window by entities that are wholly owned or operated by the hospital to which the patient is ultimately admitted. The 3-day payment window policy would not apply to the majority of services provided by a hospital's wholly-owned or wholly-operated physician offices. Furthermore, the effects of applying the 3-day window policy would be limited to the practice expense component of the payment rate, and the professional component is not affected by the 3-day window payment policy. We are unable to estimate the impact of this final policy at this time. However, we note that if we were able to estimate the effects of this policy on Part B payments, the program savings would be redistributed across all other services paid under the PFS in accordance with due to the PFS budget neutrality provisions.

11. Clinical Laboratory Fee Schedule: Signature on Requisition

As discussed in section VI.D. of this final rule with comment period, we are retracting the policy that was finalized in the CY 2011 PFS final rule with comment period, which required a physician's or NPP's signature on a requisition for clinical diagnostic laboratory tests paid under the CLFS and are reinstating our prior policy that the signature of the physician or NPP is not required on a requisition for a clinical diagnostic laboratory test paid under the CLFS for Medicare purposes. There are no expenditures or fiscal impact on the Medicare program associated with this policy. While this policy may have an effect on beneficiaries, we believe that any effect would be positive because we are changing a requirement that might have

impeded access to care in some cases. This policy does not impact payment rates under the CLFS, or any other part of the Medicare program.

I. Alternatives Considered

This final rule with comment period contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our policies and, where relevant, alternatives that were considered.

J. Impact on Beneficiaries

There are a number of changes in this final rule with comment period that would have an effect on beneficiaries. In general, we believe that many of the final changes, including the refinements of the Physician Quality Reporting System with its focus on measuring, submitting, and analyzing quality data will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

The regulatory provisions may affect beneficiary liability in some cases. Most changes in aggregate beneficiary liability due to a particular provision would be a function of the coinsurance (20 percent if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in Table 87, the CY 2011 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $102.95, which means that in CY 2011 a beneficiary would be responsible for 20 percent of this amount, or $20.59. Based on this final rule with comment period, including the negative update, the CY 2012 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 87, is $76.23, which means that, in CY 2012, the beneficiary coinsurance for this service would be $15.25. Most policies discussed in this final rule with comment period that impact payment rates, such as the expansion of the MPPR to the professional component of imaging procedures, would similarly impact beneficiaries' coinsurance.

K. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 89, we have prepared an accounting statement showing the estimated expenditures associated with this final rule with comment period. This estimate includes the estimated CY 2012 incurred benefit impact associated with the estimated CY 2012 PFS conversion factor update based on a midsession review of the FY 2012 President's Budget.

TABLE 89: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS

CATEGORY	TRANSFERS
CY 2012 Annualized Monetized Transfers	Estimated decrease in expenditures of $19.2 billion for the PFS update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

L. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides a Final Regulatory Flexibility Act Analysis. The previous analysis, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

X. Addenda Referenced in This Final Rule With Comment Period and Available Only Through the Internet on the CMS Web Site

This section lists the Addenda referred to throughout the preamble of this final rule with comment period. Beginning with the CY 2012 PFS proposed rule, the PFS Addenda A, B, C, D, E, F, G, and H will no longer appear in the **Federal Register**. In addition, beginning with the CY 2012 PFS final rule with comment period, the Designated Health Services Code List (Addendum J) will no longer appear in the **Federal Register**. Instead, these Addenda, along with other supplemental documents, will be available through the Internet.

Readers who experience any problems accessing any of the Addenda that are posted on the CMS Web sites identified in this section should contact Erin Smith at (410) 786–4497.

The following PFS Addenda for CY 2012 PFS final rule with comment period rule with are available through the Internet on the CMS Web site at *http://www.cms.gov/PhysicianFeeSched/.* Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2012 PFS final rule with comment period, refer to item CMS–1524–FC.

Addendum A—Explanation and Use of Addendum B

Addendum B—Relative Value Units and Related Information Used in Determining Medicare Payments for CY 2012

Addendum C—[Reserved]

Addendum D—CY 2012 Geographic Adjustment Factors (GAFs)

Addendum E—CY 2012 Geographic Practice Cost Indices (GPCIs) by States and Medicare Locality

Addendum F—CY 2012 Diagnostic Imaging Services Subject to the Multiple Procedure Payment Reduction

Addendum G—CPT/HCPCS Imaging Codes Defined by Section 5102(b) of the DRA

Addendum H—CY 2011 ''Always Therapy'' Services Subject to the Multiple Procedure Payment Reduction

The Designated Health Services Code List Addendum for CY 2012 PFS final rule with comment period entitled ''Addendum J: List of CPT [1]/HCPCS Codes Used to Define Certain Designated Health Service Categories [2] Under Section 1877 of the Social Security Act Effective January 1, 2012'' is available through the Internet on the CMS Web site at *http://www.cms.gov/PhysicianSelfReferral/40_List_of_Codes.asp#TopOfPage.*

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble of this final rule with comment period, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

■ 2. Amend § 410.15(a) as follows:
■ A. Amending the definition of ''First annual wellness visit providing personalized prevention plan services'' by—
■ i. Revising the introductory text.
■ ii. Redesignating paragraphs (i) through (ix) as paragraphs (ii) through (x).
■ iii. Adding a new paragraph (i).
■ iv. Revising newly redesignated paragraph (viii)(A).
■ B. Adding the definition of ''Health risk assessment''.
■ C. In the definition of ''Subsequent annual wellness visit providing personalized prevention plan services''.
■ i. Revising the introductory text.
■ ii. Redesignating paragraphs (i) through (vii) as paragraphs (ii) through (viii).
■ iii. Adding a new paragraph (i).
■ iv. Revising newly redesigned paragraphs (iii) and (vi)(B).

The revisions and additions read as follows:

§ 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

(a) * * *

First annual wellness visit providing personalized prevention plan services means the following services furnished to an eligible beneficiary by a health professional that include, and take into account the results of, a health risk assessment, as those terms are defined in this section:

(i) Review (and administration if needed) of a health risk assessment (as defined in this section).

* * * * *

(viii) * * *

(A) A written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual's health risk assessment (as that term is defined in this section), health status, screening history, and age-appropriate preventive services covered by Medicare.

* * * * *

Health risk assessment means, for the purposes of this section, an evaluation tool that meets the following criteria:

(i) Collects self-reported information about the beneficiary.

(ii) Can be administered independently by the beneficiary or administered by a health professional prior to or as part of the AWV encounter.

(iii) Is appropriately tailored to and takes into account the communication needs of underserved populations, persons with limited English proficiency, and persons with health literacy needs.

(iv) Takes no more than 20 minutes to complete.

(v) Addresses, at a minimum, the following topics:

(A) Demographic data, including but not limited to age, gender, race, and ethnicity.

(B) Self assessment of health status, frailty, and physical functioning.

(C) Psychosocial risks, including but not limited to, depression/life satisfaction, stress, anger, loneliness/social isolation, pain, and fatigue.

(D) Behavioral risks, including but not limited to, tobacco use, physical activity, nutrition and oral health, alcohol consumption, sexual health, motor vehicle safety (seat belt use), and home safety.

(E) Activities of daily living (ADLs), including but not limited to, dressing, feeding, toileting, grooming, physical ambulation (including balance/risk of falls), and bathing.

(F) Instrumental activities of daily living (IADLs), including but not limited to, shopping, food preparation, using the telephone, housekeeping, laundry, mode of transportation, responsibility for own medications, and ability to handle finances.

* * * * *

Subsequent annual wellness visit providing personalized prevention plan services means the following services furnished to an eligible beneficiary by a health professional that include, and take into account the results of an updated health risk assessment, as those terms are defined in this section:

(i) Review (and administration, if needed) of an updated health risk assessment (as defined in this section).

* * * * *

(iii) An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.

* * * * *

(vi) * * *

(B) The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.

* * * * *

■ 3. In § 410.62 amend paragraph (b) by revising the heading to read as follows:

§ 410.62 Outpatient speech-language pathology services: Conditions and exclusions.

* * * * *

(b) *Condition for coverage of outpatient speech-language pathology services furnished to certain inpatients of a hospital or a CAH or SNF.* * * *

* * * * *

§ 410.78 [Amended]

4. In § 410.78, amend paragraph (b) introductory text by removing the phrase ''and individual and group health and behavior assessment and intervention services furnished by an interactive telecommunications system if the following conditions are met:'' and adding in its place the phrase ''individual and group health and behavior assessment and intervention

services, and smoking cessation services furnished by an interactive telecommunications system if the following conditions are met:''.

■ 5. Amend § 410.140 by revising the definition of ''Deemed entity'' to read as follows:

§ 410.140 Definitions.

* * * * *

Deemed entity means an individual, physician, or entity accredited by an approved organization, but that has not yet been approved by CMS under § 410.145(b) to furnish training.

* * * * *

§ 410.141 [Amended]

■ 6. Amend § 410.141(b)(1) by:

■ A. Removing the term ''it'' and adding the phrase ''the training'' in its place.

■ B. Removing the cross-reference ''§ 410.32(a)'' and adding the cross-reference ''§ 410.32(a)(2)'' in its place.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 7. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 8. Amend § 414.22 by revising paragraphs (b)(5)(i)(A) through (C) to read as follows:

§ 414.22 Relative value units (RVUs).

* * * * *

(b) * * *

(5) * * *

(i) * * *

(A) *Facility practice expense RVUs.* The facility practice expense RVUs apply to services furnished to patients in places of service including, but not limited to, a hospital, a skilled nursing facility, a community mental health center, a hospice, or an ambulatory surgical center, or in a wholly owned or wholly operated entity providing preadmission services under § 412.2(c)(5).

(B) *Nonfacility practice expense RVUs.* The nonfacility practice expense RVUs apply to services furnished to patients in places of service including, but not limited to, a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility (CORF).

(C) *Outpatient therapy and CORF services.* Outpatient therapy services (including physical therapy, occupational therapy, and speech-language pathology services) and CORF services billed under the physician fee schedule are paid using the nonfacility practice expense RVUs.

* * * * *

§ 414.65 [Amended]

■ 9. In § 414.65, amend paragraph (a)(1) introductory text by removing the phrase ''and individual and group health and behavior assessment and intervention furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.'' and adding in its place the phrase ''individual and group health and behavior assessment and intervention, and smoking cessation services furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.''

■ 10. Amend § 414.90 as follows:

■ A. In paragraph (b), by revising the definition of ''Group practice''.

■ B. In paragraph (c)(2) introductory text, by removing the phrases ''during the applicable reporting period. For purposes of this paragraph,'' at the end of the paragraph and adding the phrase ''during the reporting period.'' in its place.

■ C. Adding paragraph (c)(4) introductory text.

■ D. Redesignating paragraphs (c)(2)(i) through (c)(2)(iii) as paragraphs (c)(4)(i) through (c)(4)(iii), respectively.

■ E. Revising paragraph (f)(1).

■ F. Removing paragraph (f)(2).

■ G. Redesignating paragraph (f)(3) as paragraph (f)(2).

■ H. Revising newly redesignated paragraph (f)(2) introductory text.

■ I. In newly redesignated paragraph (f)(2)(ii), removing the phrase ''behalf; or'' and adding the phrase ''behalf.'' in its place.

■ J. In newly redesignated paragraph (f)(2)(iii), removing the phrase ''containing real or dummy'' and adding in its place the phrase ''containing dummy''.

■ K. Revising paragraphs (g)(1) and (g)(3).

■ L. Redesignating paragraphs (g)(4) and (g)(5) as paragraphs (g)(5) and (g)(6).

■ M. Adding a new paragraph (g)(4).

■ N. In newly redesignated paragraph (g)(5), by removing the ''.'' and adding ''; and'' in its place.

■ O. Revising newly redesignated paragraph (g)(6).

■ P. Revising paragraphs (i)(1) and (i)(2) introductory text.

The revisions and additions read as follows:

§ 414.90 Physician Quality Reporting System.

* * * * *

(b) * * *

Group practice means a physician group practice, as defined by a TIN, with 25 or more individual eligible professionals (or, as identified by NPIs) who have reassigned their billing rights to the TIN.

* * * * *

(c) * * *

* * * * *

(2) For purposes of this paragraph—

* * * * *

(4) For purposes of this paragraph—

* * * * *

(f) * * *

(1) *Reporting periods.* For purposes of this paragraph, the reporting period is—

(i) The 12-month period from January 1 through December 31 of such program year.

(ii) A 6-month period from July 1 through December 31 of such program year.

(A) For 2011, such 6-month reporting period is not available for EHR-based reporting of individual Physician Quality Reporting System quality measures.

(B) For 2012 and subsequent program years, such 6-month reporting period from July 1 through December 31 of such program year is only available for registry-based reporting of Physician Quality Reporting System measures groups by eligible professionals.

(2) *Reporting mechanisms.* For program year 2011 and subsequent program years, an eligible professional who wishes to participate in the Physician Quality Reporting System must report information on the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups identified by CMS in one of the following manners:

(g) * * *

(1) Meets the participation requirements specified by CMS for the Physician Quality Reporting System group practice reporting option;

* * * * *

(3) Reports measures in the form and manner specified by CMS;

(4) For purposes of paragraph (g), the reporting period is the 12-month period from January 1 through December 31 of such program year;

* * * * *

(6) Payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the Physician Quality Reporting System to eligible

professionals in the group practice for meeting the criteria for satisfactory reporting for individual eligible professionals.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a TIN selected to participate in the Physician Quality Reporting System group practice reporting option for a program year, then for that program year the eligible professional must participate in the Physician Quality Reporting System via the group practice reporting option. For any program year in which the TIN is selected to participate in the Physician Quality Reporting System group practice reporting option, the eligible professional cannot individually qualify for a Physician Quality Reporting System incentive payment by meeting the requirements specified in paragraph (f) of this section.

(ii) If, for the program year, the eligible professional participates in the Physician Quality Reporting System under a TIN that is not selected to participate in the Physician Quality Reporting System group practice reporting option for that program year, then the eligible professional may individually qualify for a Physician Quality Reporting System incentive by meeting the requirements specified in paragraph (f) of this section under that TIN.

* * * * *

(i) * * *

(1) To request an informal review, an eligible professional (or in the case of reporting under paragraph (g) of this section, group practices) must submit a request to CMS within 90 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(2) CMS will provide a written response within 90 days of the receipt of the original request.

* * * * *

■ 11. Amend§ 414.92 as follows:

■ A. In paragraph (b), by adding the definition of ''Certified electronic health record technology''.

■ B. In paragraph (b), in the definition of ''Group practice,'' by redesignating paragraphs (i), (ii)(A), and (ii)(B) as paragraphs (i)(A), (i)(B) and (ii), respectively.

■ C. In paragraph (b), in the definition of ''Group practice,'' by revising newly redesginated paragraph (i)(B).

■ D. In paragraph (c)(2) introductory text, by revising the paragraph heading.

■ E. In paragraph (c)(2)(ii) introductory text, removing the phrase ''significant hardship exemption from the 2012 eRx payment adjustment if one of the following circumstances apply:'' and adding the phrase ''significant hardship exemption from a eRx payment adjustment if one of the following circumstances apply:'' in its place.

■ F. Redesignating paragraphs (c)(2)(ii)(A) through (F) as paragraphs (c)(2)(ii)(A)(*1*) through (c)(2)(ii)(A)(*6*), respectively.

■ G. Adding paragraphs (c)(2)(ii)(A) introductory text, (c)(2)(ii)(B), and (c)(2)(iii).

■ H. In paragraph (d) introductory text, by removing the phrase ''must meet the criteria for successful'' and the phrase ''must meet the criteria for being a successful'' is added in its place.

■ I. In paragraph (d)(1), by removing the phrase ''For purposes of this paragraph in 2011,'' is removed and adding in its place the phrase ''For purposes of this paragraph,''.

■ J. In paragraph (d)(2) introductory text, by removing the phrase ''For program year 2011, an eligible professional'' and adding the phrase ''An eligible professional'' in its place.

■ K. In paragraph (e)(2)(ii), by removing the phrase ''under another TIN'' and adding the phrase ''under a TIN'' in its place.

■ L. Redesignating paragraph (f) as (g).

■ M. Adding a new paragraph (f).

■ The revisions and additions read as follows:

§ 414.92 Electronic Prescribing Incentive Program.

* * * * *

(b) * * *

Certified electronic health record technology means an electronic health record vendor's product and version as described in 45 CFR 170.102.

Group practice

* * * * *

(i) * * *

(B) In a Medicare-approved demonstration project or other Medicare program, under which Physician Quality Reporting System requirements and incentives have been incorporated; and

* * * * *

(c) * * *

(2) *Payment adjustment.** * *

(ii) * * *

(A) From the 2012 payment adjustments by meeting one of the following:

* * * * *

(B) From the 2013 and 2014 payment adjustments by meeting one of the following:

(*1*) The eligible professional or group practice is located in a rural area without high speed internet access.

(*2*) The eligible professional or group practice is located in an area without sufficient available pharmacies for electronic prescribing.

(*3*) The eligible professional or group practice is unable to electronically prescribe due to local, State, or Federal law or regulation.

(*4*) The eligible professional or group practice has limited prescribing activity, as defined by an eligible professional generating fewer than 100 prescriptions during a 6-month reporting period.

(iii) *Other limitations to the payment adjustment.* An eligible professional (or in the case of a group practice under paragraph (b) of this section, a group practice) is exempt from the application of the payment adjustment under paragraph (c)(2) of this section if one of the following applies:

(A) The eligible professional is not an MD, DO, podiatrist, nurse practitioner, or physician assistant.

(B) The eligible professional does not have at least 100 cases containing an encounter code that falls within the denominator of the electronic prescribing measure for dates of service during the 6-month reporting period specified in paragraph (f)(1) of this section.

* * * * *

(f) *Requirements for individual eligible professionals and group practices for the payment adjustment.* In order to be considered a successful electronic prescriber for the electronic prescribing payment adjustment, an individual eligible professional (or, in the case of a group practice under paragraph (b) of this section, a group practice), as identified by a unique TIN/NPI combination, must meet the criteria for being a successful electronic prescriber specified by CMS, in the form and manner specified in paragraph (f)(2) of this section, and during the reporting period specified in paragraph (f)(1) of this section.

(1) *Reporting periods.* (i) For purposes of this paragraph (f), the reporting period for the 2013 payment adjustment is either of the following:

(A) The 12-month period from January 1, 2011 through December 31, 2011.

(B) The 6-month period from January 1, 2012 through June 30, 2012.

(ii) For purposes of this paragraph (f), the reporting period for the 2014 payment adjustment is either of the following:

(A) The 12-month period from January 1, 2012 through December 31, 2012.

(B) The 6-month period from January 1, 2013 through June 30, 2013.

(2) *Reporting mechanisms.* An eligible professional (or, in the case of a group practice under paragraph (e) of this section, a group practice) who wishes to participate in the Electronic Prescribing Incentive Program must report information on the electronic prescribing measure identified by CMS to one of the following:

(i) For the 6- and 12-month reporting periods under paragraph (f)(1) of this section, CMS, by no later than 2 months after the end of the applicable 12-month reporting period or by no later than 1 month after the end of the applicable 6-month reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section.

(ii) For the 12-month reporting period under paragraph (f)(1) of this section, a qualified registry (as defined in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected qualified registry submits information, as required by CMS, for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section to CMS on the eligible professional's behalf.

(iii) For the 12-month reporting period under paragraph (f)(1) of this section, CMS by extracting clinical data using a secure data submission method, as required by CMS, from a qualified electronic health record product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section. Prior to actual data submission for a given program year and by a date specified by CMS, the eligible professional must submit a test file containing dummy clinical quality data extracted from the qualified electronic health record product selected by the eligible professional using a secure data submission method, as required by CMS.

* * * * *

■ 12. In § 414.802 amend the definition of ''Unit'' by revising the first sentence to reads as follows:

§ 414.802 Definitions.

* * * * *

Unit means the product represented by the 11-digit National Drug Code, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by a National Drug Code varies. * * *

* * * * *

■ 13. Amend § 414.904 by revising paragraph (d)(3) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(d) * * *

(3) *Widely available market price and average manufacturer price.* If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by the applicable threshold percentage specified in paragraph (d)(3)(iii) or (iv) of this section, the Inspector General is responsible for informing the Secretary (at such times as specified by the Secretary) and the payment amount for the drug or biological will be substituted subject to the following adjustments:

(i) The payment amount substitution will be applied at the next average sales price payment amount calculation period after the Inspector General informs the Secretary (at such times specified by the Secretary) about billing codes for which the average sales price has exceeded the average manufacturer price by the applicable threshold percentage, and will remain in effect for 1 quarter after publication.

(ii) Payment at 103 percent of the average manufacturer price for a billing code will be applied at such times when—

(A) The threshold for making price substitutions, as defined in paragraph (d)(3)(iii) of this section is met; and

(B) 103 percent of the average manufacturer price is less than the 106 percent of the average sales price for the quarter in which the substitution would be applied.

(iii) The applicable percentage threshold for average manufacturer price comparisons for CYs 2005 through 2011 is 5 percent. For CY 2012, the applicable percentage threshold for average sales price comparisons is reached when—

(A) The average sales price for the billing code has exceeded the average manufacturer price for the billing code by 5 percent or more in 2 consecutive quarters, or 3 of the previous 4 quarters immediately preceding the quarter to which the price substitution would be applied; and

(B) The average manufacturer price for the billing code is calculated using the same set of National Drug Codes used for the average sales price for the billing code.

(iv) The applicable percentage threshold for widely available market price comparisons for CYs 2005 through 2012 is 5 percent.

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 14. The authority citation for part 415 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 415.130 [Amended]

■ 15. In § 415.130, amend paragraphs (d)(1) and (d)(2) by removing the date ''December 31, 2010'' and adding the date ''December 31, 2011'' in its place.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 16. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 17. Amend § 495.8 as follows:

■ A. In paragraph (a)(2)(ii), by removing the phrase ''selected by CMS electronically to CMS (or in the case of Medicaid EPs, the States) in the manner specified by CMS (or in the case of Medicaid EPs, the States).'' and adding the phrase ''selected by CMS to CMS (or in the case of Medicaid EPs, the States) in the form and manner specified by CMS (or in the case of Medicaid EPs, the States).'' in its place.

■ B. Adding a new paragraph (a)(2)(v) to read as follows:

§ 495.8 Demonstration of meaningful use criteria.

(a) * * *

(2) * * *

(v) *Exception for Medicare EPs for PY 2012—Participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot.* In order to satisfy the clinical quality measure reporting objective in § 495.6(d)(10), aside from attestation, an EP participating in the Physician Quality Reporting System may also participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot through one of the following methods:

(A) Submission of data extracted from the EP's certified EHR technology through a Physician Quality Reporting System qualified EHR data submission vendor; or

(B) Submission of data extracted from the EP's certified EHR technology, which must also be through a Physician Quality Reporting System qualified EHR.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: October 26, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 31, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–28597 Filed 11–1–11; 4:15 pm]

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